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Rules and Regulations

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

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

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

RIN 3245–AG22

Small Business Subcontracting; Correction

AGENCY: U.S. Small Business Administration.

ACTION: Correcting amendment.

SUMMARY: The U.S. Small Business Administration (SBA) published a final rule in the **Federal Register** on July 16, 2013 (78 FR 42391), amending its regulations governing small business subcontracting. That document amended § 121.411 without incorporating the amendments made to that section by a final rule published on June 28, 2013 (78 FR 38811), which unintentionally resulted in duplicate paragraphs. This document corrects the final regulations by properly designating the paragraphs in § 121.411.

DATES: Effective May 23, 2014

FOR FURTHER INFORMATION CONTACT: Dean Koppel, Office of Government Contracting, U.S. Small Business Administration, 409 Third Street SW., 8th Floor, Washington, DC 20416, (202) 205–7322, *dean.koppel@sba.gov.*

SUPPLEMENTARY INFORMATION: On June 28, 2013, SBA published a final rule to implement provisions in the Small Business Jobs Act of 2010 pertaining to small business size and status integrity. 78 FR 38811. That rule amended 13 CFR 121.411 by adding new paragraphs (d) through (h). On July 16, 2013, at 78 FR 42391, SBA published a second final rule to implement provisions, also in the Small Business Jobs Act of 2010, concerning subcontracting compliance. In pertinent part, this final rule amended 13 CFR 121.411. However, in so doing, SBA inadvertently failed to incorporate the new paragraphs added to § 121.411 by the final rule published on June 28, 2013. When SBA published the rule on July 16, 2013, the Agency should have amended § 121.411 by revising paragraph (a), redesignating paragraphs (b) through (h) as paragraphs (c) through (i), and adding a new paragraph (b). As a result of the Agency's oversight, the current regulations in § 121.411 contain two paragraphs (d). This correcting amendment is necessary to ensure the proper designation of the paragraphs in that section.

List of Subjects in 13 CFR Part 121

Government contracting programs, Small business subcontracting program.

Accordingly, 13 CFR part 121 is corrected by making the following correcting amendments:

PART 121—SMALL BUSINESS SIZE REGULATIONS

■ 1. The authority citation for part 121 continues to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 662, and 694a(9).

■ 2. Amend § 121.411 by redesignating the second paragraph (d) through paragraph (h) as paragraphs (e) through (i).

Calvin Jenkins,

Deputy Associate Administrator for Government Contracting and Business Development.

[FR Doc. 2014–11986 Filed 5–22–14; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2013–0729; Airspace Docket No. 13–AEA–14]

RIN 2120–AA66

Modification and Establishment of Restricted Areas; Aberdeen Proving Ground, MD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes a new restricted area, designated R–4001C, within a part of the existing restricted areas R–4001A and R–4001B, at the U.S. Army's Aberdeen Proving Ground in Maryland. The purpose of the new area is to contain two moored balloons, called Aerostats, operating continuously at approximately 10,000 feet MSL. This action segregates nonparticipating aircraft from a hazard to navigation in Aberdeen Proving Ground airspace.

DATES: Effective date 0901 UTC, July 24, 2014.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace Policy and Regulations Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

On October 1, 2013, the FAA published in the **Federal Register** a notice of proposed rulemaking to establish a new restricted area, designated R–4001C, within a portion of existing restricted areas R–4001A and R–4001B, at the U.S. Army's Aberdeen Proving Ground in Maryland (78 FR 60238). The U.S. Army requested this action to contain two moored Aerostat balloons that will be operated at approximately 10,000 feet MSL, without lights, and therefore must be contained within restricted airspace.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

The Rule

The FAA is amending 14 CFR part 73 by creating a new restricted area, designated R–4001C, within a part of existing restricted areas R–4001A and R–4001B at Aberdeen Proving Ground, MD. R–4001C is a rectangular area, approximately 4.5 nautical miles (NM) by 2 NM in size, that extends from the surface to 10,000 feet MSL. The time of designation for R–4001C is ''continuous.'' Because the moored balloons contained in the area will be airborne 24 hours per day (except for periods when maintenance is required, or the winds exceed 60 knots), R–4001C is not a joint-use restricted area. R–4001A and R–4001B continue to be joint-use areas, meaning that they may be released, in whole or in part, to the FAA controlling agency when the airspace is not needed by the using agency. During times when the airspace

is released to the controlling agency, air traffic may be cleared through R–4001A and/or R–4001B. In addition, an editorial change is made to the using agency name for R–4001A and R–4001B by adding ''U.S. Army'' at the beginning of the agency name for format standardization purposes.

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. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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 only affects air traffic procedures and air navigation, it is certified that this rule, does 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 United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. 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 modifies restricted area airspace to support military requirements at Aberdeen Proving Ground, MD.

Environmental Review

In accordance with FAA Order 1050.1E, paragraphs 402 and 404d, the FAA has conducted an independent evaluation of the United States Army's Final Environmental Assessment for the Joint Land Attack Cruise Missile Defense Elevated Netted Sensor System (JLENS) at Army Garrison Aberdeen Proving Group, Maryland, dated February 2014 (hereinafter ''the FEA'') regarding the construction of sites for the operational exercise of the JLENS at Aberdeen Proving Ground. The FAA adopted the FEA and prepared a Finding of No Significant Impact/Record of Decision dated May 2014. The FAA has determined that no significant impacts would occur as a result of the Federal action and therefore that preparation of an Environmental Impact Statement is not warranted and a Finding of No Significant Impact in accordance with 40 CFR Part 1501.4(e) is appropriate.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 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.

§ 73.40 [Amended]

■ 2. § 73.40 is amended as follows:

R–4001A Aberdeen, MD [Amended]

■ By removing the current boundaries and using agency and adding in their place:

Boundaries. Beginning at lat. 39°30′30″ N., long. 76°09′59″ W.; to lat. 39°29′00″ N., long. 76°07′59″ W.; to lat. 39°29′30″ N., long. 76°04′59″ W.; to lat. 39°27′00″ N., long. 76°00′29″ W.; to lat. 39°19′47″ N., long. 76°11′33″ W.; to lat. 39°17′30″ N., long. 76°12′58″ W.; to lat. 39°16′24″ N., long. 76°16′17″ W.; to lat. 39°17′13″ N., long. 76°18′48″ W.; to lat. 39°18′42″ N., long. 76°18′48″ W.; to lat. 39°20′03″ N., long. 76°20′30″ W.; to lat. 39°19′56″ N., long. 76°21′02″ W.; to lat. 39°20′39″ N., long. 76°21′59″ W.; to lat. 39°22′00″ N., long. 76°21′59″ W.; to lat. 39°23′28″ N., long. 76°20′39″ W.; to lat. 39°26′10″ N., long. 76°14′49″ W.; to lat. 39°27′00″ N., long. 76°12′29″ W.; to the point of beginning, excluding R–4001C.

Using agency. U.S. Army, Commander, Aberdeen Proving Ground, MD.

R–4001B Aberdeen, MD [Amended]

■ By removing the current boundaries and using agency and adding in their place:

Boundaries. Beginning at lat. 39°17′30″ N., long. 76°12′58″ W.; to lat. 39°12′10″ N., long. 76°16′29″ W.; to lat. 39°12′45″ N., long. 76°22′29″ W.; to lat. 39°17′30″ N., long. 76°19′44″ W.; to lat. 39°18′30″ N., long. 76°21′59″ W.; to lat. 39°20′39″ N., long. 76°21′59″ W.; to lat. 39°19′56″ N., long. 76°21′02″ W.; to lat. 39°20′03″ N., long. 76°20′30″ W.; to lat. 39°18′42″ N., long. 76°18′48″ W.; to lat. 39°17′13″ N., long. 76°18′48″ W.; to lat. 39°16′24″ N., long. 76°16′17″ W.; to the point of beginning.

Using agency. U.S. Army, Commander, Aberdeen Proving Ground, MD.

R–4001C Aberdeen, MD [New]

Boundaries. Beginning at lat. 39°21′50″ N., long. 76°21′59″ W.; to lat. 39°23′01″ N., long. 76°16′35″ W.; to lat. 39°21′04″ N., long. 76°15′52″ W.; to lat. 39°19′56″ N., long. 76°21′02″ W.; to lat. 39°20′39″ N., long. 76°21′59″ W.; to the point of beginning.

Designated altitudes. Surface to 10,000 feet MSL.

Time of designation. Continuous.

Controlling agency. FAA, Potomac TRACON.

Using agency. U.S. Army, Commander, Aberdeen Proving Ground, MD.

Issued in Washington, DC, on May 20, 2014.

Colby Abbott,

Acting Manager, Airspace Policy and Regulations Group.

[FR Doc. 2014–11976 Filed 5–22–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30956; Amdt. No. 3589]

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 May 23, 2014. 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 May 23, 2014.

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 part 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 April 25, 2014.

John Duncan,

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 29 MAY 2014

Chatom, AL, Roy Wilcox, RNAV (GPS) RWY 12, Orig
Chatom, AL, Roy Wilcox, RNAV (GPS) RWY 30, Orig
Chatom, AL, Roy Wilcox, Takeoff Minimums and Obstacle DP, Orig
Troy, AL, Troy Municipal At N. Kenneth Campbell Field, ILS OR LOC RWY 7, Amdt 10
Troy, AL, Troy Municipal At N. Kenneth Campbell Field, NDB RWY 7, Amdt 12
Troy, AL, Troy Municipal At N. Kenneth Campbell Field, RNAV (GPS) RWY 7, Amdt 2

Troy, AL, Troy Municipal At N. Kenneth Campbell Field, RNAV (GPS) RWY 14, Amdt 1
Troy, AL, Troy Municipal At N. Kenneth Campbell Field, RNAV (GPS) RWY 25, Amdt 2
Troy, AL, Troy Municipal At N. Kenneth Campbell Field, RNAV (GPS) RWY 32, Amdt 1
Troy, AL, Troy Municipal At N. Kenneth Campbell Field, Takeoff Minimums and Obstacle DP, Amdt 6
Prescott, AZ, Ernest A. Love Field, RNAV (GPS) Y RWY 3R, Orig
Prescott, AZ, Ernest A. Love Field, RNAV (RNP) Z RWY 3R, Amdt 1
Lake City, FL, Lake City Gateway, Takeoff Minimums and Obstacle DP, Amdt 1
Louisville, KY, Louisville Intl-Standiford Field, ILS OR LOC RWY 17L, Amdt 4A
Louisville, KY, Louisville Intl-Standiford Field, ILS OR LOC RWY 17R, Amdt 3A
Louisville, KY, Louisville Intl-Standiford Field, ILS OR LOC RWY 35R, ILS RWY 35R (SA CAT I), ILS RWY 35R (CAT II), ILS RWY 35R (CAT III), Amdt 4A
Louisville, KY, Louisville Intl-Standiford Field, LOC RWY 29, Orig-A
Louisville, KY, Louisville Intl-Standiford Field, RNAV (GPS) Y RWY 17L, Amdt 1A
Louisville, KY, Louisville Intl-Standiford Field, RNAV (GPS) Y RWY 17R, Amdt 1A
Norwood, MA, Norwood Memorial, Takeoff Minimums and Obstacle DP, Amdt 7
Boyne Falls, MI, Boyne Mountain, Takeoff Minimums and Obstacle DP, Amdt 4
Muskegon, MI, Muskegon County, ILS OR LOC RWY 32, Amdt 19
Muskegon, MI, Muskegon County, RNAV (GPS) RWY 32, Amdt 2
Muskegon, MI, Muskegon County, VOR–A, Amdt 21
Bemidji, MN, Bemidji Rgnl, ILS OR LOC RWY 31, Amdt 5A
Bemidji, MN, Bemidji Rgnl, ILS OR LOC/DME RWY 25, Amdt 1A
Bemidji, MN, Bemidji Rgnl, RNAV (GPS) RWY 13, Amdt 1
Bemidji, MN, Bemidji Rgnl, RNAV (GPS) RWY 25, Orig-B
Bemidji, MN, Bemidji Rgnl, RNAV (GPS) RWY 31, Amdt 1A
Magee, MS, Magee Muni, RNAV (GPS) RWY 18, Orig
Magee, MS, Magee Muni, RNAV (GPS) RWY 36, Orig
Magee, MS, Magee Muni, Takeoff Minimums and Obstacle DP, Orig
Greensboro, NC, Piedmont Triad Intl, NDB RWY 14, Amdt 15E, CANCELED
Kinston, NC, Kinston Rgnl Jetport at Stallings Fld, ILS OR LOC RWY 5, Amdt 11
Kinston, NC, Kinston Rgnl Jetport at Stallings Fld, RNAV (GPS) RWY 5, Amdt 3
Kinston, NC, Kinston Rgnl Jetport at Stallings Fld, RNAV (GPS) RWY 23, Amdt 3
Rutherfordton, NC, Rutherford Co—Marchman Field, LOC RWY 1, Amdt 3
Rutherfordton, NC, Rutherford Co—Marchman Field, RNAV (GPS) RWY 1, Amdt 2
Rutherfordton, NC, Rutherford Co—Marchman Field, RNAV (GPS) RWY 19, Amdt 1
Concord, NH, Concord Muni, Takeoff Minimums and Obstacle DP, Amdt 4
Jaffrey, NH, Jaffrey Airport-Silver Ranch, RNAV (GPS)-B, Orig
Jaffrey, NH, Jaffrey Airport-Silver Ranch, RNAV (GPS)-C, Orig
Jaffrey, NH, Jaffrey Airport-Silver Ranch, Takeoff Minimums and Obstacle DP, Amdt 1
Jaffrey, NH, Jaffrey Airport-Silver Ranch, VOR–A, Amdt 8
Lakewood, NJ, Lakewood, Takeoff Minimums and Obstacle DP, Amdt 2
Newark, NJ, Newark Liberty Intl, GLS RWY 22R, Orig-D
Newark, NJ, Newark Liberty Intl, ILS OR LOC RWY 4L, ILS RWY 4L (SA CAT I), ILS RWY 4L (SA CAT II), Amdt 15
Newark, NJ, Newark Liberty Intl, ILS OR LOC RWY 22R, Amdt 6
Newark, NJ, Newark Liberty Intl, RNAV (GPS) RWY 4L, Amdt 2B
Princeton/Rocky Hill, NJ, Princeton, Takeoff Minimums and Obstacle DP, Amdt 3
Robbinsville, NJ, Trenton-Robbinsville, Takeoff Minimums and Obstacle DP, Amdt 2
Sussex, NJ, Sussex, Takeoff Minimums and Obstacle DP, Amdt 3
East Hampton, NY, East Hampton, Takeoff Minimums and Obstacle DP, Amdt 3
Millbrook, NY, Sky Acres, Takeoff Minimums and Obstacle DP, Amdt 2
New York, NY, La Guardia, RNAV (GPS) Y RWY 4, Amdt 3
Potsdam, NY, Potsdam Muni/Damon Fld/, NDB RWY 24, Amdt 5
Prague, OK, Prague Muni, GPS RWY 17, Orig, CANCELED
Prague, OK, Prague Muni, RNAV (GPS) RWY 17, Orig
Prague, OK, Prague Muni, RNAV (GPS)-A, Orig
Prague, OK, Prague Muni, Takeoff Minimums and Obstacle DP, Orig
Pottstown, PA, Heritage Field, GPS RWY 10, Orig, CANCELED
Pottstown, PA, Heritage Field, GPS RWY 28, Orig-A, CANCELED
Pottstown, PA, Heritage Field, LOC RWY 28, Amdt 3
Pottstown, PA, Heritage Field, RNAV (GPS) RWY 28, Orig
Pottstown, PA, Heritage Field, RNAV (GPS)-A, Orig
Pottstown, PA, Heritage Field, VOR/DME–A, Amdt 4
Reading, PA, Reading Rgnl/Carl A Spaatz Field, Takeoff Minimums and Obstacle DP, Amdt 5
Brookings, SD, Brookings Rgnl, RNAV (GPS) RWY 12, Orig
Cleveland, TN, Cleveland Rgnl Jetport, RNAV (GPS) RWY 3, Amdt 1
Cleveland, TN, Cleveland Rgnl Jetport, RNAV (GPS) RWY 21, Amdt 1
Cleveland, TN, Cleveland Rgnl Jetport, Takeoff Minimums and Obstacle DP, Amdt 1
Tazewell, TN, New Tazewell Muni, RNAV (GPS) RWY 7, Orig
Tazewell, TN, New Tazewell Muni, Takeoff Minimums and Obstacle DP, Orig
Waverly, TN, Humphreys County, NDB RWY 21, Amdt 3C
Houston, TX, George Bush Intercontinental/Houston, RNAV (RNP) Y RWY 8R, Amdt 1
Orange, VA, Orange County, RNAV (GPS) RWY 8, Orig
Orange, VA, Orange County, RNAV (GPS) RWY 26, Orig
Orange, VA, Orange County, Takeoff Minimums and Obstacle DP, Amdt 1
Orange, VA, Orange County, VOR/DME–A, Amdt 3
Philippi, WV, Philippi/Barbour County Rgnl, RNAV (GPS) RWY 8, Orig, CANCELED

[FR Doc. 2014–11558 Filed 5–22–14; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30957; Amdt. No. 3590]

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 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 May 23, 2014. 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 May 23, 2014.

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 April 25, 2014.

John Duncan,

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.

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

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

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
29-May-14	AR	Nashville	Howard County	4/2509	3/14/14	This NOTAM, published in TL 14–10, is hereby rescinded in its entirety.
29-May-14	AR	Camden	Harrell Field	4/2916	3/18/14	This NOTAM, published in TL 14–10, is hereby rescinded in its entirety.
29-May-14	AR	Camden	Harrell Field	4/2917	3/18/14	This NOTAM, published in TL 14–10, is hereby rescinded in its entirety.

AIRAC Date	State	City	Airport	FDC No.	FDC Date	Subject
29-May-14	CQ	Rota Island	Benjamin Taisacan Mangiona Intl.	4/4153	3/18/14	This NOTAM, published in TL 14–10, is hereby rescinded in its entirety.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/0423	4/22/14	RNAV (GPS) RWY 14L, Amdt 1E.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/0424	4/22/14	RNAV (GPS) RWY 27R, Amdt 2A.
29-May-14	CA	La Verne	Brackett Field	4/0973	4/17/14	LOC RWY 26L, Orig.
29-May-14	CA	La Verne	Brackett Field	4/0974	4/17/14	RNAV (GPS) RWY 26L, Orig.
29-May-14	CA	La Verne	Brackett Field	4/0975	4/17/14	ILS RWY 26L, Amdt 3.
29-May-14	CA	La Verne	Brackett Field	4/0976	4/17/14	VOR OR GPS A, Amdt 5C.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1209	4/22/14	LOC RWY 4L, Amdt 22.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1210	4/22/14	RNAV (GPS) RWY 4L, Amdt 2.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1212	4/22/14	RNAV (GPS) RWY 27L, Amdt 3A.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1213	4/22/14	RNAV (GPS) RWY 10C, Orig.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1215	4/22/14	RNAV (GPS) RWY 22R, Amdt 2.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1216	4/22/14	ILS OR LOC RWY 22R, Amdt 9.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1217	4/22/14	RNAV (GPS) RWY 28C, Orig-A.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1218	4/22/14	RNAV (GPS) RWY 14R, Amdt 2B.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1229	4/22/14	RNAV (GPS) RWY 28R, Amdt 3.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1238	4/22/14	RNAV (GPS) RWY 9L, Amdt 2A.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1242	4/22/14	ILS OR LOC RWY 9R, Amdt 10A.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1243	4/22/14	RNAV (GPS) RWY 9R, Amdt 3A.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1248	4/22/14	RNAV (GPS) RWY 10L, Amdt 4.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1249	4/22/14	RNAV (GPS) RWY 4R, Amdt 1.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1250	4/22/14	ILS OR LOC RWY 22L, Amdt 5.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/1251	4/22/14	RNAV (GPS) RWY 22L, Amdt 1.
29-May-14	WA	Spokane	Felts Field	4/1542	4/18/14	ILS OR LOC/DME RWY 22R, Amdt 1.
29-May-14	VA	Abingdon	Virginia Highlands	4/2152	4/15/14	LOC RWY 24, Amdt 4.
29-May-14	VA	Abingdon	Virginia Highlands	4/2153	4/15/14	RNAV (GPS) RWY 6, Amdt 1.
29-May-14	VA	Abingdon	Virginia Highlands	4/2162	4/15/14	RNAV (GPS) RWY 24, Amdt 1.
29-May-14	FL	Tampa	Tampa Executive	4/2165	4/15/14	ILS OR LOC RWY 23, Amdt 1A.
29-May-14	FL	Tampa	Tampa Executive	4/2166	4/15/14	RNAV (GPS) RWY 5, Orig.
29-May-14	FL	Tampa	Tampa Executive	4/2167	4/15/14	RNAV (GPS) RWY 23, Amdt 1A.
29-May-14	NY	Farmingdale	Republic	4/2227	4/17/14	ILS OR LOC RWY 14, Amdt 8B.
29-May-14	NY	Farmingdale	Republic	4/2228	4/17/14	RNAV (RNP) Z RWY 14, Orig.
29-May-14	NY	Farmingdale	Republic	4/2229	4/17/14	RNAV (GPS) Y RWY 14, Amdt 2A.
29-May-14	NY	Farmingdale	Republic	4/2230	4/17/14	RNAV (GPS) RWY 1, Amdt 2.
29-May-14	NY	Farmingdale	Republic	4/2250	4/17/14	RNAV (GPS) RWY 19, Amdt 2A.
29-May-14	WY	Sheridan	Sheridan County	4/2365	4/11/14	RNAV (GPS) RWY 32, Orig-A.
29-May-14	WY	Sheridan	Sheridan County	4/2366	4/11/14	RNAV (GPS) RWY 14, Orig-A.
29-May-14	WY	Sheridan	Sheridan County	4/2367	4/11/14	VOR RWY 14, Amdt 1A.
29-May-14	WY	Sheridan	Sheridan County	4/2368	4/11/14	ILS OR LOC/DME RWY 32, Amdt 1A.
29-May-14	MS	Cleveland	Cleveland Muni	4/2750	4/11/14	RNAV (GPS) RWY 36, Orig-A.
29-May-14	DC	Washington	Manassas Rgnl/Harry P. Davis Field.	4/3262	4/11/14	RNAV (GPS) RWY 16L, Amdt 1A.
29-May-14	FL	Daytona Beach	Daytona Beach Intl	4/3268	4/21/14	VOR RWY 16, Amdt 18B.
29-May-14	FL	Daytona Beach	Daytona Beach Intl	4/3269	4/21/14	RNAV (GPS) RWY 34, Amdt 2C.
29-May-14	FL	Daytona Beach	Daytona Beach Intl	4/3273	4/21/14	RNAV (GPS) RWY 25L, Amdt 1A.
29-May-14	FL	Daytona Beach	Daytona Beach Intl	4/3274	4/21/14	RNAV (GPS) RWY 25R, Amdt 3A.
29-May-14	FL	Daytona Beach	Daytona Beach Intl	4/3275	4/21/14	RNAV (GPS) RWY 7R, Orig-D.
29-May-14	FL	Daytona Beach	Daytona Beach Intl	4/3276	4/21/14	ILS OR LOC RWY 25R, Orig-A.
29-May-14	FL	Daytona Beach	Daytona Beach Intl	4/3277	4/21/14	RNAV (GPS) RWY 7L, Amdt 1A.
29-May-14	FL	Daytona Beach	Daytona Beach Intl	4/3278	4/21/14	RNAV (GPS) RWY 16, Amdt 1B.
29-May-14	FL	Daytona Beach	Daytona Beach Intl	4/3279	4/21/14	ILS OR LOC RWY 7L, Amdt 31A.
29-May-14	PA	Hazleton	Hazleton Regional	4/3301	4/17/14	RNAV (GPS) RWY 28, Orig.
29-May-14	PA	Hazleton	Hazleton Regional	4/3302	4/17/14	LOC RWY 28, Amdt 6.
29-May-14	PA	Hazleton	Hazleton Regional	4/3303	4/17/14	RNAV (GPS) RWY 10, Amdt 1.
29-May-14	PA	Hazleton	Hazleton Regional	4/3315	4/17/14	VOR RWY 10, Amdt 11.
29-May-14	PA	Hazleton	Hazleton Regional	4/3316	4/17/14	VOR RWY 28, Amdt 9.
29-May-14	PA	Hazleton	Hazleton Regional	4/3323	4/18/14	Takeoff Minimums and Obstacle DP, Amdt 2.
29-May-14	MO	Sedalia	Sedalia Rgnl	4/3328	4/17/14	NDB RWY 18, Amdt 8A.
29-May-14	TN	Lawrenceburg	Lawrenceburg-Lawrence County.	4/3330	4/11/14	RNAV (GPS) RWY 35, Orig.

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29-May-14	VA	South Hill	Mecklenburg-Brunswick Rgnl	4/3340	4/18/14	RNAV (GPS) RWY 1, Orig-A.
29-May-14	VA	South Hill	Mecklenburg-Brunswick Rgnl	4/3341	4/18/14	LOC RWY 1, Orig-B.
29-May-14	VA	South Hill	Mecklenburg-Brunswick Rgnl	4/3344	4/18/14	RNAV (GPS) RWY 19, Orig-A.
29-May-14	MS	Cleveland	Cleveland Muni	4/3346	4/11/14	VOR A, Amdt 9.
29-May-14	AK	St Mary's	St Mary's	4/3388	4/15/14	RNAV (GPS) RWY 17, Amdt 3.
29-May-14	NJ	Old Bridge	Old Bridge	4/3425	4/11/14	VOR RWY 24, Amdt 4A.
29-May-14	AK	Deadhorse	Deadhorse	4/3534	4/21/14	ILS OR LOC/DME RWY 5, Amdt 2D.
29-May-14	AK	Deadhorse	Deadhorse	4/3535	4/21/14	RNAV (GPS) Y RWY 23, Amdt 1B.
29-May-14	AK	Deadhorse	Deadhorse	4/3536	4/21/14	VOR/DME RWY 5, Amdt 2.
29-May-14	AK	Deadhorse	Deadhorse	4/3537	4/21/14	VOR/DME RWY 23, Amdt 4.
29-May-14	AK	Deadhorse	Deadhorse	4/3538	4/21/14	RNAV (GPS) Y RWY 5, Amdt 1B.
29-May-14	CA	Brawley	Brawley Muni	4/3561	4/18/14	VOR/DME A, Amdt 1.
29-May-14	CA	Brawley	Brawley Muni	4/3563	4/18/14	VOR/DME B, Amdt 2.
29-May-14	AL	Aliceville	George Downer	4/3638	4/11/14	RNAV (GPS) RWY 6, Orig.
29-May-14	NC	Pinehurst/Southern Pines.	Moore County	4/3639	4/11/14	ILS Z OR LOC/DME Z RWY 5, Amdt 2.
29-May-14	NC	Pinehurst/Southern Pines.	Moore County	4/3640	4/11/14	ILS Y OR LOC/DME Y RWY, 5 Orig.
29-May-14	NY	Syracuse	Syracuse Hancock Intl	4/4166	4/21/14	ILS OR LOC RWY 28, Amdt 34.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/4170	4/17/14	ILS OR LOC RWY 34R, Amdt 2B.
29-May-14	TX	Panhandle	Panhandle-Carson County	4/4546	4/11/14	VOR A, Orig.
29-May-14	ID	Rexburg	Rexburg-Madison County	4/4604	4/21/14	RNAV (GPS) RWY 35, Amdt 1A.
29-May-14	NY	Syracuse	Syracuse Hancock Intl	4/4606	4/15/14	RNAV (RNP) Y RWY 10, Orig.
29-May-14	NY	Syracuse	Syracuse Hancock Intl	4/4607	4/15/14	RNAV (GPS) Z RWY 10, Amdt 2B.
29-May-14	NY	Syracuse	Syracuse Hancock Intl	4/4609	4/15/14	RNAV (RNP) Y RWY 28, Orig.
29-May-14	NY	Syracuse	Syracuse Hancock Intl	4/4611	4/15/14	RNAV (GPS) Z RWY 28, Amdt 2A.
29-May-14	NY	Syracuse	Syracuse Hancock Intl	4/4612	4/15/14	ILS RWY 28 (CAT II), Amdt 34.
29-May-14	NY	Syracuse	Syracuse Hancock Intl	4/4614	4/15/14	TACAN RWY 33, Orig.
29-May-14	NY	Syracuse	Syracuse Hancock Intl	4/4615	4/15/14	ILS RWY 28 (SA CAT I), Amdt 34.
29-May-14	NY	Syracuse	Syracuse Hancock Intl	4/4616	4/15/14	VOR RWY 15, Amdt 23.
29-May-14	ID	Bonners Ferry	Boundary County	4/4620	4/11/14	RNAV (GPS) RWY 2, Orig-B.
29-May-14	TN	Lawrenceburg	Lawrenceburg-Lawrence County.	4/4651	4/18/14	RNAV (GPS) RWY 17, Orig.
29-May-14	MT	Ennis	Ennis-Big Sky	4/5141	4/15/14	RNAV (GPS) RWY 16, Orig.
29-May-14	MI	Flint	Bishop Intl	4/6129	4/18/14	ILS OR LOC RWY 9, Amdt 22B.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/6260	4/22/14	ILS OR LOC RWY 10C, ILS RWY 10C (SA CAT I), ILS RWY 10C (CAT II & III), Orig-A.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/6261	4/22/14	ILS OR LOC RWY 9L, ILS RWY 9L (SA CAT I), ILS RWY 9L (CAT II & III), Amdt 2B.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/6262	4/22/14	ILS OR LOC RWY 10L, ILS RWY 10L (SA CAT I), ILS RWY 10L (CAT I & II), Amdt 17.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/6263	4/22/14	ILS OR LOC RWY 28R, ILS RWY 28R (SA CAT I), ILS RWY 29R (SA CAT II & III), Amdt 16.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/6264	4/22/14	ILS OR LOC RWY 27L, ILS RWY 27L (SA CAT I), ILS RWY 27L (CAT II & III), Amdt 29A.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/6267	4/22/14	ILS OR LOC RWY 28C, ILS RWY 28C (SA CAT I), ILS RWY 28C (CAT II & III), Orig.
29-May-14	IL	Chicago	Chicago O'Hare Intl	4/6273	4/22/14	ILS OR LOC RWY 27R, ILS RWY 27R (SA CAT I), ILS RWY 27R (SA CAT II & III), Amdt 2A.
29-May-14	AK	Deadhorse	Deadhorse	4/6502	4/21/14	RNAV (RNP) Z RWY 23, Orig-A.
29-May-14	GA	Atlanta	Atlanta South Rgnl	4/6802	4/16/14	RNAV (GPS) RWY 6, Amdt 1A.
29-May-14	AK	Chevak	Chevak	4/6850	4/18/14	RNAV (GPS) RWY 2, Orig-A.
29-May-14	AK	Chevak	Chevak	4/6851	4/18/14	RNAV (GPS) RWY 20, Orig-A.
29-May-14	AK	Hooper Bay	Hooper Bay	4/7005	4/17/14	RNAV (GPS) RWY 13, Amdt 1.
29-May-14	AK	Hooper Bay	Hooper Bay	4/7006	4/17/14	RNAV (GPS) RWY 31, Amdt 1.

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29-May-14	IN	Kokomo	Kokomo Muni	4/7031	4/15/14	RNAV (GPS) RWY 23, Amdt 1.
29-May-14	IN	Kokomo	Kokomo Muni	4/7032	4/15/14	RNAV (GPS) RWY 32, Orig.
29-May-14	IN	Kokomo	Kokomo Muni	4/7033	4/15/14	ILS OR LOC RWY 23, Amdt 10.
29-May-14	TX	Carrizo Springs	Dimmit County	4/7211	4/17/14	RNAV (GPS) RWY 13, Orig.
29-May-14	OH	Hamilton	Butler Co Rgnl-Hogan Field	4/7382	4/15/14	ILS OR LOC RWY 29, Amdt 1B.
29-May-14	MO	Fort Leonard Wood	Waynesville-St. Robert Rgnl Forney Fld.	4/7397	4/16/14	ILS OR LOC RWY 14, Amdt 1.
29-May-14	SC	Walterboro	Lowcountry Rgnl	4/7404	4/17/14	RNAV (GPS) RWY 5, Amdt 1.
29-May-14	SC	Walterboro	Lowcountry Rgnl	4/7405	4/17/14	RNAV (GPS) RWY 23, Amdt 1.
29-May-14	SC	Walterboro	Lowcountry Rgnl	4/7414	4/17/14	ILS OR LOC/DME RWY 23, Amdt 1A.
29-May-14	IL	De Kalb	De Kalb Taylor Muni	4/7415	4/16/14	ILS OR LOC RWY 2, Orig-C.
29-May-14	AR	Walnut Ridge	Walnut Ridge Rgnl	4/7417	4/16/14	RNAV (GPS) RWY 4, Orig.
29-May-14	AK	McGrath	McGrath	4/7434	4/17/14	RNAV (GPS) RWY 16, Amdt 1.
29-May-14	WA	Spokane	Felts Field	4/7435	4/15/14	VOR RWY 4L, Amdt 5.
29-May-14	AR	Melbourne	Melbourne Muni-John E Miller Field.	4/7436	4/16/14	RNAV (GPS) RWY 3, Amdt 1A.
29-May-14	WA	Spokane	Felts Field	4/7438	4/15/14	RNAV (GPS) RWY 4L, Amdt 1A.
29-May-14	OH	Lebanon	Warren County/John Lane Field.	4/7441	4/17/14	RNAV (GPS) RWY 19, Amdt 3.
29-May-14	IL	Flora	Flora Muni	4/7443	4/16/14	RNAV (GPS) RWY 3, Amdt 2.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7453	4/17/14	ILS RWY 34L (SA CAT I & II), Amdt 1B.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7454	4/17/14	ILS RWY 16 C (CAT II & III), Amdt 14.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7455	4/17/14	ILS RWY 16R (CAT II & III), Amdt 2A.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7456	4/17/14	ILS OR LOC RWY 34C, Amdt 3B.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7457	4/17/14	ILS RWY 16C (SA CAT I), Amdt 14.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7458	4/17/14	RNAV (RNP) Z RWY 16C, Orig-A.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7459	4/17/14	RNAV (RNP) Z RWY 34C, Orig.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7460	4/17/14	RNAV (GPS) Y RWY 16L, Amdt 3.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7461	4/17/14	RNAV (RNP) Z RWY 34L, Orig-A.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7462	4/17/14	ILS OR LOC RWY 16L, Amdt 5A.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7463	4/17/14	ILS OR LOC RWY 16R, Amdt 2A.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7464	4/17/14	RNAV (RNP) Z RWY 16R, Orig.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7465	4/17/14	ILS OR LOC RWY 34L, Amdt 1B.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7466	4/17/14	RNAV (GPS) Y RWY 34C, Amdt 2A.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7467	4/17/14	ILS RWY 16R (SA CAT I), Amdt 2A.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7468	4/17/14	ILS RWY 34C (SA CAT I & II), Amdt 3B.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7470	4/17/14	ILS RWY 16L (CAT II & III), Amdt 5A.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7471	4/17/14	ILS RWY 16L (SA CAT I), Amdt 5A.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7472	4/17/14	RNAV (RNP) Z RWY 16L, Orig.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7473	4/17/14	RNAV (RNP) Z RWY 34R, Orig-A.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7475	4/17/14	RNAV (GPS) Y RWY 16C, Amdt 2.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7476	4/17/14	RNAV (GPS) Y RWY 16R, Amdt 1.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/7477	4/17/14	RNAV (GPS) Y RWY 34L, Amdt 1A.
29-May-14	HI	Honolulu	Honolulu Intl	4/7499	4/15/14	ILS Y RWY 4R, Amdt 1.
29-May-14	HI	Honolulu	Honolulu Intl	4/7502	4/15/14	ILS Z RWY 4R, Amdt 1.
29-May-14	WY	Cowley/Lovell/Byron	North Big Horn County	4/7844	4/17/14	NDB RWY 9, Amdt 2.
29-May-14	WY	Cowley/Lovell/Byron	North Big Horn County	4/7845	4/17/14	RNAV (GPS) RWY 9, Orig.
29-May-14	LA	Springhill	Springhill	4/7846	4/16/14	RNAV (GPS) RWY 36, Orig.
29-May-14	FL	Fort Pierce	St Lucie County Intl	4/7890	4/16/14	VOR/DME RWY 14, Amdt 9A.
29-May-14	FL	Fort Pierce	St Lucie County Intl	4/7891	4/16/14	RNAV (GPS) RWY 14, Amdt 2.
29-May-14	FL	Fort Pierce	St Lucie County Intl	4/7892	4/16/14	RNAV (GPS) RWY 32, Amdt 1A.
29-May-14	AK	St Mary's	St Mary's	4/7900	4/15/14	RNAV (GPS) RWY 35, Amdt 2.
29-May-14	AK	St Mary's	St Mary's	4/7901	4/15/14	LOC/DME RWY 17, Amdt 5.

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29-May-14	TX	Breckenridge	Stephens County	4/7909	4/17/14	RNAV (GPS) RWY 35, Orig.
29-May-14	LA	Opelousas	St Landry Parish-Ahart Field	4/7912	4/16/14	NDB RWY 18, Amdt 3.
29-May-14	LA	Opelousas	St Landry Parish-Ahart Field	4/7913	4/16/14	RNAV (GPS) RWY 18, Amdt 1.
29-May-14	WI	Sheboygan	Sheboygan County Memorial	4/7916	4/17/14	RNAV (GPS) RWY 4, Amdt 3.
29-May-14	WI	Sheboygan	Sheboygan County Memorial	4/7917	4/17/14	VOR RWY 22, Amdt 9.
29-May-14	WI	Sheboygan	Sheboygan County Memorial	4/7919	4/17/14	RNAV (GPS) RWY 31, Orig.
29-May-14	WI	Sheboygan	Sheboygan County Memorial	4/7922	4/17/14	RNAV (GPS) RWY 22, Amdt 3.
29-May-14	NE	Scribner	Scribner State	4/7964	4/15/14	RNAV (GPS) RWY 35, Amdt 1.
29-May-14	NY	Schenectady	Schenectady County	4/7966	4/17/14	RNAV (GPS) RWY 10, Orig-B.
29-May-14	MI	Manistique	Schoolcraft County	4/7968	4/15/14	RNAV (GPS) RWY 10, Orig.
29-May-14	OR	Madras	Madras Municipal	4/7969	4/15/14	RNAV (GPS) RWY 16, Amdt 1.
29-May-14	OR	Madras	Madras Municipal	4/7970	4/15/14	RNAV (GPS) RWY 34, Orig.
29-May-14	MT	Shelby	Shelby	4/7971	4/15/14	RNAV (GPS) RWY 23, Amdt 2.
29-May-14	MT	Shelby	Shelby	4/7975	4/15/14	RNAV (GPS) RWY 5, Orig.
29-May-14	OR	Eugene	Mahlon Sweet Field	4/8027	4/15/14	RNAV (RNP) Z RWY 34L, Orig.
29-May-14	OR	Eugene	Mahlon Sweet Field	4/8028	4/15/14	RNAV (RNP) Z RWY 34R, Orig-A.
29-May-14	OR	Eugene	Mahlon Sweet Field	4/8030	4/15/14	RNAV (GPS) Y RWY 16L, Amdt 2.
29-May-14	OR	Eugene	Mahlon Sweet Field	4/8031	4/15/14	RNAV (GPS) Y RWY 34R, Amdt 2.
29-May-14	OR	Eugene	Mahlon Sweet Field	4/8032	4/15/14	RNAV (GPS) Y RWY 16R, Amdt 1.
29-May-14	NJ	Atlantic City	Atlantic City Intl	4/8036	4/21/14	RNAV (GPS) RWY 22, Amdt 4.
29-May-14	NJ	Atlantic City	Atlantic City Intl	4/8037	4/21/14	RNAV (GPS) RWY 4, Amdt 2A.
29-May-14	NJ	Atlantic City	Atlantic City Intl	4/8039	4/21/14	VOR/DME RWY 22, Amdt 6A.
29-May-14	OR	Eugene	Mahlon Sweet Field	4/8041	4/15/14	RNAV (GPS) Y RWY 34L, Amdt 2.
29-May-14	OR	Eugene	Mahlon Sweet Field	4/8042	4/15/14	RNAV (RNP) Z RWY 16L, Orig-A.
29-May-14	OR	Eugene	Mahlon Sweet Field	4/8043	4/15/14	RNAV (RNP) Z RWY 16R, Orig.
29-May-14	NE	Ogallala	Searle Field	4/8045	4/17/14	VOR/DME RWY 8, Amdt 1.
29-May-14	NE	Ogallala	Searle Field	4/8046	4/17/14	RNAV (GPS) RWY 8, Amdt 2.
29-May-14	NE	Ogallala	Searle Field	4/8047	4/17/14	VOR RWY 8, Amdt 6.
29-May-14	IA	Clarinda	Schenck Field	4/8049	4/16/14	RNAV (GPS) RWY 2, Orig-A.
29-May-14	NE	Ogallala	Searle Field	4/8050	4/17/14	RNAV (GPS) RWY 13, Orig-A.
29-May-14	IA	Clarinda	Schenck Field	4/8051	4/16/14	RNAV (GPS) RWY 20, Orig-A.
29-May-14	MA	Beverly	Beverly Muni	4/8088	4/16/14	RNAV (GPS) RWY 27, Orig.
29-May-14	LA	Gonzales	Louisiana Rgnl	4/8090	4/16/14	RNAV (GPS) RWY 17, Amdt 1.
29-May-14	LA	Gonzales	Louisiana Rgnl	4/8091	4/16/14	RNAV (GPS) RWY 35, Amdt 1.
29-May-14	AK	Deadhorse	Deadhorse	4/8108	4/21/14	VOR RWY 23, Amdt 6.
29-May-14	AK	Deadhorse	Deadhorse	4/8111	4/21/14	VOR RWY 5, Amdt 4.
29-May-14	AK	Deadhorse	Deadhorse	4/8121	4/21/14	RNAV (RNP) Z RWY 5, Orig-A.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/8222	4/17/14	ILS RWY 34R (SA CAT I & II), Amdt 2B.
29-May-14	AK	Big Lake	Big Lake	4/8295	4/15/14	RNAV (GPS) RWY 7, Amdt 1.
29-May-14	AK	Big Lake	Big Lake	4/8296	4/15/14	VOR RWY 7, Amdt 7.
29-May-14	AK	Big Lake	Big Lake	4/8297	4/15/14	RNAV (GPS) RWY 25, Amdt 1.
29-May-14	AZ	Mesa	Falcon Fld	4/8337	4/15/14	RNAV (GPS) RWY 4L, Amdt 1.
29-May-14	AZ	Mesa	Falcon Fld	4/8342	4/15/14	RNAV (GPS) RWY 4R, Amdt 1A.
29-May-14	CA	Torrance	Zamperini Field	4/8358	4/17/14	RNAV (GPS) RWY 11L, Orig.
29-May-14	CA	Torrance	Zamperini Field	4/8359	4/17/14	RNAV (GPS) RWY 29R, Orig-A.
29-May-14	CA	Torrance	Zamperini Field	4/8360	4/17/14	VOR RWY 11L, Amdt 15.
29-May-14	NV	Ely	Ely Arpt/Yelland Fld	4/8361	4/17/14	RNAV (GPS) RWY 18, Amdt 1.
29-May-14	IN	Evansville	Evansville Rgnl	4/8362	4/16/14	RNAV (GPS) RWY 18, Amdt 1.
29-May-14	CA	Shafter	Shafter-Minter Field	4/8363	4/15/14	RNAV (GPS) RWY 12, Amdt 1.
29-May-14	NV	Eureka	Eureka	4/8365	4/15/14	RNAV (GPS) RWY 18, Orig.
29-May-14	KY	Richmond	Madison	4/8370	4/16/14	RNAV (GPS) RWY 18, Amdt 1.
29-May-14	KY	Richmond	Madison	4/8371	4/16/14	RNAV (GPS) RWY 36, Amdt 1.
29-May-14	KY	Richmond	Madison	4/8372	4/16/14	VOR/DME RWY 18, Amdt 7.
29-May-14	VA	Luray	Luray Caverns	4/8377	4/17/14	RNAV (GPS) RWY 4, Orig-A.
29-May-14	VA	Luray	Luray Caverns	4/8380	4/17/14	RNAV (GPS) RWY 22, Amdt 1A.
29-May-14	IA	Dubuque	Dubuque Rgnl	4/8403	4/16/14	RNAV (GPS) RWY 18, Orig.
29-May-14	FL	Panama City	Northwest Florida Beaches Intl	4/8406	4/16/14	RNAV (GPS) RWY 16, Amdt 2.
29-May-14	FL	Panama City	Northwest Florida Beaches Intl	4/8407	4/16/14	ILS OR LOC/DME RWY 16, Amdt 2.
29-May-14	AR	Fayetteville/Springdale.	Northwest Arkansas Rgnl	4/8408	4/16/14	ILS OR LOC/DME RWY 17, Orig-A.
29-May-14	AR	Fayetteville/Springdale.	Northwest Arkansas Rgnl	4/8409	4/16/14	RNAV (GPS) RWY 17, Orig-A.
29-May-14	AK	Savoonga	Savoonga	4/8416	4/15/14	RNAV (GPS) RWY 5, Amdt 1B.
29-May-14	AK	Savoonga	Savoonga	4/8417	4/15/14	RNAV (GPS) RWY 23, Amdt 1C.
29-May-14	ME	Sanford	Sanford Seacoast Rgnl	4/8418	4/16/14	RNAV (GPS) RWY 7, Orig-A.
29-May-14	ME	Sanford	Sanford Seacoast Rgnl	4/8419	4/16/14	VOR RWY 7, Amdt 4B.

AIRAC Date	State	City	Airport	FDC No.	FDC Date	Subject
29-May-14	ME	Sanford	Sanford Seacoast Rgnl	4/8421	4/16/14	ILS OR LOC RWY 7, Amdt 4B.
29-May-14	NC	Goldsboro	Wayne Executive Jetport	4/8473	4/17/14	RNAV (GPS) RWY 23, Amdt 1.
29-May-14	NE	Wayne	Wayne Muni/Stan Morris Fld	4/8474	4/17/14	NDB RWY 36, Orig-A.
29-May-14	KY	Hazard	Wendell H Ford	4/8478	4/16/14	LOC/DME RWY 14, Orig-A.
29-May-14	KY	Hazard	Wendell H Ford	4/8480	4/16/14	VOR/DME RWY 14, Amdt 1B.
29-May-14	NE	Wayne	Wayne Muni/Stan Morris Fld	4/8481	4/17/14	NDB RWY 18, Orig-A.
29-May-14	CA	Watsonville	Watsonville Muni	4/8482	4/17/14	LOC RWY 2, Amdt 4.
29-May-14	NE	Wayne	Wayne Muni/Stan Morris Fld	4/8484	4/17/14	RNAV (GPS) RWY 36, Amdt 2.
29-May-14	NC	Goldsboro	Wayne Executive Jetport	4/8486	4/17/14	ILS OR LOC RWY 23, Amdt 2.
29-May-14	CA	Watsonville	Watsonville Muni	4/8487	4/17/14	RNAV (GPS) RWY 2, Amdt 1A.
29-May-14	NC	Goldsboro	Wayne Executive Jetport	4/8488	4/17/14	RNAV (GPS) RWY 5, Amdt 1.
29-May-14	KY	Hazard	Wendell H Ford	4/8489	4/16/14	RNAV (GPS) RWY 14, Amdt 1A.
29-May-14	NE	Wayne	Wayne Muni/Stan Morris Fld	4/8490	4/17/14	RNAV (GPS) RWY 18, Amdt 2.
29-May-14	KY	Hazard	Wendell H Ford	4/8491	4/16/14	RNAV (GPS) RWY 32, Orig-A.
29-May-14	MO	Sedalia	Sedalia Rgnl	4/8535	4/17/14	RNAV (GPS) RWY 18, Amdt 2.
29-May-14	MO	Sedalia	Sedalia Rgnl	4/8536	4/17/14	RNAV (GPS) RWY 36, Amdt 2.
29-May-14	UT	St George	St George Muni	4/8560	4/15/14	RNAV (GPS) RWY 1, Orig-A.
29-May-14	HI	Honolulu	Honolulu Intl	4/8675	4/15/14	RNAV (RNP) Z RWY 4R, Amdt 1.
29-May-14	HI	Honolulu	Honolulu Intl	4/8676	4/15/14	RNAV (RNP) Z RWY 8L, Amdt 1.
29-May-14	HI	Honolulu	Honolulu Intl	4/8678	4/15/14	LOC/DME RWY 4R, Amdt 1.
29-May-14	CA	San Luis Obispo	San Luis County Rgnl	4/8700	4/17/14	ILS RWY 11, Amdt 2A.
29-May-14	CA	San Luis Obispo	San Luis County Rgnl	4/8701	4/17/14	LOC RWY 11, Orig-A.
29-May-14	CA	San Luis Obispo	San Luis County Rgnl	4/8702	4/17/14	RNAV (GPS) RWY 11, Amdt 1.
29-May-14	HI	Honolulu	Honolulu Intl	4/8704	4/15/14	RNAV (GPS) Y RWY 4R, Amdt 2.
29-May-14	TX	Mason	Mason County	4/9055	4/15/14	RNAV (GPS) RWY 36, Orig.
29-May-14	CA	Carlsbad	McClellan-Palomar	4/9058	4/16/14	RNAV (RNP) Z RWY 24, Orig-A.
29-May-14	CA	Carlsbad	McClellan-Palomar	4/9059	4/16/14	ILS OR LOC/DME RWY 24, Amdt 9A.
29-May-14	KS	Meade	Meade Muni	4/9060	4/16/14	RNAV (GPS) RWY 17, Orig.
29-May-14	CA	Carlsbad	McClellan-Palomar	4/9064	4/16/14	RNAV (GPS) X RWY 24, Orig.
29-May-14	CA	Carlsbad	McClellan-Palomar	4/9066	4/16/14	RNAV (GPS) Y RWY 24, Amdt 3.
29-May-14	AR	McGehee	McGehee Muni	4/9067	4/16/14	RNAV (GPS) RWY 18, Orig.
29-May-14	AR	McGehee	McGehee Muni	4/9068	4/16/14	RNAV (GPS) RWY 36, Orig.
29-May-14	MI	Mason	Mason Jewett Field	4/9071	4/17/14	RNAV (GPS) RWY 10, Orig-A.
29-May-14	CO	Canon City	Fremont County	4/9079	4/15/14	RNAV (RNP) RWY 11, Orig.
29-May-14	CO	Canon City	Fremont County	4/9080	4/15/14	RNAV (GPS) Y RWY 29, Orig.
29-May-14	CO	Canon City	Fremont County	4/9081	4/15/14	RNAV (RNP) Z RWY 29, Orig.
29-May-14	MO	Maryville	Northwest Missouri Rgnl	4/9119	4/17/14	RNAV (GPS) RWY 32, Amdt 1.
29-May-14	TX	Robstown	Nueces County	4/9120	4/17/14	RNAV (GPS) RWY 13, Orig.
29-May-14	AL	Reform	North Pickens	4/9121	4/16/14	RNAV (GPS) RWY 19, Amdt 1.
29-May-14	AL	Reform	North Pickens	4/9122	4/16/14	RNAV (GPS) RWY 1, Orig.
29-May-14	TX	Sherman/Denison	North Texas Rgnl/Perrin Field	4/9123	4/15/14	RNAV (GPS) RWY 17L, Orig.
29-May-14	TX	Sherman/Denison	North Texas Rgnl/Perrin Field	4/9125	4/15/14	ILS OR LOC RWY 17L, Amdt 1.
29-May-14	TX	Sherman/Denison	North Texas Rgnl/Perrin Field	4/9126	4/15/14	RNAV (GPS) RWY 35R, Orig.
29-May-14	TX	Sherman/Denison	North Texas Rgnl/Perrin Field	4/9127	4/15/14	NDB RWY 17L, Amdt 10.
29-May-14	TX	Olney	Olney Muni	4/9274	4/17/14	RNAV (GPS) RWY 17, Orig.
29-May-14	IA	Mason City	Mason City Muni	4/9280	4/16/14	ILS OR LOC RWY 36, Amdt 6D.
29-May-14	IA	Mason City	Mason City Muni	4/9282	4/16/14	RNAV (GPS) RWY 36, Amdt 1.
29-May-14	IA	Mason City	Mason City Muni	4/9283	4/16/14	VOR RWY 36, Amdt 6C.
29-May-14	WI	Green Bay	Austin Straubel Intl	4/9295	4/16/14	LOC BC RWY 24, Amdt 19.
29-May-14	MN	Austin	Austin Muni	4/9296	4/16/14	ILS OR LOC RWY 35, Amdt 1.
29-May-14	KS	Augusta	Augusta Muni	4/9297	4/16/14	RNAV (GPS) RWY 36, Orig.
29-May-14	TX	Austin	Austin-Bergstrom Intl	4/9298	4/15/14	ILS OR LOC RWY 17R, Amdt 4.
29-May-14	TX	Austin	Austin-Bergstrom Intl	4/9302	4/15/14	RNAV (GPS) RWY 17L, Amdt 1.
29-May-14	TX	Austin	Austin-Bergstrom Intl	4/9303	4/15/14	RNAV (GPS) RWY 17R, Amdt 1.
29-May-14	MN	Austin	Austin Muni	4/9304	4/16/14	VOR RWY 35, Amdt 2.
29-May-14	MN	Austin	Austin Muni	4/9305	4/16/14	RNAV (GPS) RWY 35, Amdt 1.
29-May-14	WI	Marshfield	Marshfield Muni	4/9339	4/16/14	RNAV (GPS) RWY 16, Orig-B.
29-May-14	WI	Marshfield	Marshfield Muni	4/9340	4/16/14	NDB RWY 16, Amdt 10.
29-May-14	MI	Marlette	Marlette	4/9341	4/17/14	RNAV (GPS) RWY 19, Orig.
29-May-14	AR	Marianna	Marianna/Lee County-Steve Edwards Field.	4/9347	4/16/14	RNAV (GPS) RWY 36, Amdt 1.
29-May-14	AR	Marianna	Marianna/Lee County-Steve Edwards Field.	4/9348	4/16/14	RNAV (GPS) RWY 18, Amdt 1.
29-May-14	AK	Marshall	Marshall Don Hunter Sr	4/9349	4/15/14	RNAV (GPS) RWY 7, Amdt 2.
29-May-14	AZ	Marana	Marana Rgnl	4/9350	4/15/14	RNAV (GPS) RWY 12, Amdt 1A.
29-May-14	CA	Marina	Marina Muni	4/9351	4/17/14	VOR RWY 11, Amdt 2.
29-May-14	CA	Marina	Marina Muni	4/9352	4/17/14	VOR/DME RWY 29, Amdt 2B.
29-May-14	AZ	Marana	Marana Rgnl	4/9353	4/15/14	RNAV (GPS) RWY 21, Amdt 1A.
29-May-14	TX	Austin	Austin-Bergstrom Intl	4/9373	4/15/14	ILS OR LOC RWY 17L, Amdt 2.

AIRAC Date	State	City	Airport	FDC No.	FDC Date	Subject
29-May-14	CQ	Rota Island	Benjamin Taisacan Manglona Intl.	4/9439	4/22/14	RNAV (GPS) RWY 9, Amdt 1.
29-May-14	GA	Butler	Butler Muni	4/9568	4/16/14	RNAV (GPS) RWY 36, Amdt 1.
29-May-14	KS	Topeka	Forbes Field	4/9593	4/15/14	NDB RWY 13, Amdt 7.
29-May-14	KS	Topeka	Forbes Field	4/9594	4/15/14	RNAV (GPS) RWY 21, Amdt 1.
29-May-14	KS	Topeka	Forbes Field	4/9595	4/15/14	RNAV (GPS) RWY 3, Amdt 1.
29-May-14	KS	Topeka	Forbes Field	4/9596	4/15/14	VOR/DME OR TACAN RWY 3, Amdt 6.
29-May-14	WI	Park Falls	Park Falls Muni	4/9636	4/11/14	NDB RWY 36, Amdt 1.
29-May-14	WI	Park Falls	Park Falls Muni	4/9637	4/11/14	RNAV (GPS) RWY 18, Orig-A.
29-May-14	WI	Park Falls	Park Falls Muni	4/9638	4/11/14	RNAV (GPS) RWY 36, Orig-A.
29-May-14	AZ	Flagstaff	Flagstaff Pulliam	4/9661	4/17/14	ILS OR LOC/DME RWY 21, Orig-F.
29-May-14	WI	Sheboygan	Sheboygan County Memorial	4/9683	4/17/14	ILS OR LOC/DME RWY 22, Amdt 5.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/9693	4/17/14	ILS OR LOC RWY 16C, Amdt 14.
29-May-14	WA	Seattle	Seattle-Tacoma Intl	4/9698	4/17/14	RNAV (GPS) Y RWY 34R, Amdt 2A.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 8

[Docket No. FR–5784–N–01]

Nondiscrimination on the Basis of Disability in Federally Assisted Programs and Activities

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Instructions for use of alternative accessibility standard.

SUMMARY: HUD is issuing this document to permit recipients of Federal financial assistance from HUD (HUD recipients) to use an alternative accessibility standard for purposes of complying with Section 504 of the Rehabilitation Act of 1973 (Section 504) and HUD's implementing regulation at 24 CFR part 8 (Section 504 regulation) until HUD formally revises its Section 504 regulation to adopt an updated accessibility standard. In March 2011, the Department of Justice (DOJ), pursuant to its coordination authority under Section 504, advised Federal agencies that they may permit covered entities to use the 2010 ADA Standards for Accessible Design (2010 Standards) as an acceptable alternative to the Uniform Federal Accessibility Standards (UFAS) until such time as they update their agency's regulation implementing the Federally assisted provisions of Section 504. Consistent with DOJ's advice, this document provides HUD recipients the option of using the 2010 Standards under title II of the ADA, except for certain specific provisions identified in this document, as an alternative accessibility standard to UFAS for purposes of complying with Section 504 and HUD's Section 504 regulation for new construction and alterations commenced on or after May 23, 2014. This document is in effect until HUD formally revises its Section 504 regulation to adopt an updated accessibility standard.

DATES: *Effective Date:* May 23, 2014.

FOR FURTHER INFORMATION CONTACT: Cheryl Kent, Special Advisor for Disability Policy, Office of Program Compliance and Disability Rights, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone 202–402–7058 (this is not a toll-free number). Individuals who are deaf, are hard of hearing, or have speech impairments may access this number via TTY by calling the toll-free Federal Information Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Overview

HUD's Section 504 regulation requires that programs or activities receiving Federal financial assistance be readily accessible to and usable by persons with disabilities. HUD's Section 504 regulation provides that the design, construction, or alteration of buildings and facilities in conformance with UFAS is deemed to be in compliance with the accessibility requirements of Section 504 (24 CFR 8.32). Many of the programs or activities that are subject to HUD's Section 504 regulation, however, are also subject to title II of the ADA, which applies to public entities, or title III of the ADA, which covers certain private entities, including public accommodations, and are therefore required to comply with the 2010 Standards. When more than one law and accessibility standard applies, it is currently necessary for the recipient to determine on a section-by-section basis which standard affords greater accessibility.

In March 2011, DOJ advised Federal agencies that they may provide covered entities the option of using the 2010 Standards as an acceptable alternative to UFAS (*www.ada.gov/504_memo_standards.htm*) until such time as they update their agency's regulation implementing the Federally assisted provisions of Section 504. Because many recipients of Federal financial assistance are also subject to the Americans with Disabilities Act (ADA), Federal agencies requested this authority to minimize the number of accessibility standards with which recipients of Federal financial assistance must comply.

HUD has identified certain provisions in the 2010 Standards that provide less accessibility than is currently required by UFAS and/or HUD's Section 504 regulation. As a result, HUD is not deeming use of those specific provisions of the 2010 Standards as a means of providing accessibility under Section 504 because HUD cannot decrease the level of accessibility currently required by its Section 504 regulation without engaging in notice and comment rulemaking. Those provisions are summarized in the Appendix of this document.

The option to utilize the 2010 Standards under title II of the ADA, except for certain provisions identified in this document, is available to all HUD recipients for purposes of complying with HUD's Section 504 regulation whether they are private or

public entities, including HUD recipients covered by Section 504 but not title II or III of the ADA. For purposes of complying with Section 504, a HUD recipient must designate the accessibility standard it is using: The 2010 Standards with identified exceptions outlined in this document or UFAS. Recipients that prefer to use UFAS as the accessibility standard under Section 504 may continue to do so. If a recipient subject to both Section 504 and the ADA decides to continue to use UFAS to comply with HUD's Section 504 requirements, it must determine, section-by-section, which standard (2010 Standards or UFAS) affords greater accessibility and comply with that provision. If choosing the 2010 Standards for purposes of compliance with Section 504, the recipient need only comply with the 2010 Standards except that it must not apply those provisions not deemed as compliant in this document and must continue to apply those provisions of UFAS or the HUD regulation that are specifically identified in this document. HUD also reminds recipients that the design and construction requirements of the Fair Housing Act (FHAct) continue to apply to new construction of covered multifamily dwellings. These requirements are not affected by this document. However, some of these requirements impose greater accessibility requirements than the 2010 Standards.

II. Definitions of Standards and Guidelines Referenced in This Document

1991 Standards means the requirements in the ADA Standards for Accessible Design published as Appendix A to 28 CFR part 36 on July 26, 1991, and republished as Appendix D to 28 CFR part 36 on September 15, 2010. For purposes of compliance with title II of the ADA, covered entities were not permitted to use the elevator exemption contained at sections 4.1.3(5) and 4.1.6(1)(j) of the 1991 Standards.

2004 ADA and ABA Accessibility Guidelines means the minimum accessibility guidelines published by the United States Access Board in 2004 for both the ADA and the Architectural Barriers Act (ABA).[1]

2004 ADAAG means the requirements set forth in Appendices B and D to 36 CFR 1191 which are the ADA scoping chapters and the common technical requirements in the ADA and ABA Accessibility Guidelines.

2004 ABAAG means the requirements set forth in Appendices C and D to 36 CFR 1191 which are the ABA scoping chapters and the common technical requirements in the ADA and ABA Accessibility Guidelines.

UFAS means the Uniform Federal Accessibility Standards. HUD's Section 504 regulation references sections 3 through 8 of UFAS for purposes of compliance with Section 504.[2]

2010 Standards means the 2010 ADA Standards for Accessible Design as defined in the regulation implementing title II of the ADA and consists of the 2004 ADAAG as applied to entities covered by title II of the ADA (*i.e.,* public entities) and the requirements contained in 28 CFR 35.151.

III. Background

A. Section 504

Section 504 and HUD's Section 504 regulation prohibit discrimination on the basis of disability in any program or activity that receives Federal financial assistance from the Department.[3] HUD's Section 504 regulation specifically prohibits the denial of benefits of, exclusion from participation in, or other discrimination against qualified individuals with disabilities in Federally assisted programs or activities because a recipient's facilities are inaccessible to or unusable by individuals with disabilities.[4] Among other things, the regulation requires that the design, construction, and alteration of projects meet physical accessibility requirements.[5]

Currently, pursuant to HUD's Section 504 regulation, the design, construction, or alteration of buildings in conformance with UFAS is deemed to be in compliance with the accessibility requirements of Section 504.[6] UFAS is based on the minimum accessibility guidelines developed by the United States Access Board (Access Board) that were adopted as enforceable standards by the General Services Administration, the Department of Defense, the Department of Housing and Urban Development, and the United States Postal Service for purposes of compliance with the ABA. Subsequently, UFAS was also adopted as the referenced accessibility standard in HUD's Section 504 regulation. HUD's Section 504 regulation provides that departures from particular technical and scoping requirements of UFAS by the use of other methods are permitted where substantially equivalent or greater access to and usability of the building is provided (24 CFR 8.32).

B. 2004 ADA and ABA Accessibility Guidelines

On July 23, 2004, the Access Board published updated minimum accessibility guidelines for both the ADA and the ABA known as the Americans with Disabilities Act and Architectural Barriers Act Accessibility Guidelines (2004 ADA and ABA Accessibility Guidelines). The 2004 ADA and ABA Accessibility Guidelines updated the accessibility provisions contained in UFAS and the 1991 ADA Accessibility Guidelines. The 2004 ADA and ABA Accessibility Guidelines contain three parts: application and scoping requirements for facilities covered by the ADA (ADA Chapters 1 and 2); application and scoping requirements for facilities covered by the ABA (ABA Chapters 1 and 2); and a common set of technical provisions (Chapters 3 through 10). The 2004 ABAAG refers to ABA scoping Chapters 1 and 2 and technical provisions in Chapters 3 through 10, and the 2004 ADAAG refers to ADA scoping Chapters 1 and 2 and technical provisions in Chapters 3 through 10.

HUD will engage in the rulemaking process in order to replace UFAS with a new accessibility standard based on the updated guidelines for purposes of both Section 504 and ABA compliance. Until HUD adopts a new accessibility standard, HUD recipients who undertake alterations or new construction of a project may continue to utilize UFAS and HUD's Section 504 or ABA regulations.

C. Title II of the ADA

Title II of the ADA prohibits discrimination on the basis of disability by state and local government entities, including by requiring facilities designed, constructed, or altered by or on behalf of a public entity, or as part of a public entity's program, to be readily accessible to and usable by individuals with disabilities.[7] Except for transportation facilities, DOJ is the Federal agency responsible for adopting accessibility standards under title II of the ADA.[8] The Department of

[1] 36 CFR part 1191. The full text of the 2004 ADA and ABA Accessibility Guidelines is available at the U.S. Access Board's Web site, *http://www.access-board.gov/guidelines-and-standards/buildings-and-sites/about-the-ada-standards/background/ada-aba-accessibility-guidelines-2004.*

[2] 24 CFR 8.32.

[3] 29 U.S.C. 794.

[4] 24 CFR 8.20.

[5] 24 CFR 8.21, 8.22, 8.23, 8.24, 8.25.

[6] 24 CFR 8.32.

[7] 42 U.S.C. 12131 *et. seq.*

[8] The Department of Justice (DOJ) is also the Federal agency responsible for adopting accessibility standards under title III of the ADA, which prohibits discrimination on the basis of disability by public accommodations and requires places of public accommodation and commercial facilities to be designed, constructed, and altered in

Transportation establishes accessibility standards for transportation facilities subject to title II of the ADA. In 1991, DOJ issued a regulation establishing the 1991 Standards or UFAS as legally enforceable accessibility standards under title II.

On September 15, 2010, DOJ published a final rule revising its title II regulation at 28 CFR part 35. Among other requirements, the revised regulation adopted a new accessibility standard referred to as the 2010 ADA Standards for Accessible Design (2010 Standards).[9] For new construction and alterations that commence on or after March 15, 2012, entities covered by title II must comply with the 2010 Standards.[10] The 2010 Standards can be found at *http://www.ada.gov/2010ADAstandards_index.htm.*

For title II entities, the 2010 Standards consist of the 2004 ADAAG and requirements contained in 28 CFR 35.151. Section 35.151 sets forth requirements that have the effect of modifying provisions in 2004 ADAAG and include scoping and technical requirements for social service center establishments, housing at places of education, assembly areas, medical care facilities, residential dwelling units for sale to individuals, and detention and correctional facilities. For example, social service center establishments, which include group homes, halfway houses, shelters, and similar facilities providing temporary sleeping accommodations, must comply with the 2010 Standards applicable to residential facilities including certain requirements specified at 28 CFR 35.151(e). Most housing at a place of education (defined in the title II and title III regulations) must comply with the 2010 Standards applicable to transient lodging including certain requirements specified at 28 CFR 35.151(f).

IV. Deeming 2010 Standards as an Alternative Accessibility Standard for Section 504 Compliance

In March 2011, pursuant to its coordination authority under Section 504, DOJ advised Federal agencies that until such time as they update their agency's regulation implementing the Federally assisted provisions of Section 504, they may notify covered entities that they may use the 2010 Standards as an acceptable alternative to UFAS. Consistent with this guidance, HUD will permit, but not require HUD recipients to use the 2010 Standards under title II of the ADA, except for those provisions identified in this document, as an alternative accessibility standard to UFAS until HUD revises its Section 504 regulation to formally adopt an updated accessibility standard.[11] HUD is not permitting use of certain identified provisions in the 2010 Standards because those provisions provide a lower level of accessibility than is currently required under UFAS and/or HUD's Section 504 regulation and HUD cannot reduce the level of accessibility provided under its Section 504 regulation without engaging in notice and comment rulemaking.

It is important to emphasize that HUD recipients electing to use the 2010 Standards must use the 2010 Standards applicable to public entities under title II of the ADA, with the exceptions noted below, to the entire project; they may not rely on some requirements contained in the 2010 Standards and some requirements contained in UFAS. For purposes of Section 504 compliance, this does not mean that existing buildings that are part of a project and which are not being altered must be brought up to the 2010 Standards. Rather, it means that when a HUD recipient undertakes new construction or alterations and chooses to use the 2010 Standards with the exceptions outlined in this document, the recipient must apply the 2010 Standards to all of the new construction or alterations. It should be noted that the 2010 Standards include a safe harbor for portions of a path of travel complying with UFAS or the 1991 Standards (28 CFR 35.151(b)(4)(ii)(C)). This safe harbor does not apply to existing elements that are altered. The 2010 Standards are available at *http://www.ada.gov/2010ADAstandards_index.htm.*

This option applies to all HUD recipients for purposes of compliance with HUD's Section 504 regulation, including private and public entities, and entities covered by Section 504 but not title II or III of the ADA. Most recipients covered by Section 504 based on the receipt of Federal financial assistance from HUD are state or local government entities or private entities covered by the ADA, and are therefore required to comply with ADA accessibility requirements.[12] By issuing this document, HUD is offering covered entities the option of reducing the burden of complying with different accessibility standards under Section 504 and the ADA until HUD issues a rule adopting a new accessibility standard under Section 504. HUD recipients may utilize the 2010 Standards, with the exceptions outlined in this document, for compliance with both statutes.

This document makes no changes for entities that choose to use UFAS for purposes of Section 504 compliance along with HUD's Section 504 regulation when undertaking alterations or new construction. HUD recipients may continue to use HUD's Section 504 regulation and UFAS for Section 504 compliance until HUD formally adopts an updated accessibility standard through rulemaking. However, because UFAS is no longer an option for ensuring compliance with title II of the ADA, HUD recipients subject to both Section 504 and title II of the ADA must take an additional step in order to ensure compliance with the ADA if they use UFAS for purposes of Section 504. Specifically, in addition to complying with each scoping and technical provision of UFAS, they must also comply with each scoping and technical provision of the 2010 Standards that affords greater accessibility than UFAS.[13]

V. Utilizing the 2010 Standards

As stated above, the 2010 Standards under title II consist of the 2004 ADAAG and requirements in 28 CFR 35.151. HUD is permitting use of the 2010 Standards as an alternative accessibility standard with the following exceptions. These exceptions are necessary to ensure that HUD recipients construct or alter buildings and facilities with at least the same degree of accessibility as is currently required under HUD's Section 504 regulation and UFAS. The Department lacks the authority to allow the use of an alternative standard that would reduce accessibility or usability for individuals with disabilities in housing

compliance with established accessibility standards. The DOJ implementing regulation is at 28 CFR part 36.

[9] DOJ's September 15, 2010 final rule also revised its title III regulation. For title III entities, the 2010 Standards consist of the 2004 ADAAG and requirements under 28 CFR Part 36—Subpart D.

[10] See 28 CFR 35.151(c) for accessibility standards and compliance dates prior to March 15, 2012.

[11] Memorandum dated March 29, 2011, from Thomas E. Perez, Assistant Attorney General, Division of Civil Rights, U.S. Department of Justice, to Federal Agency Civil Rights Directors and General Counsels, ''Permitting Entities Covered by the Federally Assisted Provisions of Section 504 of the Rehabilitation Act to Use the 2010 ADA Standards for Accessible Design as an Alternative Accessibility Standard for New Construction and Alterations,'' *http://www.ada.gov/504_standards.htm.*

[12] State or local governments are ''public entities'' covered by title II of the ADA, 42 U.S.C. 12131–12134. ''Public accommodations'' include private for-profit or not-for-profit entities that are subject to the requirements of title III of the ADA, 42 U.S.C. 12181–12189.

[13] HUD's scoping continues to apply regarding the required number of accessible residential dwelling units.

settings below the level required by its Section 504 regulation without engaging in notice and comment rulemaking. As discussed below, these exceptions will also maintain consistency with certain requirements of the FHAct.

Definitions

The 2010 Standards define some terms that are also defined in HUD's Section 504 regulation. In such cases, the definition in HUD's Section 504 regulation shall control.

Scoping for Residential Dwelling Units

The 2010 Standards generally defer to HUD on scoping of *residential dwelling units* provided by entities subject to HUD's Section 504 regulation.[14] Specifically, entities receiving Federal financial assistance from the Department must provide residential dwelling units containing mobility features and residential dwelling units containing communication features complying with the 2010 Standards *in a quantity* identified in HUD's Section 504 regulation. For purposes of this document, HUD is not changing its scoping requirements for residential dwelling units under its part 8 regulation.[15] HUD recipients designing, constructing, altering, or operating residential facilities must utilize HUD's scoping to determine the number of required accessible units and utilize the 2010 Standards, with the identified exceptions noted below, for other scoping requirements as well as for the technical standards. If HUD's Section 504 rule does not provide scoping, a HUD recipient using the 2010 Standards for Section 504 compliance must use the scoping provided in the 2010 Standards. This does not preclude HUD from considering scoping or other changes when it undertakes rulemaking to adopt a new accessibility standard.

Structural Impracticability—28 CFR 35.151

Under § 35.151(a)(2) full compliance with the requirements of the 2010 Standards is not required in new construction where a public entity can demonstrate that it is structurally impracticable to do so. Full compliance is considered structurally impracticable ''only in those rare circumstances when the unique characteristics of terrain prevent the incorporation of accessibility features.'' [16] HUD's Section 504 regulation does not contain a comparable exception from compliance with the applicable accessibility requirements when HUD recipients undertake *new construction* of facilities. HUD's regulation also precludes a HUD recipient from selecting a site or location of a facility which would have the purpose or effect of excluding qualified individuals with disabilities from, denying benefits of, or otherwise subjecting them to discrimination under, any program or activity that receives Federal financial assistance.[17] Under HUD's Section 504 regulation, if a site cannot be made accessible to individuals with disabilities, it must not be selected. As emphasized above, HUD cannot allow the use of an alternative standard which conflicts with HUD's regulatory requirements and may reduce accessibility in housing settings without the opportunity for public input through notice and comment rulemaking. Accordingly, recipients may not apply the structural impracticability exception contained in § 35.151(a)(2) of the 2010 Standards through this document.

Alterations—28 CFR 35.151

The 2010 Standards at 28 CFR 35.151(b) and section 202 contain criteria detailing when alterations of facilities must be made accessible. In certain situations, application of the 2010 Standards may result in fewer units containing accessibility features. Because HUD cannot use this document to permit the use of a lesser requirement than that required by its Section 504 regulation, HUD is not permitting use of § 35.151(b). Therefore, multifamily housing projects must continue to utilize the terms ''substantial alterations'' and ''other alterations'' as defined in HUD's Section 504 regulation to determine accessibility requirements.[18] This does not preclude HUD from considering changes to its alterations criteria for residential dwelling units when it revises its regulation to adopt a new accessibility standard.

Additions—Section 202.2 of the 2010 Standards

Section 202.2 of the 2010 Standards contains scoping requirements which may, in certain situations, afford less accessibility for individuals with disabilities than is currently provided by HUD's rules at 24 CFR part 8 and UFAS. Because the Department is precluded from permitting the use of an alternative standard that might reduce accessibility for individuals with disabilities in housing settings without notice and comment rulemaking, HUD is not permitting use of the scoping requirements for additions at section 202.2 of the 2010 Standards.

Alterations Affecting Primary Function Areas—Exception to Section 202.4 of the 2010 Standards

Section 202.4 of the 2010 Standards includes a path of travel obligation when areas containing a primary function are altered. Under the Exception to Section 202.4, residential dwelling units are exempted from this requirement. Under HUD's Section 504 regulation, when accessible dwelling units are newly constructed or where alterations include the provision of accessible dwelling units, the dwelling units must be on an accessible route. HUD is not permitting use of the Exception to Section 202.4 because this may conflict with HUD's Section 504 regulation.

Common Use Areas in Residential Facilities—Section 203.8 of the 2010 Standards

Section 203.8 of the 2010 Standards provides that, in residential facilities, common use areas that do not serve residential dwelling units required to provide mobility features are not required to be accessible or on an accessible route. By contrast, common use areas in residential facilities subject to the new construction requirements of the FHAct must comply with FHAct accessibility requirements, including the requirement to be on an accessible route, regardless of whether or not the common use areas serve units required to have mobility features pursuant to the ADA or Section 504. The only exception would be common use areas provided on upper stories of a non-elevator building provided the same common use areas are provided on the ground floor. In addition, this general exception for common use areas may result in less accessibility than is currently required under HUD's Section 504 regulation and UFAS. Accordingly, HUD is not permitting use of Section 203.8 under this document.

Employee Work Areas—Section 203.9 of the 2010 Standards, and Similar Sections

The 2010 Standards require a more limited level of access within employee work areas in ADA-covered facilities than UFAS, which requires employee work areas to be fully accessible. As stated above, the Department has no authority to allow the use of an alternative standard that may reduce accessibility for individuals with disabilities without notice and comment rulemaking. Section 203.9, as well as

[14] Section 233.2 Residential Dwelling Units Provided by Entities Subject to HUD Section 504 Regulations.

[15] 24 CFR part 8, subpart C.

[16] 28 CFR 35.151(a)(2)(i).

[17] 24 CFR 8.4(b)(5).

[18] 24 CFR part 8, subpart C.

Section 206.2.8, the Exception to Section 403.5, and the Exception to Section 405.8, all require less accessibility in employee work areas than UFAS. For this reason, HUD is not permitting use of the aforementioned sections of the 2010 Standards for employee work areas.

Vehicular Route Exceptions—Sections 206.2.1 and 206.2.2 of the 2010 Standards

The 2010 Standards contain an exception for accessibility at site arrival points which provides that an ''*accessible* route shall not be required between *site* arrival points and the *building* or *facility entrance* if the only means of access between them is a *vehicular* way not providing pedestrian access'' (Section 206.2.1 Site Arrival Points, Exception 2). The 2010 Standards also contain an exception for accessibility within a site which provides that an ''*accessible* route shall not be required between *accessible buildings, accessible facilities, accessible elements,* and *accessible spaces* if the only means of access between them is a *vehicular way* not providing pedestrian access'' (Section 206.2.2 Within a Site, Exception). Neither exception is in UFAS,[19] which requires pedestrian access routes, and both conflict with HUD's Section 504 regulation, which requires that all programs and activities receiving Federal funds be readily accessible to and usable by persons with disabilities, as well as the requirements of the FHAct and HUD's Fair Housing Accessibility Guidelines. Accordingly, HUD is not permitting the use of Exception 2 to Section 206.2.1 Site Arrival Points, and the Exception to Section 206.2.2 Within a Site.

Elevator Exception 1—Section 206.2.3 of the 2010 Standards

The 2010 Standards contain specific exceptions to the general provision requiring at least one accessible route to connect each story and mezzanine in multi-story buildings or facilities (Section 206.2.3). Exception 1 to Section 206.2.3 of the 2010 Standards contains an elevator exception for private buildings or facilities that are less than three stories or that have less than 3,000 square feet per story (unless the type of building is omitted in the standard from the exception, *e.g.,* a shopping center, a shopping mall, the professional office of a health care provider, *etc.*). HUD's Section 504 regulation does not impose different requirements on recipients that are public entities as compared to recipients that are private entities. In order to ensure that all HUD recipients are subject to the same accessibility requirements, regardless of whether they are public or private entities, HUD is not permitting use of Exception 1 to Section 206.2.3 by private entities subject to its Section 504 regulation.

Washing Machines; Clothes Dryers—Sections 214.2 and 214.3 of the 2010 Standards

UFAS requires front loading washing machines and clothes dryers in common use laundry rooms in facilities serving accessible residential dwelling units.[20] UFAS' requirements for front-loading machines reflect the fact that not all persons with disabilities will be able to use top loading machines. The 2010 Standards, however, permit either top loading or front loading machines in such facilities (Section 214.2 Washing Machines; Section 214.3 Clothes Dryers). Consequently, HUD is not permitting application of the scoping requirements for washing and drying machines found at sections 214.2 and 214.3 of the 2010 Standards. Recipients must continue to comply with section 4.34.7 of UFAS. These requirements apply to each laundry room except that HUD's Section 504 regulation and UFAS would not require a laundry room on an upper story of a non-elevator building to be accessible provided that there is an accessible laundry room serving that same building on the ground floor. HUD recipients should also be aware that, when washing machines and clothes dryers are provided in individual dwelling units, front loading accessible washing machines and clothes dryers may be required in accessible dwelling units as a reasonable accommodation for individuals with disabilities.

Visible Alarms—Exception to Section 215.1 of the 2010 Standards

Section 215.1 includes a new exception for visible alarms in the alteration of existing facilities, providing that visible alarms must be installed only when an existing fire alarm system is upgraded or replaced, or a new fire alarm system is installed. Under this exception, visible alarms would not be required as part of alterations unless the alarm system is upgraded, replaced, or newly installed. HUD is not permitting use of this exception because its application may result in less accessibility than is currently required under HUD's Section 504 regulation. Instead, recipients engaged in alterations must refer to HUD's regulation at 24 CFR 8.22, 8.23, 8.24, and 8.25 to determine whether visible alarms must be installed. For recipients engaged in substantial alterations, the new construction requirements apply (with the exception that building alterations are not required that have little likelihood of being accomplished without removing or altering a load-bearing structural member) and visible alarms would be included in the alterations. For recipients engaged in other alterations not rising to the level of substantial alterations, any alterations (including alterations to dwelling units, common areas, or parts of facilities that affect accessibility of existing housing facilities) must, to the maximum extent feasible, be made to be readily accessible to and usable by individuals with disabilities. ''To the maximum extent feasible'' means recipients are not required to make alterations if doing so would impose undue financial and administrative burdens on the operation of the multifamily housing project, but must provide for accessibility up to the point of undue financial and administrative burdens. This is a high threshold to meet. Therefore, HUD recipients must continue to comply with the provisions in HUD's Section 504 regulation, and not utilize the exception in the 2010 Standards. If visible alarms are not provided, there must be an effective means of alerting individuals who are deaf or hard of hearing to fires and other emergencies in order to afford them an equal opportunity to evacuate to safety.

For the convenience of the reader, the Appendix to this document provides a table that lists in column one the exceptions contained in the document and in the second column, the UFAS and/or HUD Section 504 regulation provisions that would need to be complied with because the entity could not use that section of the ADA 2010 Standards. The table is provided so that it can be used by HUD recipients as a stand-alone chart that lists, in a single table, not only what the exceptions are, but what actions recipients must undertake in lieu of using the exceptions.

VI. Relationship to Other Laws

Recipients of HUD funding must be aware of and comply with the accessibility requirements of all

[19] *See, e.g.,* UFAS, Section 4.1.1(1): At least one accessible route complying with 4.3 shall be provided *within the boundary of the site* from public transportation stops, accessible parking spaces, passenger loading zones if provided, and public streets or sidewalks to an accessible building entrance. UFAS, Section 4.1.1(2): At least one accessible route complying with 4.3 shall connect accessible buildings, facilities, elements, and spaces that are on the same site. *See also,* UFAS, Section 4.3 Accessible Route.

[20] UFAS, Section 4.34.7.2.

applicable laws, including Section 504, the ABA, the ADA, and the FHAct. Compliance with one of these statutes does not ensure compliance with other Federal disability nondiscrimination laws. For example, compliance with Section 504, the ABA, or the ADA does not ensure compliance with the FHAct; similarly, compliance with FHAct accessibility requirements does not ensure compliance with the accessibility requirements of Section 504, the ABA, or the ADA. The FHAct prohibits discrimination in housing because of race, color, religion, sex, national origin, familial status, and disability.[21] One type of disability discrimination prohibited by the FHAct is the failure to design and construct covered multifamily dwellings with certain features of accessible design.[22]

The FHAct design and construction requirements apply to ''covered multifamily dwellings'' designed and constructed for first occupancy after March 13, 1991. ''Covered multifamily dwellings'' means all buildings consisting of four or more dwelling units: In buildings without an elevator, all of the ground floor dwelling units are covered; in buildings with one or more elevators, all of the dwelling units are covered. HUD encourages entities to refer to HUD's FHAct regulation and technical guidance issued by HUD to ensure compliance with FHAct accessibility requirements.[23]

Date: May 16, 2014.

David R. Ziaya,

Deputy Assistant Secretary for Operations and Programs.

Appendix to May 23, 2014 Document

Exceptions to the 2010 Standards

This table is provided for HUD recipients that elect to use the 2010 Standards under title II of the Americans with Disabilities Act (ADA) as an alternative accessibility standard to UFAS for purposes of complying with Section 504 until HUD formally revises its Section 504 regulation. Please note that, for purposes of Section 504 compliance, the 2010 Standards may be used with the following exceptions.

Provisions in 2010 standards not deemed as equivalent alternatives to UFAS	Provisions HUD recipients must comply with for purposes of section 504 compliance
1. Section 35.151(a)(2) Exception for structural impracticability	2010 Standards at Section 35.151 without Section 35.151(a)(2) and (b) (see below) and HUD's Section 504 regulation at 24 CFR § 8.4(b)(5).
2. Section 35.151(b) Alterations	HUD's Section 504 regulation at 24 CFR §§ 8.20, 8.21, 8.22, 8.23, 8.24, 8.25, 8.26 and UFAS 4.1.6.
3. Section 202.2 Additions	HUD's Section 504 regulation at 24 CFR §§ 8.20, 8.21, 8.22, 8.23, 8.24, 8.25, 8.26 and UFAS 4.1.5.
4. Exception to Section 202.4 Alterations Affecting Primary Function Areas.	2010 Standards at Section 202.4 without the Exception and HUD's Section 504 regulation at 24 CFR §§ 8.20, 8.21, 8.22, 8.23, 8.24, 8.25, and 8.26.
5. Section 203.8 General Exceptions—Residential Facilities	2010 Standards without Section 203.8 and HUD's Section 504 regulation at 24 CFR § § 8.20, 8.21, 8.22, 8.23, 8.24, 8.25, and 8.26.
6. Employee Work Areas: Sections 203.9 (General exception for employee work areas), 206.2.8 (Circulation paths in employee work areas), and the Exceptions to 403.5 (Clearances within employee work areas) and 405.8 (Handrails within employee work areas).	2010 Standards without these provisions; Note that HUD is permitting use of Section 215.3 (Fire Alarm Systems in Employee Work Areas).
7. Exception 2 to Section 206.2.1 Site Arrival Points	2010 Standards at Section 206.2.1 without Exception 2.
8. Exception to Section 206.2.2 Within a Site	2010 Standards at Section 206.2.2 without the Exception.
9. Exception 1 to Section 206.2.3 Multi-Story Buildings and Facilities	2010 Standards at Section 206.2.3 without Exception 1.
10. Section 214—Scoping of Washing Machines and Clothes Dryers	HUD's Section 504 regulation and UFAS 4.34.7 Laundry Facilities. HUD recipients should also be aware that, when washing machines and clothes dryers are provided in individual dwelling units, front loading accessible washing machines and clothes dryers may be required in accessible dwelling units as a reasonable accommodation for individuals with disabilities.
11. Exception to Section 215.1 Visible Alarms	2010 Standards at Section 215 without the Exception to Section 215.1 and HUD's Section 504 regulation at 24 CFR 8.20, 8.21, 8.22, 8.23, 8.24, 8.25, and 8.26.

The option to use the 2010 Standards under title II of the ADA, with identified exceptions, is available to all HUD recipients for purposes of complying with Section 504. HUD recipients must designate the accessibility standard they are using: The 2010 Standards with the identified exceptions outlined in this May 23, 2014 Notice, or UFAS. If HUD recipients choose to use the 2010 Standards, they must apply the 2010 Standards, with the identified exceptions, to the entire project. This option applies until HUD revises its Section 504 regulation to adopt an updated accessibility standard. This table provides a summary. Additional explanatory information is provided in other parts of the May 23, 2014 document.

[FR Doc. 2014–11844 Filed 5–22–14; 8:45 am]

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[21] The Act uses the term ''handicap'' instead of ''disability.'' Both terms have the same legal meaning.

[22] 42 U.S.C. 3604(f).

[23] *See* HUD regulation implementing the design and construction provisions at 24 CFR 100.200 *et seq.; Final Fair Housing Accessibility Guidelines* (''Guidelines''), 56 FR 9472 (Mar. 6, 1991); *Supplement to Notice of Fair Housing Accessibility Guidelines: Questions and Answers About the Guidelines* (''Questions and Answers''), 59 FR 33362–68 (June 28, 1994); *Fair Housing Act Design Manual* (''Design Manual'') (August 1996, Revised April 1998). For additional technical assistance, *see* the Fair Housing Act Accessibility FIRST Web site, *www.fairhousingfirst.org.*

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2014–0279]

RIN 1625–AA09

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Titusville, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is removing the existing drawbridge operation regulation for the drawbridge across the Atlantic Intracoastal Waterway mile 878.9, Titusville, Florida. The drawbridge was replaced with a fixed bridge in 2011 and the operating regulation is no longer applicable or necessary.

DATES: This rule is effective May 23, 2014.

ADDRESSES: The docket for this final rule [USCG–2014–0279], is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this final rule. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Michael Lieberum, Coast Guard; telephone 305–415–6744, email *michael.b.lieberum@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

A. Regulatory History and Information

The Coast Guard is issuing this final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the SR 402/Max Brewer Bridge, that once required draw operations in 33 CFR 117.261(k), was removed from Atlantic Intracoastal Waterway mile 878.9 and replaced with a fixed bridge in 2011. Therefore, the regulation is no longer applicable and shall be removed from publication. It is unnecessary to publish an NPRM because this regulatory action does not place any restrictions on mariners. It removes a regulation that has no further use or value.

Under 5 U.S.C. 553(d)(1), a rule that relieves a restriction is not required to provide the 30 day notice period before its effective date. This rule removes the SR 402/Max Brewer Bridge draw operation requirements under 33 CFR 117.261(k), thus removing a regulatory restriction on the public. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**. The bridge has been a fixed bridge for 3 years and this rule merely requires an administrative change to the **Federal Register**, in order to omit a regulatory requirement that is no longer applicable or necessary.

B. Basis and Purpose

The SR 402/Max Brewer Bridge across the Atlantic Intracoastal Waterway mile 878.9 was removed and replaced with a fixed bridge in 2011. It has come to the attention of the Coast Guard that the governing regulation for this drawbridge was never removed subsequent to the completion of the fixed bridge that replaced it. The elimination of this drawbridge necessitates the removal of the drawbridge operation regulation, 33 CFR 117.261(k), that pertaining to the former drawbridge.

The purpose of this rule is to remove the section (k) of 33 CFR 117.261 that refers to the SR 402/Max Brewer Bridge at mile 878.9, from the Code of Federal Regulations because it governs a bridge that is no longer able to be opened.

C. Discussion of Rule

The Coast Guard is changing the regulation in 33 CFR 117.261(k) by removing restrictions and the regulatory burden related to the draw operations for this bridge that no longer exists. The change removes the section (k) of the regulation governing the SR 402/Max Brewer Bridge because the bridge has been replaced with a fixed bridge and the old bascule bridge was removed from the waterway. This Final Rule seeks to update the Code of Federal Regulations by removing language that governs the operation of the SR 402/Max Brewer Bridge, which in fact no longer exists as a drawbridge. This change does not affect waterway or land traffic. This change does not affect nor does it alter the operating schedules in 33 CFR 117.261 that govern the remaining active drawbridges on the Atlantic Intracoastal Waterway.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

The Coast Guard does not consider this rule to be ''significant'' under that Order because it is an administrative change and does not affect the way vessels operate on the waterway.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will have no effect on small entities since this drawbridge has been removed and replaced with a fixed bridge and the regulation governing draw operations for this bridge is no longer applicable. There is no new restriction or regulation being imposed by this rule; therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities

3. Collection of Information

This rule calls for no new collection of information under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501–3520).

4. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

5. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

6. Unfunded Mandates Reform Act

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

7. Taking of Private Property

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

8. Civil Justice Reform

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

9. Protection of Children

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

10. Indian Tribal Governments

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

11. Energy Effects

This action is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

12. Technical Standards

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

13. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment because it removes a regulation that applied to a drawbridge that no longer exists. This rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 491; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

§ 117.261 [Amended]

■ 2. In § 117.261, remove and reserve paragraph (k).

Dated: May 7, 2014.

J.H. Korn,

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

[FR Doc. 2014–11956 Filed 5–22–14; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2014–0258]

RIN 1625–AA00

Safety Zone; BMA Media Group Fireworks, Presque Isle Bay, Erie, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a 300-foot-radius, temporary safety zone on Presque Isle Bay, Erie, PA for a fireworks display May 31, 2014. This temporary safety zone is necessary to protect mariners and vessels from the navigational hazards associated with this fireworks display. This safety zone will restrict vessels from a portion of Presque Isle Bay during the BMA Media Group Fireworks display.

DATES: The temporary final rule is effective from 9:30 p.m. until 10:30 p.m. on May 31, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2014–0258]. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Christopher Mercurio, Chief of Waterways Management, U.S. Coast Guard Sector Buffalo; telephone 716–843–9573, email *SectorBuffaloMarineSafety@uscg.mil.* If you have questions on viewing the docket, call Ms. Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826 or 1–800–647–5527.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
§ Section

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. The final details for this event were not known to the Coast Guard until there was insufficient time remaining before the event to publish an NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be both impracticable and contrary to the public interest because it would inhibit the Coast Guard's ability to protect spectators and vessels from the hazards associated with a maritime fireworks display.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30-day notice period to run would be impracticable and contrary to the public interest.

B. Basis and Purpose

Between 9:30 p.m. and 10:30 p.m. on May 31, 2014, a fireworks display will be held on Presque Isle Bay in Erie, PA. The Captain of the Port Buffalo has determined that fireworks launched in close proximity to a gathering of watercraft pose a significant risk to public safety and property. Such hazards include premature and accidental detonations, dangerous projectiles, explosions, ignition of flammable materials, burn injuries, and falling or burning debris.

C. Discussion of Rule

With the aforementioned hazards in mind, the Captain of the Port Buffalo has determined that this temporary safety zone is necessary to ensure the safety of spectators. This zone will encompass all waters of Presque Isle Bay, Erie, PA within a 300-foot radius of position 42°08′19.082″ N and 080°05′28.903″ W (NAD 83). This zone will be effective and enforced from 9:30 p.m. until 10:30 p.m. on May 31, 2014.

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and enforced for relatively short time. Also, the safety zone is designed to minimize its impact on navigable waters. Furthermore, the safety zone has been designed to allow vessels to transit around it. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

This rule will affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in a portion of Presque Isle Bay on the evening of May 31, 2014.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This safety zone will be effective, and thus subject to enforcement, for only 60 minutes late in the day. Traffic may be allowed to pass through the zone with the permission of the Captain of the Port. The Captain of the Port can be reached via VHF channel 16. Before this rule becomes effective, we will issue local Broadcast Notice to Mariners.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

4. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of

power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children

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

11. Indian Tribal Governments

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

12. Energy Effects

This action is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

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

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a safety zone and, therefore it is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T09–0258 to read as follows:

§ 165.T09–0258 Safety Zone; BMA Media Group Fireworks, Presque Isle Bay, Erie, PA.

(a) *Location.* This safety zone encompass all waters of Presque Isle Bay, Erie, PA within a 300-foot radius of position 42°8′19.082″ N and 80°5′28.903″ W (NAD 83).

(b) *Effective and enforcement period.* This section is effective and will be enforced on May 31, 2014 from 9:30 p.m. until 10:30 p.m.

(c) *Regulations.* (1) Under general regulations in § 165.23, entry into, transiting, or anchoring within the safety zone described in paragraph (a) of this temporary section is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The ''on-scene representative'' of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.

Dated: May 12, 2014.

B.W. Roche,

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

[FR Doc. 2014–11951 Filed 5–22–14; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2013–0823; FRL–9911–06–Region 9]

Interim Final Determination To Defer Sanctions, State of California, Los Angeles-South Coast Air Basin

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Interim Final Rule.

SUMMARY: The Environmental Protection Agency (EPA) is making an interim final determination to defer the imposition of sanctions based on a proposed approval published elsewhere in this **Federal Register** of a state implementation plan revision submitted by the State of

California to meet the vehicle miles traveled emissions offset requirement under the Clean Air Act for the 1-hour ozone and 1997 8-hour ozone national ambient air quality standards (NAAQS) in the Los Angeles-South Coast Air Basin (South Coast).

DATES: This interim final determination is effective on May 23, 2014. However, comments will be accepted until June 23, 2014.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2013–0823, by one of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.
- *Email: ungvarsky.john@epa.gov.*
- *Mail or deliver:* John Ungvarsky, Air Planning Office (AIR–2), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Instructions: All comments 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *www.regulations.gov* or email. *www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at *www.regulations.gov*, some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., 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: John Ungvarsky, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX, (415) 972–3963, *ungvarsky.john@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

I. Background

On March 28, 2013 (78 FR 18849), we published a final action to disapprove revisions to the state implementation plan (SIP) submitted by the State of California to demonstrate compliance with the vehicle miles traveled (VMT) emissions offset requirement under Clean Air Act (CAA) section 182(d)(1)(A) with respect to the 1-hour ozone and 8-hour ozone NAAQS in the South Coast nonattainment area. Under section 110(k) of the CAA, we disapproved these plan elements because they reflect an approach to showing compliance with section 182(d)(1)(A) that was rejected by the Ninth Circuit Court of Appeals in *Association of Irritated Residents* v. *EPA.* This disapproval action became effective on April 29, 2013 and started a sanctions clock for imposition of offset sanctions 18 months after April 29, 2013 and highway sanctions 6 months later, pursuant to CAA section 179 and our regulations at 40 CFR 52.31. As such, offset sanctions will be applied on October 29, 2014, and highway sanctions will be applied on April 29, 2015, unless EPA determines the disapproval has been corrected.

On February 13, 2013, the State of California submitted, as a revision to the California SIP, the *Final 2012 Air Quality Management Plan* (2012 South Coast AQMP) for the South Coast Air Basin (2012 South Coast AQMP). The 2012 South Coast AQMP submittal includes *Appendix VIII, Vehicle Miles Traveled Emissions Offset Demonstration* (''Appendix VIII''). On April 3, 2014, the State of California submitted a technical supplement to the VMT offset demonstrations in Appendix VIII of the 2012 South Coast AQMP.

In the Proposed Rules section of today's **Federal Register**, we are proposing to approve Appendix VIII and the related technical supplement as a SIP revision because we believe that it corrects the deficiency identified in our March 28, 2013 disapproval action. Based on today's proposed approval, we are taking this interim final rulemaking action, effective on publication, to defer the imposition of the offset sanctions and highway sanctions triggered by our March 28, 2013 disapproval.

EPA is providing the public with an opportunity to comment on this deferral of sanctions. If comments are submitted that change our assessment described in this interim final determination and the proposed full approval of the South Coast VMT Emissions Offset Demonstrations in Appendix VIII, we intend to take subsequent final action to reimpose sanctions pursuant to 40 CFR 52.31(d). If no comments are submitted that change our assessment, then all sanctions and sanction clocks will be permanently terminated on the effective date of a final rule approval.

II. EPA Action

We are making an interim final determination to defer the imposition of sanctions associated with our disapproval of revisions to the California SIP based on our concurrent proposal to approve the State's revision to the Los Angeles-South Coast portion of the California SIP as correcting the deficiency that initiated sanctions.

Because EPA has preliminarily determined that the State has corrected the deficiencies identified in EPA's disapproval action, relief from sanctions should be provided as quickly as possible. Therefore, EPA is invoking the good cause exception under the Administrative Procedure Act (APA) in not providing an opportunity for comment before this action takes effect (5 U.S.C. 553(b)(3)). However, by this action EPA is providing the public with a chance to comment on EPA's determination after the effective date, and EPA will consider any comments received in determining whether to reverse such action.

EPA believes that notice-and-comment rulemaking before the effective date of this action is impracticable and contrary to the public interest. EPA has reviewed the State's submittal and, through its proposed action, is indicating that it is more likely than not that the State has corrected the deficiencies that started the sanctions clocks. Therefore, it is not in the public interest to initially impose sanctions or to keep applied sanctions in place when the State has most likely done all it can to correct the deficiencies that triggered the sanctions clocks. Moreover, it would be impracticable to go through notice-and-comment rulemaking on a finding that the State has corrected the deficiencies prior to the rulemaking approving the State's submittal. Therefore, EPA believes that it is necessary to use the interim final rulemaking process to defer sanctions while EPA completes its rulemaking process on the approvability of the State's submittal. Moreover, with respect to the effective date of this action, EPA is invoking the good cause exception to the 30-day notice requirement of the APA because the

purpose of this notice is to relieve a restriction (5 U.S.C. 553(d)(1)).

III. Statutory and Executive Order Reviews

This action defers federal sanctions and imposes no additional requirements.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget.

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.

The administrator certifies that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

This rule does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

This rule does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

This action does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

This rule 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.

The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) do not apply to this rule because it imposes no standards.

This rule 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 to Congress and the Comptroller General. However, section 808 provides that any rule for which the issuing agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the agency promulgating the rule determines. 5 U.S.C. 808(2). EPA has made such a good cause finding, including the reasons therefore, and established an effective date of May 23, 2014. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule 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 July 22, 2014. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purpose of judicial review nor does it extend the time within which 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 in 40 CFR Part 52

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

Dated: May 5, 2014.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2014–11509 Filed 5–22–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2012–0580; FRL–9911–42–OAR]

RIN 2060–AM09

Protection of Stratospheric Ozone: Revision of the Venting Prohibition for Specific Refrigerant Substitutes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA, the Agency) is amending the regulations promulgated as part of the National Recycling and Emission Reduction Program under section 608 of the Clean Air Act. EPA is amending those regulations to exempt certain refrigerant substitutes, listed as acceptable subject to use conditions in regulations promulgated as part of EPA's Significant New Alternative Policy program under section 612 of the Act, from the prohibition under section 608 on venting, release or disposal on the basis of current evidence that their venting, release or disposal does not pose a threat to the environment. Specifically, EPA is exempting from the venting prohibition isobutane (R–600a) and R–441A, as refrigerant substitutes in household refrigerators, freezers, and combination refrigerators and freezers, and propane (R–290), as a refrigerant substitute in retail food refrigerators and freezers (stand-alone units only).

DATES: This final rule is effective on June 23, 2014.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2012–0580. 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, 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 *www.regulations.gov* or in hard copy from the EPA Air and Radiation Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. This Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744,

and the telephone number for the Air and Radiation Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Sally Hamlin, Stratospheric Protection Division, Office of Air and Radiation, MC 6205J, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 343–9711; fax number: (202) 343–2338; email address: *hamlin.sally@epa.gov.*

SUPPLEMENTARY INFORMATION: This final action extends the exemption from the venting prohibition at 40 CFR 82.154(a)(1) to certain refrigerant substitutes in certain end-uses for which EPA has found the refrigerant substitutes acceptable subject to use conditions under CAA section 612 and the implementing regulations at 40 CFR Part 82, Subpart G. Specifically, EPA is exempting from the venting prohibition isobutane (R–600a) and R–441A as refrigerant substitutes in household refrigerators, freezers, and combination refrigerators and freezers, and propane (R–290), as a refrigerant substitute in retail food refrigerators and freezers (stand-alone units only).

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I. General Information

A. Does this action apply to me?

Potentially regulated entities may include, but are not limited to, the following.

TABLE 1—POTENTIALLY REGULATED ENTITIES, BY NORTH AMERICAN INDUSTRIAL CLASSIFICATION SYSTEM (NAICS) CODE

Category	NAICS code	Description of regulated entities
Services	811412	Appliance repair and maintenance.
Industry	333415	Manufacturers of refrigerators, freezers, and other refrigerating or freezing equipment, electric or other; heat pumps not elsewhere specified or included (NESOI); and parts thereof.
Industry	445110	Supermarkets and other grocery (except convenience) stores.
Industry	445120	Convenience stores.
Industry	562920, 423930	Facilities separating and sorting recyclable materials from non-hazardous waste streams (e.g., scrap yards) and merchant wholesale distribution of industrial scrap and other recyclable materials.

This table is not intended to be exhaustive, but rather provides a guide regarding entities likely to be regulated by this action. Other types of entities not listed in the table could also be affected. To determine whether your company is regulated by this action, you should carefully examine the applicability criteria contained in section 608 of the Clean Air Act (CAA, the Act) as amended, and relevant implementing regulations at 40 CFR Part 82, Subpart F. If you have any questions about whether this action applies to a particular entity, consult the person listed in the preceding section, **FOR FURTHER INFORMATION CONTACT.**

B. What abbreviations and acronyms are used in this action?

ASHRAE—American Society of Heating, Refrigerating and Air-Conditioning Engineers
CAA—Clean Air Act
CAS—Chemical Abstracts Service
CBI—confidential business information
CFC—chlorofluorocarbon
CFR—Code of Federal Regulations
EPA—United States Environmental Protection Agency
EO—Executive Order
FR—Federal Register
GWP—Global warming potential
HC—hydrocarbon
HCFC—hydrochlorofluorocarbon
HFC—hydrofluorocarbon
IPR—industrial process refrigeration
LFL—lower flammability limit
NPRM—Notice of Proposed Rulemaking
NTTAA—National Technology Transfer and Advancement Act
ODP—ozone depletion potential
ODS—ozone-depleting substance
OMB—United States Office of Management and Budget
OSHA—United States Occupational Safety and Health Administration
RCRA—Resource Conservation and Recovery Act
RFA—Regulatory Flexibility Act
SBREFA—Small Business Regulatory Enforcement Fairness Act
SNAP—Significant New Alternatives Policy
UL—Underwriters Laboratories
UMRA—Unfunded Mandates Reform Act
VOC—volatile organic compound

II. How does the National Recycling and Emission Reduction Program work?

A. What are the statutory requirements under section 608 of the Clean Air Act?

Section 608 of the Act as amended, titled *National Recycling and Emission Reduction Program,* requires EPA to establish regulations governing the use and disposal of ozone-depleting substances (ODS) used as refrigerants, such as certain chlorofluorocarbons (CFCs) and hydrochlorofluorocarbons (HCFCs), during the service, repair, or disposal of appliances and industrial process refrigeration (IPR), including air-conditioning and refrigeration equipment. Section 608 also prohibits any person in the course of maintaining, servicing, repairing, or disposing of an appliance or industrial process refrigeration, from knowingly venting or

otherwise knowingly releasing or disposing of such ODS used as refrigerants therein in a manner which permits such substances to enter the environment. This prohibition similarly applies to the venting, release, or disposal of substitutes for such ODS used as refrigerants, unless the Administrator determines that venting, releasing, or disposing of such a substitute does not pose a threat to the environment.

Section 608 is divided into three subsections. Briefly, section 608(a) requires EPA to promulgate regulations to reduce the use and the emissions of class I substances (e.g., CFCs and halons) and class II substances (HCFCs) to the lowest achievable level and to maximize the recapture and recycling of such substances. Section 608(b) requires that the regulations promulgated pursuant to subsection (a) contain standards and requirements for the safe disposal of class I and class II substances. Finally, section 608(c) contains self-effectuating provisions that prohibit any person from knowingly venting, releasing or disposing of any class I or class II substances, and their substitutes, used as refrigerants in appliances or IPR in a manner which permits such substances to enter the environment during maintenance, repairing, servicing, or disposal of appliances or IPR.

EPA's authority for the requirements in this action is based on section 608. As noted above, section 608(a) requires EPA to promulgate regulations regarding use and disposal of class I and II substances to ''reduce the use and emission of such substances to the lowest achievable level'' and ''maximize the recapture and recycling of such substances.'' Section 608(a) further provides that ''[s]uch regulations may include requirements to use alternative substances (including substances which are not class I or class II substances) . . . or to promote the use of safe alternatives pursuant to section [612] or any combination of the foregoing.'' Section 608(c)(1) provides that, effective July 1, 1992, it is ''unlawful for any person, in the course of maintaining, servicing, repairing, or disposing of an appliance or industrial process refrigeration, to knowingly vent or otherwise knowingly release or dispose of any class I or class II substance used as a refrigerant in such appliance (or industrial process refrigeration) in a manner which permits such substance to enter the environment.'' The statute exempts from this self-effectuating prohibition ''[d]e minimis releases associated with good faith attempts to recapture and recycle or safely dispose'' of such a substance. To implement and enforce the venting prohibition,[1] EPA, as codified in its regulations, interprets releases to meet the criteria for exempted ''de minimis'' releases if they occur when the recycling and recovery requirements of regulations promulgated under sections 608 and 609 are followed. 40 CFR 82.154(a)(2).

Effective November 15, 1995, section 608(c)(2) of the Act extends the prohibition in section 608(c)(1) to knowingly venting or otherwise knowingly releasing or disposing of any refrigerant substitute for class I or class II substances by any person maintaining, servicing, repairing, or disposing of appliances or IPR. This prohibition applies to any such substitute substance unless the Administrator determines that such venting, releasing, or disposing ''does not pose a threat to the environment.'' Thus, section 608(c) provides EPA authority to promulgate regulations to interpret, implement, and enforce this venting prohibition, including authority to implement section 608(c)(2) by exempting certain substitutes for class I or class II substances from the prohibition when the Administrator determines that such venting, release, or disposal does not pose a threat to the environment.

B. What are the regulations against venting, releasing or disposing of refrigerant substitutes?

Final regulations promulgated under section 608 of the Act, published on May 14, 1993 (58 FR 28660), established a recycling program for ozone-depleting refrigerants recovered during the servicing and maintenance of air-conditioning and refrigeration appliances. In the same 1993 final rule, EPA also promulgated regulations implementing the section 608(c) prohibition on knowingly venting, releasing or disposing of class I or class II controlled substances.[2] These regulations are intended to substantially reduce the use and emissions of ozone-depleting refrigerants.

On June 11, 1998, EPA proposed to implement and clarify the requirements of section 608(c)(2) of the Act by clarifying how the venting prohibition extends to substitutes for CFC and HCFC refrigerants (63 FR 32044). EPA issued a final rule March 12, 2004 (69 FR 11946) and a second rule on April 13, 2005 (70 FR 19273) clarifying how the venting prohibition in section 608(c) applies to refrigerant substitutes (e.g., hydrofluorocarbons (HFCs) and perfluorocarbons (PFCs) in part or whole) during the maintenance, service, repair, or disposal of appliances. These regulations implementing section 608's recycling and emission reduction program were codified at 40 CFR part 82, subpart F. Before the amendments finalized in the present action, the regulation at 40 CFR 82.154(a) stated in part that:

> ''[e]ffective June 13, 2005, no person maintaining, servicing, repairing, or disposing of appliances may knowingly vent or otherwise release into the environment any refrigerant or substitute[3] from such appliances, with the exception of the following substitutes in the following end-uses:
>
> i. Ammonia in commercial or industrial process refrigeration or in absorption units;
>
> ii. Hydrocarbons in industrial process refrigeration (processing of hydrocarbons);
>
> iii. Chlorine in industrial process refrigeration (processing of chlorine and chlorine compounds);
>
> iv. Carbon dioxide in any application;
>
> v. Nitrogen in any application; or
>
> vi. Water in any application.
>
> (2) The knowing release of a refrigerant or non-exempt substitute subsequent to its recovery from an appliance shall be considered a violation of this prohibition. De minimis releases associated with good faith attempts to recycle or recover refrigerants or non-exempt substitutes are not subject to this prohibition. . . . ''

As explained in EPA's earlier rulemaking concerning refrigerant substitutes, EPA has not promulgated regulations requiring certification of refrigerant recycling/recovery equipment intended for use with substitutes to date (70 FR 19275; April 13, 2005). However, as EPA has noted, the lack of a current regulatory provision should not be considered as an exemption from the venting prohibition for substitutes that are not expressly exempted in § 82.154(a). *Id.* EPA has also noted that, in accordance with section 608(c) of the Act, the regulatory prohibition at § 82.154(a) reflects the statutory references to *de minimis* releases of substitutes as they pertain to good faith attempts to recapture and recycle or safely dispose of non-exempted substitutes. *Id.*

[1] In this action, EPA sometimes uses the shorthand ''venting prohibition'' to refer to the section 608(c) prohibition of knowingly venting, releasing, or disposing of class I or class II substances, and their substitutes.

[2] A list of ozone-depleting substances is available in Appendices A and B to Subpart A of Part 82.

[3] ''Substitute,'' as defined at 40 CFR part 82, subpart F, is ''any chemical or product, whether existing or new, that is used by any person as an EPA approved replacement for a class I or II ozone-depleting substance in a given refrigeration or air-conditioning end-use.'' 40 CFR 82.152.

III. What factors did EPA consider in determining whether venting, release or disposal poses a threat to the environment?

Section 608(c)(2) extends the venting prohibition in section 608(c)(1) to substitutes for class I or class II substances, unless the Administrator determines that such venting, releasing, or disposing does not pose a threat to the environment.

For purposes of section 608(c)(2) of the CAA, EPA considers two factors in determining whether or not venting, release, or disposal of a refrigerant substitute during the maintenance, service, repair or disposing of appliances poses a threat to the environment. See 69 FR 11948 (March 12, 2004). First, EPA determines whether venting, release, or disposal of the refrigerant substitute poses a threat to the environment due to inherent characteristics of the refrigerant, such as global warming potential. Second, EPA determines whether and to what extent such venting, release, or disposal actually takes place during the maintenance, servicing, repairing, or disposing of appliances, and to what extent such venting, release, or disposal is controlled by other authorities, regulations, or practices. To the extent that such releases are adequately controlled by other authorities, EPA defers to those authorities.

In addressing the two factors mentioned in the paragraph above, the analysis in the proposed rulemaking published on April 12, 2012 (78 FR 21871) discussed the potential environmental impacts and existing authorities, practices, and controls for isobutane (R–600a) and R–441A as substitutes in household refrigerators, freezers, and combination refrigerators and freezers; and propane (R–290) as a substitute in retail food refrigerators and freezers (stand-alone units only). These refrigerant substitutes and end-uses were evaluated and determined to be acceptable subject to use conditions under SNAP in the December 20, 2011 final rule (76 FR 78838) (2011 SNAP rule).

EPA received comments on the revisions to the venting prohibition proposed on April 12, 2012, seeking clarification about the applicability of the exemption to the venting prohibition to various types of equipment not mentioned in the proposal. Three comments were received asking whether the determination of an exemption to the venting prohibition for isobutane (R–600a) and R–441A as substitutes in household refrigerators, freezers, and combination refrigerators and freezers would also apply to ''household wine coolers'' and ''household beverage centers'' and ''stand-alone ice makers designed for household use.'' This final action exempts isobutane (R–600a) and R–441A as refrigerant substitutes in household refrigerators, freezers, and combination refrigerators and freezers. The exemption under 608(c)(2), as proposed and as it is being finalized with this action, applies only to the uses that are acceptable subject to use conditions under the 2011 SNAP rule. The issue raised by the commenters concerns how the SNAP listing is interpreted and the issue of these end uses was not raised during the comment period for the 2011 SNAP rule. Under SNAP, we have explained that ''household refrigerators, freezers and combination refrigerators and freezers'' includes household refrigerators, freezers, and combination refrigerator/freezers intended primarily for residential use, although they may be used outside the home. Household freezers only offer storage space at freezing temperatures, unlike household refrigerators. See 76 FR at 78833. The 2011 SNAP rule also notes that the two hydrocarbon refrigerant substitutes can be used only in refrigerators or freezers that meet all requirements listed in Supplement SA to UL 250. Id. at 78837, codified at appendix R of subpart G to 40 CFR part 82. To the extent that household wine coolers, household beverage centers or stand-alone ice makers designed for household use meet these conditions, they would fit within the end use designed in the 2011 SNAP rule as ''household refrigerators, freezers and combination refrigerators and freezers.''

A. Inherent Characteristics of These Substances

Based on the analysis in the proposal for this action (April 12, 2012, 78 FR 21871), EPA finds that the venting, release, or disposal of isobutane (R–600a) and R–441A as substitutes in household refrigerators, freezers, and combination refrigerators and freezers and propane (R–290) as a substitute in retail food refrigerators and freezers (stand-alone units only) does not pose a threat to the environment based on the inherent characteristics of these substances, as well as the limited quantities used in the relevant applications.

In the proposal (April 12, 2012, 78 FR 21871), EPA provided an analysis that focused on the environmental impacts identified as a potential concern under SNAP (76 FR 78838) for these refrigerant substitutes: Ozone depletion potential, global warming potential, volatile organic compound (VOC) effects, and ecosystem risks. As discussed in the proposal, this analysis was based in part on the fact that the volume of hydrocarbons listed as acceptable with use conditions under the 2011 SNAP rule that could be released from the specific uses relevant to this exemption would be small. Based on this analysis, EPA determines that the venting, release, or disposal of isobutane (R–600a) and R–441A as substitutes in household refrigerators, freezers, and combination refrigerators and freezers and propane (R–290) as a substitute in retail food refrigerators and freezers (stand-alone units only) does not pose a significant threat to the environment with respect to the inherent characteristics of these substances.

The discussion in the proposal also noted that in prior rulemakings EPA evaluated the potential risks of fire from the use of hydrocarbons as refrigerant substitutes in certain appliances, and engineering approaches to avoid ignition sources from within the appliance. To address flammability risks of hydrocarbon refrigerant substitutes, EPA issued recommendations for their safe use in certain end-uses and specified use conditions for some end-uses through SNAP rulemakings (59 FR 13044; 76 FR 78832).[4] These SNAP rules rely on existing regulatory requirements and industry standards and practices that protect workers, the general population, and the environment from the flammability risks from hydrocarbon refrigerant substitutes. EPA additionally provided information about potential toxicity and occupational exposure of these three hydrocarbon refrigerant substitutes, noting that in prior actions under SNAP, EPA had found that these hydrocarbons are unlikely to pose such risks, when used according to the applicable use conditions or regulations. EPA explained that the Agency believes that the flammability risks and occupational exposures to hydrocarbons are adequately regulated by Occupational Safety and Health Administration (OSHA), building, and fire codes at a local and national level.

In support of EPA's proposed determination to exempt these hydrocarbon refrigerant substitutes from the venting prohibition in certain end uses, the proposal received comments from four commenters agreeing with EPA's cited reasons for determining that

[4] Use conditions for hydrocarbons in certain refrigeration end-uses are found at 40 CFR part 82 subpart G, appendix R.

release into the environment would not pose a threat. The commenters stated that it would be safer to vent the small amounts than to try to recover them in a special container and to transport these substitutes afterwards in larger containers.

Three commenters also stated that the overall greenhouse gas impact of all the activities involved in capture, transport, recycling or destruction would generate greater greenhouse gas emissions than would simply venting the small charge of hydrocarbon refrigerant substitutes in the appliances.

One commenter supported EPA's proposed determination to exempt venting, release, or disposal of these hydrocarbon refrigerant substitutes because ''there are currently no commercially available reclaim devices [sic] available in the US rated for use with hydrocarbon or other flammable refrigerants'' and because the commenter is unaware of facilities equipped to accept reclaimed hydrocarbon refrigerants from a service company. EPA notes, however, that it does not believe this commenter means ''reclaim devices'' and ''reclaimed hydrocarbon refrigerants,'' as the proposed rule focuses on the release of the three hydrocarbon refrigerant substitutes from appliances during the maintenance, service, repair, or disposal of appliances, and the reclamation of refrigerants is a purification process often involving a distillation column, to which refrigerant recovered from appliances is transported in bulk. We believe that the commenter means ''recovery devices'' and ''recovered hydrocarbon refrigerants.''

Another commenter provided the following information in support of EPA's proposed determination to exempt from the venting prohibition the hydrocarbon refrigerant substitutes determined to be acceptable subject to use conditions under the 2011 SNAP rule. This commenter stated that the release of the amounts of hydrocarbon (HC) refrigerant approved for residential equipment (57g) and commercial stand-alone equipment (150g) is smaller than the amount contained in many individual aerosol cans that are used every day in the United States. The total release from the 2 billion aerosol cans sold in the U.S. each year ''are several orders of magnitude higher than any releases of [the proposed] refrigerant charges.''

This same commenter also supports EPA's determination noting that there can be energy savings of 12 to 55 percent from a unit using HC refrigerants as compared to a unit using HFC refrigerants, with a much greater reduction in greenhouse gas emissions than the amount that might be released during maintenance, servicing or repair.

Finally, another commenter ''agrees that the release of HC based refrigerants during the maintenance, service or repair would have a negligible environmental impact.''

EPA received two comments that question the determination that the venting, release, or disposal of isobutane (R–600a) and R–441A as substitutes in household refrigerators, freezers, and combination refrigerators and freezers; and propane (R–290) as a substitute in retail food refrigerators and freezers (stand-alone units only) does not pose a significant threat to the environment based on the inherent characteristics of these substances. One commenter believes it is necessary to have recapture or recycling requirements for HCs, because safety risk still exists at end of life, recovery equipment designed for flammable refrigerants is available, and recovered flammable refrigerants can be re-used. EPA agrees that proper safe handling practices should be followed for hydrocarbon refrigerant substitutes, both for disposal of appliances at the end-of-life and for the repair and maintenance of appliances. EPA included recommendations on the safe use and handling of hydrocarbons in the 2011 SNAP rule, and there are also recommendations at 40 CFR part 82, subpart G, appendix R.

The Agency supports the safe, economical and environmentally beneficial recovery, recycling and reclamation (re-use) of all hydrocarbon refrigerant substitutes. However, at this time, EPA does not agree that recovery equipment designed specifically to handle the three hydrocarbon refrigerant substitutes in this action is readily available in the United States. Further, at this time, there are not applicable standards in the U.S. for certification of recovery equipment designed to handle these three hydrocarbon refrigerant substitutes. EPA is not creating a recovery requirement at this time, as it is not clear that it would be safer, economically practical or environmentally beneficial to require the use of recovery equipment. EPA further notes that the commenter did not identify an environmental threat that is posed by the venting of these three hydrocarbon refrigerant substitutes in the end-uses for which EPA has found them acceptable subject to use conditions in the 2011 SNAP rule.

Another commenter ''does not believe that there is improved safety in venting flammable hydrocarbon refrigerants versus reclaiming flammable hydrocarbon refrigerants.'' This commenter states ''it may be more hazardous to vent flammable hydrocarbon refrigerants or flammable hydrocarbon refrigerant/lubricant mixture into an uncontrolled environment.'' This commenter states that because of the very low minimum ignition energy (MIE) of hydrocarbon flammable refrigerants (class 3 flammable under ASHRAE 2010), these refrigerants are easily ignited by static electricity. EPA believes this concern about the ignition of hydrocarbon refrigerants for these three hydrocarbon refrigerant substitutes in the end uses at issue in this action was addressed in the 2011 SNAP rule in which these hydrocarbon refrigerant substitutes and end-uses were evaluated and determined to be acceptable subject to use conditions under SNAP. In section ''B. Flammability'' of part IV of that SNAP rule, titled ''What is the basis for EPA's final action?'' the Agency describes the evaluation and conclusion for approving these hydrocarbon refrigerant substitutes for the specific end-uses under the use conditions. The 2011 SNAP rule explains that, ''when the concentration of a flammable refrigerant reaches or exceeds its [lower flammability limit] LFL in the presence of an ignition source (*e.g.,* a static electricity spark resulting from closing a door, use of a torch during servicing, or a short circuit in wiring that controls the motor of a compressor), an explosion or fire could occur.'' 76 FR at 78837. The 2011 SNAP rule continues by stating that, ''To determine whether the three hydrocarbon refrigerants would present flammability concerns for service and manufacture personnel or for consumers, EPA reviewed the submitters' detailed assessments of the probability of events that might create a fire, as well as engineering approaches to avoid sparking from the refrigeration equipment. EPA also conducted risk screens, available in the docket for this rulemaking, evaluating reasonable worst-case scenarios to model the effects of the sudden release of the refrigerants. The worst-case scenario analysis for each of the three hydrocarbons revealed that even if the unit's full charge were emitted within one minute, the concentration would not reach the [lower flammability limits] LFL for that hydrocarbon.'' Id. at 78839.

The commenter also noted studies that ''show atomized lubricant (lubricant that is released within refrigerant spray, such as under venting conditions), is more flammable than liquid lubricant.'' EPA considered such studies and the influence of the

lubricant on the lower flammability limits (LFLs) of the hydrocarbon refrigerants in the specific end-uses when finding them acceptable subject to use conditions under the SNAP program (see December 20, 2011; 76 FR 78832, sections ''D. Charge Size Limitation (Household Refrigeration)'' and ''E. Charge Size Limitation (Retail Food Refrigeration)'' and discussions of standards UL 250 and UL 471 regarding lubricant oil). In this rule, EPA determines that the three hydrocarbon refrigerant substitutes do not pose a significant threat to the environment when released from the relevant end uses under the use conditions established in 2011 SNAP rule, taking into account this same information about the atomized lubricant that was discussed regarding the solubility of oil in establishing the acceptable use condition of each charge size limit in the 2011 SNAP rule. Id. at 78845–78846.

The commenter raised concerns that ''venting hydrocarbon refrigerant may potentially carry lubricants dissolved with the refrigerant . . . into the atmosphere.'' The commenter believes that an exemption for venting, release, or disposal of the three hydrocarbon refrigerant substitutes sends an incorrect message to the market on best practices, and that this message is counter to ''responsible use and handling.'' While EPA understands this perspective and agrees that product stewardship is an important overall goal, the very small amount of dissolved lubricant in the small hydrocarbon charge size established as a limit for each of the end-use categories in the 2011 SNAP rule will significantly mitigate the release into the environment and the impact of any release into the environment of lubricants dissolved in the hydrocarbon refrigerant substitutes that may result from any venting, release or disposal that may occur under this final action. EPA also notes that many of the lubricants used with hydrocarbon refrigerants, such as alkyl benzene and polyalkylene glycol, are considered environmentally acceptable because they biodegrade easily as noted in EPA's document on environmentally acceptable lubricants.[5] After considering these two comments questioning EPA's determination in this action, as well as the comments supporting that determination, we believe that the venting, release, or disposal of these three hydrocarbon refrigerant substitutes would not pose a significant threat to the environment based on the inherent characteristics of these substances, in light of the amounts that could be released under this action.

B. Limits and Controls Under Other Authorities, Regulations or Practices

In the proposal (78 FR 21871), EPA explained that the limits and controls under other authorities, regulations or practices adequately control the release of and exposure to the three hydrocarbon refrigerant substitutes and mitigate risks from any possible release in the end-uses specified in the 2011 SNAP rule. This conclusion is relevant to the second factor mentioned above in the overall determination of whether venting, release, or disposal of a refrigerant substitute poses a threat to the environment—that is, a consideration of the extent that such venting, release, or disposal is adequately controlled by other authorities, regulations, or practices. As such, this conclusion is another part of the determination that the venting, release or disposal of these three hydrocarbon refrigerant substitutes in the specified end uses under the 2011 SNAP rule does not pose a threat to the environment.

EPA notes that other applicable environmental regulatory requirements still apply and are not affected by the determination made in this action. As one example, state and local air quality agencies may include VOC emissions reductions strategies in state implementation plans developed to meet and maintain the National Ambient Air Quality Standard (NAAQS) that would apply to hydrocarbon refrigerant substitutes. For instance, for those refrigerant substitutes that are VOCs as defined in 40 CFR 50.100(s), a State might adopt additional control strategies if necessary for an ozone nonattainment area to attain the NAAQS for ozone.

Several commenters supported the determination that the release of the hydrocarbon refrigerant substitutes determined to be acceptable subject to use conditions in specified end uses under the 2011 SNAP rule does not pose a threat to the environment because of limits under other authorities, such as OSHA requirements, as well as national and local building and fire codes. These commenters believe the three hydrocarbon refrigerant substitutes in today's action should be exempt from the venting prohibition because there are sufficient limits and controls under other authorities, regulations or practices that adequately control the release and exposure in the specific end-uses.

One commenter requested an explanation of how ''knowingly venting propane . . . would not be disposal of a hazardous waste (see 40 CFR 261.21).'' The commenter is correct that propane refrigerant could technically be characterized as a hazardous waste under 40 CFR 261.21 specifying the characteristic of ignitability. However, this rule would only allow for incidental releases of propane (R–290) found acceptable subject to use conditions under the 2011 SNAP rule for use in retail food refrigerators and freezers (stand-alone units only). These releases would not be subject to RCRA requirements for the disposal of hazardous waste as the release would occur incidentally during the maintenance, service and repair of the equipment, and this would not constitute disposal of the refrigerant charge as a solid waste, per se. The Agency further notes that it discussed potential human health risks from the release of propane in this end use in the 2011 SNAP rule, and it provided information from that rule in the proposal for this rule. See 76 FR at 78839 and 78 FR at 21874–75. In the 2011 SNAP rule, the Agency considered the risk of asphyxiation to workers (store employees and consumers), and evaluated a worst-case scenario and determined that the charge size at issue was much smaller than the charge size that would result in the no observable adverse effect level (NOAEL) for hypoxia. 76 FR at 78839. The Agency also evaluated toxicity impacts from the propane end use to workers, consumers, and the general public, and found that propane in this end use did not pose a toxicity threat based on either occupational exposures, as the time-weighted average exposures were well below the industry and government exposure limits, or on consumer exposures, as the time-weighted average exposures were significantly lower than the NOAEL and/or the acute exposure guideline level (AEGL). Id. Further, for the 2011 SNAP Rule EPA modeled exposure risk to the general population for propane in this end use and concluded that it was unlikely to pose a toxicity risk to the general population when used according to the applicable use conditions or regulations because modeled exposures were significantly lower than the reference concentration. Id. In addition, in this action the Agency is determining that these releases do not pose a threat to the environment, as described elsewhere in this preamble.

EPA received several comments that support the determination that, in the words of one of the commenters,

[5] U.S. EPA (2011), ''Environmentally Acceptable Lubricants,'' United States Environmental Protection Agency, Office of Wastewater Management, November 2011, EPA 800–R–11–002.

''release of HC based refrigerants during the maintenance, service or repair would have a negligible environmental impact'' in part, because of limits and controls under other regulations and practices, such as OSHA requirements and building and fire codes. However, one commenter noted that ''requiring capture continues the best practice currently being used and does not create another process dissimilar to the current requirements for CFCs, HCFCs and HFCs and blends.'' This commenter noted that, ''there are technologies which would facilitate [recovery of HCs] . . . passive 'draw through' processes such as activated carbon adsorption capture [as] . . . one example. The process is simple and can be used with the current equipment the service and repair industry typically has available.'' EPA understands that this process could be used, although there is no applicable standard in the U.S. for how it would be implemented and it would create an additional risk with the management of the activated carbon that has adsorbed the hydrocarbon refrigerant substitute due to the aggregation of a larger quantity of a material containing a flammable substance. EPA also notes, as did other commenters, that the energy for implementing any recapture process from the appliances and transporting it, and reclaiming or disposing of the hydrocarbon refrigerant substitute, especially a process using activated carbon adsorption capture or other similar ''draw through'' substance that would then be sent for final disposal, recovery or recycling of the material, would likely generate greater greenhouse gas emissions than simply venting the very small charges of the three hydrocarbon refrigerant substitutes from the specified end-use appliances.

One commenter suggested that, ''disposal of units containing HC charges is vastly different than maintenance, service or repair.'' This commenter went on to say that ''HC refrigerants should be recovered by Certified Technicians prior to disposal to protect the recyling industry and eliminate confusion to technicians and other personnel who are not required to obtain EPA Certification to handle refrigerants.'' The Agency notes that certification of a technician is not required for recovery of refrigerant during disposal of small appliances (see 40 CFR 82.156(a)), such as the household refrigerators, freezers and refrigerator/freezer combinations addressed in this rule. At this time, the regulatory requirements for technician certification at 40 CFR 82.156(a) are limited to recovery of ODS and ODS blends. However, EPA believes employees at disposal facilities are very often certified technicians or aware of EPA requirements regarding recovery of the refrigerants from equipment during disposal. While a technician certification is not required in order to use the exemption from the venting prohibition in today's action, EPA encourages disposal facilities to ensure that employees are familiar with how to safely handle and vent the three hydrocarbon refrigerant substitutes in the specified end uses addressed by today's rule. In addition, the commenter provides no reason to believe that there is any potential environmental threat from venting during disposal that would differ from any potential environmental threat from venting during maintenance, service or repair. In fact, today's action could reduce the number of appliances that are disposed of while still charged with these three hydrocarbon refrigerant substitutes because it will no longer be prohibited to vent those refrigerant substitutes in the specified end uses during maintenance, service, and repair. Thus, EPA does not believe that it needs to address disposal separately in the regulations finalized in this action.

As a suggestion for protecting workers in the appliance recycling industry the commenter proposed that ''units using flammable refrigerants be marked in a manner that an end of life processing or recycling facility can easily identify the hazard from a distance of 36 inches while looking at the back of the unit.'' With respect to the comment regarding risks to workers during the disposal of equipment at end-of-life, EPA agrees that flammability is a reason for caution during disposal of appliances containing hydrocarbon refrigerant substitutes. EPA notes that some of the use conditions in the 2011 SNAP rule were required in order to address this potential risk. For example, the labeling requirements and the requirement for coloring of tubing will serve as notification to servicing and disposal personnel that the appliance contains a flammable refrigerant substitute. The labeling requirements in the 2011 SNAP final rule require an increased lettering size as compared to the UL standards effective when that final rule was issued (UL 2000, UL 2010) for the cautionary statement about flammability that must be attached to the appliance to provide even better notification to those involved in appliance recycling.

For the reasons explained in this action and in the proposal (78 FR 21871), EPA concludes that release of and exposure to the three hydrocarbon refrigerants during the maintenance, repair, servicing or disposal of appliances is controlled by limits and controls under other authorities, regulations or practices. EPA further concludes that those limits and controls help mitigate risks to the environment that may be posed by the venting, release or disposal of these three hydrocarbon refrigerants during the maintaining, servicing, repairing, or disposing of appliances.

IV. What is EPA's determination whether venting, release or disposal poses a threat to the environment?

Today EPA is finalizing a decision to exempt from the venting prohibition three hydrocarbon refrigerant substitutes that EPA listed as acceptable subject to use conditions in the specified end uses under the 2011 SNAP rule, as the EPA is determining that the venting, release, or disposal of these substitutes does not pose a threat to the environment. Specifically, EPA is exempting from the venting prohibition isobutane (R–600a) and R–441A, as refrigerant substitutes in household refrigerators, freezers, and combination refrigerators and freezers, and propane (R–290), as a refrigerant substitute in retail food refrigerators and freezers (stand-alone units only). EPA received seven comments supporting this decision. EPA addressed in this action commenters' concerns regarding the release of the three hydrocarbon refrigerant substitutes into the environment. The exemption to the venting prohibition in this action does not apply to refrigerants that are blends containing hydrocarbons and any amount of any CFC, HCFC, HFC,[6] or PFC.

EPA reviewed the potential environmental impacts of these three hydrocarbon refrigerant substitutes in the end uses for which they are listed as acceptable subject to use conditions under the 2011 SNAP rule, as well as the authorities, controls and practices in place for these three hydrocarbon refrigerant substitutes. EPA also considered the public comments on the proposal for this action. Based on this review, EPA concludes that the release of these three hydrocarbon refrigerant substitutes in these end uses is not expected to pose a significant threat to the environment based on the inherent characteristics of these substances and the limited quantities used in the relevant applications. EPA additionally concludes that existing authorities, controls, and practices help mitigate

[6] Hydrofluorocarbons (HFCs) also include Hydrofluoroolefins (HFOs), which have at least one double bond between carbon atoms.

environmental risk from the release of these three hydrocarbon refrigerant substitutes in these end uses. In light of these two conclusions, EPA is determining, in accordance with 608(c)(2), that based on current evidence and risk analyses, the venting, release or disposal of these hydrocarbon refrigerant substitutes during the maintenance, servicing, repairing or disposing of the relevant appliances does not pose a threat to the environment. EPA is therefore extending the regulatory exemption from the venting prohibition at 40 CFR § 82.154(a)(1) to include these three hydrocarbons in the specific end uses that were found acceptable subject to use conditions under the 2011 SNAP rule.

V. What revision to the venting prohibition is EPA finalizing today?

This rule exempts from the prohibition under section 608 of the Act against knowing venting, releasing, or disposal of refrigerant substitutes during the maintenance, servicing, repair or disposal of appliances the three hydrocarbon refrigerant substitutes in the end uses for which they were listed as acceptable subject to use conditions under the 2011 SNAP rule: Propane, isobutane, and the hydrocarbon blend R–441A.

In this action the regulatory text is presented differently from what appeared in the proposed rulemaking published on April 12, 2012 (78 FR 21871). These differences reflect modifications that EPA is making in this action to the numbering and organization of the regulations at 40 CFR 82.154(a)(1) to clarify the effective dates for the exemptions under 82.154(a)(1). In particular, EPA is creating sub-sections under 82.154(a)(1), to reflect the effective dates of individual regulatory actions. The first sub-section, 82.154(a)(1)(i), will preserve the effective date of June 13, 2005, reflecting the Agency's prior action to create an exemption to the venting prohibition. This action will be in the next sub-section, 82.154(a)(1)(ii), reflecting the Agency's decision regarding the three hydrocarbon refrigerant substitutes for the specific end-uses listed as acceptable subject to use conditions under the 2011 SNAP rule. These revisions to the numbering and organization of the regulatory text do not change the text of the regulatory provisions that were previously codified at 82.154(a)(1) and are not intended to reopen or to change the substance or effect of those regulations in any way, although the text of those provisions is reprinted for clarity.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order (E.O.) 12866 (58 FR 5135; October 4, 1993) and is therefore not subject to review under E.O. 12866 and E.O. 13563 (76 FR 3821; January 21, 2011).

B. Paperwork Reduction Act

This action does not impose any new information collection burden under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This action is an Agency determination and revision of existing regulatory provisions. It contains no new requirements for collecting information or reporting. The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations in subpart F of 40 CFR 82 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and has assigned OMB control number 2060–0256. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business that is primarily engaged in the repair and maintenance of appliances and defined by NAIC code 811412 with annual receipts of less than 14 million dollars, or engaged in separating and sorting recyclable materials from non-hazardous waste streams (e.g., scrap yards) and defined by NAIC code 562920 and fewer than 100 employees, or merchant wholesale distribution of industrial scrap and other recyclable materials and defined by NAIC code 423930 with annual receipts of less than 12.5 million dollars (based on Small Business Administration size standards), (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact of the rule on small entities.'' 5 U.S.C. 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

This final rule is primarily deregulatory as it would exempt persons from the prohibition under section 608(c)(2) of the Clean Air Act, and as implemented by regulations at 40 CFR 82.154(a)(1), against knowingly venting or otherwise knowingly releasing or disposing of refrigerant substitutes during the maintenance, servicing, repair or disposal of appliances for three specific hydrocarbon refrigerant substitutes in specific end uses. We have therefore concluded that today's final rule will relieve regulatory burden for all affected small entities.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. The action imposes no enforceable duty on any State, local or tribal governments or the private sector. Thus, this action is not subject to the requirements of sections 202 or 205 of the UMRA. This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. This action is deregulatory in nature and creates an exemption under section 608(c)(2) of the Act from a statutory and regulatory requirement.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in EO 13132 (64 FR 43255, August 10, 1999). This action is deregulatory in nature and creates an exemption under section 608(c)(2) of the Act from a statutory and regulatory requirement, which would benefit any state, local, or tribal government to the extent that they are affected. Thus, EO 13132 does not apply to this final rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on the proposed action from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in EO 13175 (65 FR 67249, November 6, 2000). This final rule is deregulatory in nature and would create an exemption under section 608(c)(2) of the Act that could be available for the tribal communities or Indian tribal governments. Thus, EO 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to the EO 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in Executive Order 12866, and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in section III in the preamble.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, Section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

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

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629; February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule exempting under section 608(c)(2) of the Act certain hydrocarbons from the venting prohibition in certain end uses listed as acceptable subject to use conditions will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because the release of these three hydrocarbon refrigerant substitutes would not pose a threat to the environment. This final action would not have any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

K. Congressional Review Act

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 rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. 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). This rule will be effective June 23, 2014.

VII. References

The documents referenced in the final rule in which the three hydrocarbon refrigerant substitutes in specific end-uses were evaluated and determined to be acceptable subject to use conditions under SNAP in the December 20, 2011 final rule (76 FR 78832), were also referenced in the preamble of the proposed rule published on April 12, 2012 (78 FR 21871). All documents for these two previously published rules are located in the Air Docket at the address listed in section titled **ADDRESSES** at the beginning of this document. Unless specified otherwise, all documents are available in Docket ID No. EPA–HQ–OAR–2012–0580 at *http://www.regulations.gov.* Listed below are only new documents not previously cited in that previously published rule and previously published proposal that were referenced in this action.

EPA, 2011, ''Environmentally Acceptable Lubricants,'' United States Environmental Protection Agency, Office of Wastewater Management, November 2011, EPA 800–R–11–002

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Recycling, Reporting and recordkeeping requirements, Stratospheric ozone layer.

Dated: May 15, 2014.

Gina McCarthy,

Administrator.

For the reasons set out in the preamble, 40 CFR Part 82 is to be amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for Part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671g.

■ 2. Section 82.154 is amended by revising paragraph (a)(1) to read as follows:

§ 82.154 Prohibitions.

(a)(1) No person maintaining, servicing, repairing, or disposing of

appliances may knowingly vent or otherwise release into the environment any refrigerant or substitute from such appliances, with the exception of the following substitutes in the following end-uses:

(i) Effective June 13, 2005,

(A) Ammonia in commercial or industrial process refrigeration or in absorption units;

(B) Hydrocarbons in industrial process refrigeration (processing of hydrocarbons);

(C) Chlorine in industrial process refrigeration (processing of chlorine and chlorine compounds);

(D) Carbon dioxide in any application;

(E) Nitrogen in any application; or

(F) Water in any application.

(ii) Effective June 23, 2014:

(A) Isobutane (R–600a) and R–441A in household refrigerators, freezers, and combination refrigerators and freezers; or

(B) Propane (R–290) in retail food refrigerators and freezers (stand-alone units only).

* * * * *

[FR Doc. 2014–12028 Filed 5–22–14; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 79, No. 100
Friday, May 23, 2014

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

DEPARTMENT OF ENERGY

10 CFR Part 429

[Docket No. EERE–2013–BT–NOC–0039]

Appliance Standards and Rulemaking Federal Advisory Committee: Notice of Open Meetings Teleconference/Webinar, Update for the Commercial and Industrial Pumps Working Group

AGENCY: Department of Energy, Office of Energy Efficiency and Renewable Energy.

ACTION: Notice of open meetings; update.

SUMMARY: The Department of Energy (DOE) published in the **Federal Register** on January 14, 2014, a notice of open meetings for the Commercial and Industrial Pumps Working Group of the Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC). Since publication of the January 14 notice of open meetings the working group has added an extra day to both series of meetings, which DOE is announcing in today's document. The Federal Advisory Committee Act requires that agencies publish notice of an advisory committee meeting in the **Federal Register**.

DATES: The last two meeting series announced in the **Federal Register** notice of open meetings on January 14, 2014 (79 FR 2383) will have a third day added and the meeting times on the second day adjusted. The meeting times for these two series of meetings will be as follows:

- June 17, 2014 from 9:00 a.m. to 5:00 p.m.
- June 18, 2014 from 9:00 a.m. to 6:00 p.m.
- June 19, 2014 from 8:00 a.m. to 3:00 p.m.
- July 23, 2014 from 9:00 a.m. to 5:00 p.m.
- July 24, 2014 from 9:00 a.m. to 6:00 p.m.
- July 25, 2014 from 8:00 a.m. to 3:00 p.m.

ADDRESSES: The meeting on June 17 will take place at 950 L'Enfant Plaza, Washington, DC 20024 in room 8037 A&B. All other meetings will be held in the U.S. Department of Energy, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585. Individuals will also have the opportunity to participate by Webinar. To register for the Webinars and receive call-in information, please register at *http://energy.gov/eere/buildings/appliance-standards-and-rulemaking-federal-advisory-committee.*

FOR FURTHER INFORMATION CONTACT: John Cymbalsky, ASRAC Designated Federal Officer, U.S. Department of Energy (DOE), Office of Energy Efficiency and Renewable Energy, 950 L'Enfant Plaza SW., Washington, DC 20024. Email: *asrac@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of Meeting: To provide advice and recommendations to the U.S. Department of Energy on a proposed rule for Commercial and Industrial pumps and equipment under the authority of the Negotiated Rulemaking Act (5 U.S.C. 561–570, Pub. L. 104–320).

Public Participation: Members of the public are welcome to observe the business of the meeting and, if time allows, may make oral statements during the specified period for public comment. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, email *asrac@ee.doe.gov.* In the email, please indicate your name, organization (if appropriate), citizenship, and contact information. Please note that foreign nationals visiting DOE Headquarters are subject to advance security screening procedures. Any foreign national wishing to participate in the meeting should advise ASRAC staff as soon as possible by emailing *asrac@ee.doe.gov* to initiate the necessary procedures. Anyone attending the meeting will be required to present a government photo identification, such as a passport, driver's license, or government identification. Due to the required security screening upon entry, individuals attending should arrive early to allow for the extra time needed.

Members of the public will be heard in the order in which they sign up for the Public Comment Period. Time allotted per speaker will depend on the number of individuals who wish to speak but will not exceed five minutes. Reasonable provision will be made to include the scheduled oral statements on the agenda. A third-party neutral facilitator will make every effort to allow the presentations of views of all interested parties and to facilitate the orderly conduct of business.

Participation in the meeting is not a prerequisite for submission of written comments. ASRAC invites written comments from all interested parties. Any comments submitted must identify the ASRAC, and provide docket number EERE–2013–BT–NOC–0039. Comments may be submitted using any of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email: ASRACworkgroup2013NOC0039@ee.doe.gov.* Include docket number EERE–2013–BT–NOC–0039 in the subject line of the message.

3. *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Telephone: (202) 586–2945. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted.

Docket: The docket is available for review at *www.regulations.gov,* including **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The Secretary of Energy has approved publication of today's notice of proposed rulemaking.

Issued in Washington, DC, on May 14, 2014.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2014–12013 Filed 5–22–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0179; Directorate Identifier 2014–NE–03–AD]

RIN 2120–AA64

Airworthiness Directives; Technify Motors GmbH Reciprocating Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Technify Motors GmbH (type certificate previously held by Thielert Aircraft Engines GmbH) TAE 125–02–99 and TAE 125–02–114 reciprocating engines. This proposed AD was prompted by in-flight shutdowns on airplanes with TAE 125–02 engines. This proposed AD would require removal of each high-pressure (HP) fuel pump before 300 flight hours (FHs) in service or within 55 FHs after the effective date of the AD, whichever occurs later. We are proposing this AD to prevent failure of the HP fuel pump, which could result in damage to the engine and damage to the airplane.

DATES: We must receive comments on this proposed AD by July 22, 2014.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

For service information identified in this proposed AD, contact Technify Motors GmbH, Platanenstrasse 14, D–09356 Sankt Egidien, Germany, phone: +49–37204–696–0; fax: +49–37204–696-55; email: *info@centurion.aero*. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0179; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (phone: 800–647–5527) is the same as the Mail address provided in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kevin Donovan, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: (781) 238–7743; fax: (781) 238–7199; email: *kevin.donovan@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2014–0179; Directorate Identifier 2014–NE–03–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2013–0279, dated November 26, 2013 (referred to hereinafter as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

In-flight shut down occurrences have been reported on aeroplanes equipped with TAE 125–02 engines. The initial results of the investigations showed that abnormal high wear of the high pressure fuel pumps was the probable cause of the engine failure.

This condition, if not corrected, could result in further cases of engine power loss events and consequent potential loss of control of the aeroplane.

We are proposing this AD to prevent damage to the engine and damage to the aircraft. You may obtain further information by examining the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0179.

Relevant Service Information

Technify Motors GmbH has issued Service Bulletin No. TM TAE 125–1017 P1, Revision 1, dated September 20, 2013. The service information describes procedures for removing and replacing the HP fuel pump.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of Germany, and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This proposed AD would require removal of each affected HP fuel pump.

Costs of Compliance

We estimate that this proposed AD affects 160 engines installed on airplanes of U.S. registry. We also estimate that it would take about 1 hour per engine to comply with this proposed AD. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $13,600.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that

section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Technify Motors GmbH (Type Certificate previously held by Thielert Aircraft Engines GmbH): Docket No. FAA–2014–0179; Directorate Identifier 2014–NE–03–AD.

(a) Comments Due Date

We must receive comments by July 22, 2014.

(b) Affected ADs

None.

(c) Applicability

This AD applies to TAE 125–02–99 and TAE 125–02–114 reciprocating engines with a high-pressure (HP) fuel pump, part number (P/N) 05–7312–K005301 or P/N 05–7312–K005302.

(d) Reason

This AD was prompted by in-flight shutdowns on airplanes with TAE 125–02 engines. We are issuing this AD to prevent failure of the HP fuel pump, which could result in damage to the engine and damage to the airplane.

(e) Actions and Compliance

Comply with this AD within the compliance times specified, unless already done. Remove each HP fuel pump, P/N 05–7312–K005301 and P/N 05–7312–K005302, before 300 flight hours (FHs) in service or within 55 FHs after the effective date of this AD, whichever occurs later.

(f) Installation Prohibition

After the effective date of this AD, do not install a TAE 125–02–99 or TAE 125–02–114 engine with HP fuel pump, P/N 05–7312–K005301 or P/N 05–7312–K005302, onto any airplane.

(g) Alternative Methods of Compliance (AMOCs)

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

(h) Related Information

(1) For more information about this AD, contact Kevin Donovan, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: (781) 238–7743; fax: (781) 238–7199; email: *kevin.donovan@faa.gov.*

(2) Refer to MCAI European Aviation Safety Agency AD 2013–0279, dated November 26, 2013, for related information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0179.

(3) Technify Motors GmbH Service Bulletin No. TM TAE 125–1017 P1, Revision 1, dated September 20, 2013, pertains to the subject of this AD and can be obtained from Technify Motors GmbH using the contact information in paragraph (h)(4) of this proposed AD.

(4) For service information identified in this proposed AD, contact Technify Motors GmbH, Platanenstrasse 14, D–09356 Sankt Egidien, Germany, phone: +49–37204–696–0; fax: +49–37204–696–55; email: *info@centurion.aero.*

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

Issued in Burlington, Massachusetts, on May 13, 2014.

Richard P. Warren,

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

[FR Doc. 2014–11983 Filed 5–22–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–1327; Directorate Identifier 2012–NE–47–AD]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede airworthiness directive (AD) 2013–12–01 that applies to all Rolls-Royce plc (RR) model RB211 Trent 768–60, 772–60, and 772B–60 turbofan engines. AD 2013–12–01 requires a one-time ultrasonic inspection (UI) of low-pressure (LP) compressor blades with more than 2,500 flight cycles since new or last inspection. Since we issued AD 2013–12–01, RR determined that repetitive UIs of the LP compressor blades are needed. This proposed AD would require initial and repetitive UIs of the affected LP compressor blades. We are proposing this AD to prevent LP compressor blade airfoil separations, damage to the engine, and damage to the airplane.

DATES: We must receive comments on this proposed AD by July 22, 2014.

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

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

For service information identified in this AD, contact Rolls-Royce plc, P.O. Box 31, Derby DE24 8BJ, UK; phone: 44

(0) 1332 242424; fax: 44 (0) 1332 249936. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2012–1327; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the mandatory continuing airworthiness information, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Robert Green, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: (781) 238–7754; fax: (781) 238–7199; email: *robert.green@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2012–1327; Directorate Identifier 2012–NE–47–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

On June 5, 2013, we issued AD 2013–12–01, Amendment 39–17478 (78 FR 37703, June 24, 2013), (''AD 2013–12–01''), for all RR model RB211 Trent 768–60, 772–60, and 772B–60 turbofan engines. AD 2013–12–01 requires a one-time UI of LP compressor blades that have accumulated more than 2,500 flight cycles since new. AD 2013–12–01 resulted from LP compressor blade partial airfoil release events. We issued AD 2013–12–01 to prevent LP compressor blade airfoil separations, engine damage, and damage to the airplane.

Actions Since Existing AD Was Issued

Since we issued AD 2013–12–01, RR's service experience and updated analysis has determined the need for repetitive inspections of the LP compressor blades. Also since we issued AD 2013–12–01, the European Aviation Safety Agency (EASA) has issued EASA AD 2014–0031, dated February 4, 2014, which requires repetitive inspection of the LP compressor blades.

Relevant Service Information

We reviewed RR Alert Non-Modification Service Bulletin No. RB.211–72–AH465, dated July 15, 2013. The service information describes procedures for an initial UI followed by repetitive UIs of the affected LP compressor blades.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would require an initial UI of LP compressor blades at 3,600 cycles since new or before further flight. For LP compressor blades that exceed 2,200 cycles since last inspection (CSLI), the AD would require a UI before exceeding 3,000 CSLI or before further flight. This proposed AD would also require repetitive UIs of the affected LP compressor blades every 2,400 CSLI thereafter.

Costs of Compliance

We estimate that this proposed AD would affect 56 engines installed on airplanes of U.S. registry. We also estimate that it would take about 44 hours per engine to comply with the intial inspection requirements in this proposed AD. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $209,440.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2013–12–01, Amendment 39–17478 (78 FR 37703, June 24, 2013), and adding the following new AD:

Rolls-Royce plc: Docket No. FAA–2012–1327; Directorate Identifier 2012–NE–47–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by July 22, 2014.

(b) Affected ADs

This AD supersedes AD 2013–12–01, Amendment 39–17478 (78 FR 37703, June 24, 2013.

(c) Applicability

This AD applies to Rolls-Royce plc (RR) model RB211 Trent 768–60, 772–60, and 772B–60 turbofan engines, with low-pressure (LP) compressor blade, part numbers (P/Ns) FK23411, FK25441, FK25968, FW11901, FW15393, FW23643, FW23741, FW23744, KH23403, or KH23404, installed.

(d) Unsafe Condition

This AD was prompted by LP compressor blade partial airfoil release events. We are issuing this AD to prevent LP compressor blade airfoil separations, engine damage, and damage to the airplane.

(e) Actions and Compliance

Unless already done, do the following actions.

(1) Ultrasonic Inspection (UI) of LP Compressor Blade

(i) After the effective date of this AD, ultrasonically inspect each LP compressor blade before the blade exceeds 3,600 cycles since new (CSN) or before further flight, whichever occurs later. Repeat the UI of the blade every 2,400 cycles since last inspection (CSLI).

(ii) For any LP compressor blade that exceeds 2,200 CSLI on the effective date of this AD, inspect the blade before exceeding 3,000 CSLI or before further flight, whichever occurs later. Thereafter, perform the repetitive inspections required by this AD.

(iii) Use paragraph 3, excluding subparagraphs 3.A.(9), 3.B.(5), 3.C.(4), 3.D.(3), 3.E.(5), 3.F.(10), and 3.G.(7), of RR Alert Non-Modification Service Bulletin (NMSB) RB.211–72–AH465, dated July 15, 2013, to perform the inspections required by this AD.

(2) Use of Replacement Blades

LP compressor blades, P/Ns FK23411, FK25441, FK25968, FW11901, FW15393, FW23643, FW23741, FW23744, KH23403, or KH23404, that have accumulated at least 3,600 CSN or 2,400 CSLI are eligible for installation if the blade has passed the UI required by this AD.

(f) Credit for Previous Actions

If you performed a UI of an affected LP compressor blade before the effective date of this AD using RR NMSB No. RB.211–72–G702, dated May 23, 2011; or RR NMSB No. RB.211–72–G872, Revision 2, dated March 8, 2013, or earlier revisions; or RR NMSB No. RB.211–72–H311, dated March 8, 2013; or Engine Manual E-Trent-1RR, Task 72–31–11–200–806, you have met the initial inspection requirements of this AD. However, you must still comply with the repetitive 2,400 CSLI requirement of this AD.

(g) Alternative Methods of Compliance (AMOCs)

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

(h) Related Information

(1) For more information about this AD, contact Robert Green, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: (781) 238–7754; fax: (781) 238–7199; email: *Robert.Green@faa.gov*.

(2) Refer to MCAI European Aviation Safety Agency AD 2014–0031, dated February 4, 2014, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2012–1327.

(3) RR Alert NMSB No. RB.211–72–AH465, dated July 15, 2013, pertains to the subject of this AD and can be obtained from Rolls-Royce plc, using the contact information in paragraph (h)(4) of this AD.

(4) For service information identified in this AD, contact Rolls-Royce plc, P.O. Box 31, Derby DE24 8BJ, UK; phone: 44 (0) 1332 242424; fax: 44 (0) 1332 249936.

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

Issued in Burlington, Massachusetts, on May 19, 2014.

Colleen M. D'Alessandro,

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

[FR Doc. 2014–11919 Filed 5–22–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2014–0220; Airspace Docket No. 14–AEA–5]

Proposed Establishment of Class D Airspace and Amendment of Class E Airspace; Blackstone, VA.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class D airspace and amend existing Class E airspace at Blackstone, VA, to accommodate the new air traffic control tower at Allen C. Perkinson Blackstone Army Airfield. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at the airfield. This action also would update the geographic coordinates of the airfield's existing Class E airspace.

DATES: 0901 UTC. Comments must be received on or before July 7, 2014.

ADDRESSES: Send comments on this rule to: U. S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey SE., Washington, DC 20590–0001; Telephone: 1–800–647–5527; Fax: 202–493–2251. You must identify the Docket Number FAA–2014–0220; Airspace Docket No. 14–AEA–5, at the beginning of your comments. You may also submit and review received comments through the Internet at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: John Fornito, Airspace Specialist, Operations Support Group, Eastern Service Center, Air Traffic Organization, Federal Aviation Administration, P. O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to comment on this rule 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 number. FAA–2014–0220; Airspace Docket No. 14–AEA–5) 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*.

Those 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 Docket No. FAA–2014–0220; Airspace Docket No. 14–AEA–5.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel

concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded from and comments submitted through *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 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 between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal Holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, Georgia 30337.

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

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to establish Class D airspace within a 4.2-mile radius of Allen C Perkinson Blackstone Army Airfield, Blackstone, VA, and amend existing Class E airspace extending upward from 700 feet above the surface to within a 6.7-mile radius of the airfield, as well as adjust the geographic coordinates of the airfield to be in concert with the FAAs aeronautical database. This action is necessary to support the operation of the new air traffic control tower, and would enhance the safety and management of IFR operations at the airfield.

Class D and E airspace designations are published in Paragraphs 5000 and 6005 respectively, of FAA Order 7400.9X, dated August 7, 2013, and effective September 15, 2013, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the 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. 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. 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 United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This proposed 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 airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This proposed regulation is within the scope of that authority as it would establish Class D and amend Class E airspace at Allen C Perkinson Blackstone Army Airfield, Blackstone, VA.

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.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, 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 part 71 will continue 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 Federal Aviation Administration Order 7400.9X, Airspace Designations and Reporting Points, dated August 7, 2013, and effective September 15, 2013, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

AEA VA D Blackstone, VA [NEW]

Allen C Perkinson Blackstone Army Airfield, VA
(Lat. 37°04′29″ N., long. 77°57′24″ W.)

That airspace extending upward from the surface up to and including 2,500 feet MSL within a 4.2-mile radius of Allen C Perkinson Blackstone Army Airfield. This Class D airspace area is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6005. Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AEA VA E5 Blackstone, VA [AMENDED]

Allen C Perkinson Blackstone Army Airfield, VA
(Lat. 37°04′29″ N., long. 77°57′24″ W.)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of Allen C Perkinson Blackstone Army Airfield.

Issued in College Park, Georgia, on May 15, 2015.

Myron A. Jenkins,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2014–11859 Filed 5–22–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2013–1074; Airspace Docket No. 13–ASO–26]

Proposed Establishment of Class E Airspace; Cynthiana, KY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E Airspace at Cynthiana, KY, to accommodate a new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedures (SIAP) serving Cynthiana-Harrison County Airport.

This action would enhance the safety and airspace management of Instrument Flight Rules (IFR) operations within the National Airspace System.

DATES: Comments must be received on or before July 7, 2014.

ADDRESSES: Send comments on this rule to: U. S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey SE., Washington, DC 20590–0001; Telephone: 1–800–647–5527; Fax: 202–493–2251. You must identify the Docket Number FAA–2013–1074; Airspace Docket No. 13–ASO–26, at the beginning of your comments. You may also submit and review received comments through the Internet at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to comment on this rule 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–2013–1074; Airspace Docket No. 13–ASO–26) 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*.

Persons 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 Docket No. FAA–2013–1074; Airspace Docket No. 13–ASO–26.'' The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRMs

An electronic copy of this document may be downloaded from and comments submitted through *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 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 between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal Holidays, at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, Georgia 30337.

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

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to establish Class E airspace at Cynthiana, KY, providing the controlled airspace required to support the new RNAV (GPS) standard instrument approach procedures for Cynthiana-Harrison County Airport. Controlled airspace extending upward from 700 feet above the surface is required for IFR operations within a 7.8-mile radius of the airport.

Class E airspace designations are published in Paragraph 6005 of FAA order 7400.9X, dated August 7, 2013, and effective September 15, 2013, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the 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. 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. 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 United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This proposed 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 airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This proposed regulation is within the scope of that authority as it would establish Class E airspace at Cynthiana-Harrison County Airport, Cynthiana, KY.

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.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 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 Federal Aviation Administration Order 7400.9X, Airspace Designations and Reporting Points, dated August 7, 2013, effective September 15, 2013, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO KY E5 Cynthiana, KY [New]

Cynthiana-Harrison County Airport, KY (Lat. 38°21′58″ N., long. 84°17′00″ W.)

That airspace extending upward from 700 feet above the surface within a 7.8-mile radius of Cynthiana-Harrison County Airport.

Issued in College Park, Georgia, on May 15, 2014.

Myron A. Jenkins,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2014–11858 Filed 5–22–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2013–N–0013]

RIN 0910–AG98

Sanitary Transportation of Human and Animal Food; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; Extension of Comment Period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice of proposed rulemaking that appeared in the **Federal Register** of February 5, 2014, entitled ''Sanitary Transportation of Human and Animal Food'' and its information collection provisions. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments. We also are taking this action to keep the comment period for the information collection provisions associated with the rule consistent with the comment period for the proposed rule.

DATES: FDA is extending the comment period on the proposed rule published February 5, 2014 (79 FR 7005), and its information collection provisions. Submit either electronic or written comments on the proposed rule and the information collection by July 30, 2014.

ADDRESSES: You may submit comments by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

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 ways:

• *Mail/Hand delivery/Courier (for paper 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, Docket No. FDA–2013–N–0013, and RIN 0910–AG98 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 ''Request for 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: *With regard to the proposed rule:* Michael E. Kashtock, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2022.

With regard to the information collection: Domini Bean, Office of Information Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *Domini.Bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 5, 2014, we published a proposed rule entitled ''Sanitary Transportation of Human and Animal Food'' with a 115-day comment period on the provisions of the proposed rule and on the information collection provisions that are subject to review by OMB under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

FDA has received requests for an extension of the comment period on the proposed rule. The requests conveyed concern that the current 115-day comment period does not allow time to thoroughly analyze the proposed rule given that the regulations would apply to a diverse array of human foods, animal feed and feed ingredients, and pet food transported by rail and truck. The requests also stated an extended comment period would allow interested persons an opportunity to consider the complexities that affect the interrelated responsibilities of shippers, carriers, and receivers. Finally, the requests stated that additional time is needed to analyze the economic impact on the affected industry sectors and to provide FDA with pertinent information to assist in the economic analysis. FDA has considered the requests and is granting a 60-day extension of the comment period to July 30, 2014, for the ''Sanitary Transportation of Human and Animal Food'' proposed rule to allow interested persons additional time to submit comments. We also are extending the comment period for the information collection provisions to July 30, 2014, to make the comment period for the information collection provisions the same as the comment period for the provisions of the proposed rule. To clarify, FDA is requesting comment on all issues raised by the proposed rule.

II. Paperwork Reduction Act of 1995

Interested persons may either submit electronic comments regarding the information collection to *oira_submission@omb.eop.gov* or fax written comments to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285. All comments should be identified with the title ''Sanitary Transportation of Human and Animal Food.''

III. Request for Comments

Interested persons may submit either electronic comments regarding the proposed rule to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: May 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12002 Filed 5–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Chapter IX

[Docket No. FR–5650–N–07]

Native American Housing Assistance and Self-Determination Act of 1996: Negotiated Rulemaking Committee; Notice of Fourth, Fifth and Sixth Meetings

AGENCY: Office of Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of meetings of negotiated rulemaking committee.

SUMMARY: This document announces the fourth, fifth, and sixth meetings of the negotiated rulemaking committee.

DATES: The fourth meeting will be held on Wednesday, June 11, 2014, Thursday, June 12, 2014, and Friday, June 13, 2014. The fifth meeting will be held on Tuesday, July 29, 2014, Wednesday, July 30, 2014, and Thursday, July 31, 2014. The sixth meeting will be held on Tuesday, August 26, 2014, Wednesday, August 27, 2014, and Thursday, August 28, 2014. On each day, the session will begin at approximately 8:30 a.m., and adjourn at approximately 5:30 p.m.

ADDRESSES: The fourth meeting will take place at the Hilton Scottsdale, 6333 North Scottsdale Road, Scottsdale, Arizona. The fifth meeting will take place at the Sheraton Denver Downtown Hotel, 1550 Court Place, Denver, Colorado. The sixth meeting will take place at the DoubleTree-Scottsdale, 5401 North Scottsdale Road, Scottsdale, Arizona.

FOR FURTHER INFORMATION CONTACT: Rodger J. Boyd, Deputy Assistant Secretary for Native American Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4126, Washington, DC 20410, telephone number 202–401–7914 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The Native American Housing and Assistance and Self-Determination Act of 1996 (25 U.S.C. 4101 *et seq.*) (NAHASDA) changed the way that housing assistance is provided to Native Americans. NAHASDA eliminated several separate assistance programs and replaced them with a single block grant program, known as the Indian Housing Block Grant (IHBG) program. The regulations governing the IHBG formula allocation are codified in subpart D of part 1000 of HUD's regulations in title 24 of the Code of Federal Regulations. In accordance with section 106 of NAHASDA, HUD developed the regulations with active tribal participation using the procedures of the Negotiated Rulemaking Act of 1990 (5 U.S.C. 561–570).

Under the IHBG program, HUD makes assistance available to eligible Indian tribes for affordable housing activities. The amount of assistance made available to each Indian tribe is determined using a formula that was developed as part of the NAHASDA negotiated process. Based on the amount of funding appropriated for the IHBG program, HUD calculates the annual grant for each Indian tribe and provides this information to the Indian tribes. An Indian Housing Plan for the Indian tribe is then submitted to HUD. If the Indian Housing Plan is found to be in compliance with statutory and regulatory requirements, the grant is made.

On July 3, 2012 at 77 FR 39452, HUD announced its intention to establish a negotiated rulemaking for the purpose of developing regulatory changes to the formula allocation for the IHBG program. On June 12, 2013 at 78 FR 35178, HUD announced in the **Federal Register** the list of proposed members for the negotiated rulemaking committee, and requested additional public comment on the proposed membership. On July 30, 2013 at 78 FR 45903, HUD announced the final list of committee members to revise the allocation formula used under the IHBG.

On August 27, 2013, and August 28, 2013, the first meeting of the negotiated rulemaking committee was held. The second meeting was held on Tuesday, September 17, 2013, Wednesday, September 18, 2013, and Thursday, September 19, 2013. The third meeting was held on Wednesday, April 23, 2014, Thursday, April 24, 2014, and Friday, April 25, 2014.

II. Fourth, Fifth, and Sixth Committee Meetings

The fourth meeting of the Indian Housing Block Grant Allocation Formula Negotiation Rulemaking Committee will be held on Wednesday, June 11, 2014, Thursday, June 12, 2014, and Friday, June 13, 2014. On each day, the session will begin at approximately 8:30 a.m., and adjourn at approximately 5:30 p.m. The meeting will take place at the Hilton Scottsdale, 6333 North Scottsdale Road, Scottsdale, Arizona.

The fifth meeting will be held on Tuesday, July 29, 2014, Wednesday, July 30, 2014, and Thursday, July 31, 2014. On each day, the session will begin at approximately 8:30 a.m., and adjourn at approximately 5:30 p.m. The meeting will take place at the Sheraton Denver Downtown Hotel, 1550 Court Place, Denver, Colorado.

The sixth meeting will be held on Tuesday, August 26, 2014, Wednesday, August 27, 2014, and Thursday, August 28, 2014. On each day, the session will begin at approximately 8:30 a.m., and adjourn at approximately 5:30 p.m. The meeting will take place at the DoubleTree-Scottsdale, 5401 North Scottsdale Road, Scottsdale, Arizona.

These meetings will be open to the public without advance registration. Public attendance may be limited to the space available. Members of the public may make statements during the meetings, to the extent time permits, and file written statements with the committee for its consideration. Written statements should be submitted to the address listed in the **FOR FURTHER INFORMATION** section of this document.

III. Future Committee Meetings

Notices of all future meetings will be published in the **Federal Register**. HUD will make every effort to publish such documents at least 15 calendar days prior to each meeting.

Dated: May 19, 2014.

Sandra B. Henriquez,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 2014–12030 Filed 5–22–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–130967–13]

RIN 1545–BL72

Regulations Relating to Information Reporting by Foreign Financial Institutions and Withholding on Certain Payments to Foreign Financial Institutions and Other Foreign Entities; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of a notice of public hearing on proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations providing guidance under chapter 4 of

Subtitle A (sections 1471 through 1474) of the Internal Revenue Code of 1986.

DATES: The public hearing originally scheduled for June 24, 2014 at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Oluwafunmilayo Taylor of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration) at (202) 317–6901 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking by cross-reference to temporary regulations and a notice of public hearing that appeared in the **Federal Register** on Thursday, March 6, 2014 (79 FR 12868) announced that a public hearing was scheduled for June 24, 2014, at 10 a.m. in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC. The subject of the public hearing is under sections 1471 through 1474 of the Internal Revenue Code.

The public comment period for these regulations expired on May 5, 2014. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be addressed. As of May 14, 2014, no one has requested to speak. Therefore, the public hearing scheduled for June 24, 2014 at 10 a.m. is cancelled.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2014–11921 Filed 5–22–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–136984–12]

RIN 1545–BL21

Section 752 and Related Party Rules

Correction

In proposed rule document 2013–29420, appearing on pages 76092 through 76096 in the issue of Monday, December 16, 2013, make the following correction:

On page 76094, in the second column, on the tenth line, insert the following:

D. Special Rule Where Entity Structured To Avoid Related Person Status

Section 1.752–4(b)(2)(iv) provides special rules for when an entity is structured to avoid related person status. The proposed regulations do not propose any changes to these rules. However, as a result of other changes made to simplify the organization of § 1.752–4, the rules in § 1.752–4(b)(2)(iv) are now in § 1.752–4(b)(4) of the proposed regulations. In addition, the example in § 1.752–4(b)(2)(iv)(C) is now *Example 5* under § 1.752–4(b)(5) of the proposed regulations.

[FR Doc. C1–2013–29420 Filed 5–22–14; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 31, and 301

[REG–134361–12]

RIN 1545–BL17

Withholding of Tax on Certain U.S. Source Income Paid to Foreign Persons and Revision of Information Reporting and Backup Withholding Regulations; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of a notice of public hearing on proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations relating to the withholding of tax on certain U.S. source income paid to foreign persons, information reporting and backup withholding with respect to payments made to certain U.S. persons, portfolio interest treatment for nonresident alien individuals and foreign corporations, and requirements for certain claims for refund or credit of income tax made by foreign persons.

DATES: The public hearing originally scheduled for June 24, 2014 at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Oluwafunmilayo Taylor of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration) at (202) 317–6901 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking by cross-reference to temporary regulations and a notice of public hearing that appeared in the **Federal Register** on Thursday, March 6, 2014 (79 FR 12880) announced that a public hearing was scheduled for June 24, 2014, at 10 a.m. in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC. The subject of the public hearing is under sections 871, 1441, 1461, 6041, 6042, 6045, and 6049 of the Internal Revenue Code.

The public comment period for these regulations expired on May 5, 2014. The notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be addressed. As of May 14, 2014, no one has requested to speak. Therefore, the public hearing scheduled for June 24, 2014 at 10 a.m. is cancelled.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2014–11920 Filed 5–22–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF EDUCATION

34 CFR Chapter III

[Docket ID ED–2014–OSERS–0023; CFDA Number: 84.133A–10]

Proposed Priority—National Institute on Disability and Rehabilitation Research—Improving Methods of Evaluating Return on Investment for the State Vocational Rehabilitation Services Program

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Proposed priority.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority under the Disability and Rehabilitation Research Projects and Centers Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR). Specifically, this notice proposes a priority for a Disability and Rehabilitation Research Project (DRRP) on Improving Methods of Evaluating Return on Investment for the State Vocational Rehabilitation (VR) Services Program. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2014 and later years. We take this action to focus research attention on areas of national need. We intend this priority to contribute to improved employment outcomes for individuals with disabilities.

DATES: We must receive your comments on or before June 23, 2014.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID 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 ''Are you new to the site?''
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about these proposed regulations, address them to Marlene Spencer, U.S. Department of Education, 400 Maryland Avenue SW., Room 5133, Potomac Center Plaza (PCP), Washington, DC 20202–2700.

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: 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 priority is in concert with NIDRR's Long-Range Plan (Plan). The Plan, which was published in the **Federal Register** on April 4, 2013 (78 FR 20299), can be accessed on the Internet at the following site: *www.ed.gov/about/offices/list/osers/nidrr/policy.html.*

Through the implementation of the currently approved Plan, NIDRR seeks to: Identify a need for research and training in a number of areas. To address this need, NIDRR seeks to: (1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of research findings, expertise, and other information to advance knowledge and understanding of the needs of individuals with disabilities and their family members, including those from among traditionally underserved populations; (3) determine effective practices, programs, and policies to improve community living and participation, employment, and health and function outcomes for individuals with disabilities of all ages; (4) identify research gaps and areas for promising research investments; (5) identify and promote effective mechanisms for integrating research and practice; and (6) disseminate research findings to all major stakeholder groups, including individuals with disabilities and their families in formats that are appropriate and meaningful to them.

This notice proposes a priority that NIDRR intends to use for a DRRP competition in FY 2014 and possibly later years. However, nothing precludes NIDRR from publishing additional priorities, if needed. Furthermore, NIDRR is under no obligation to make an award using this priority. 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 proposed priority. To ensure that your comments have maximum effect in developing the final priority, we urge you to identify clearly the specific topic that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from this proposed priority. 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 notice 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 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 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 significant 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 significant 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, utilization, dissemination, and technical assistance.

An applicant for assistance 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 PRIORITY:

This notice contains one proposed priority.

Improving Methods of Evaluating Return on Investment for the State Vocational Rehabilitation Services Program (VR Program)

Background

Under title I of the Rehabilitation Act of 1973, as amended (Rehabilitation Act), States receive Federal grants for 78.7 percent of the cost to operate a comprehensive VR program. This State-operated program is designed to assess, plan, develop, and provide VR services

to eligible individuals with disabilities, consistent with their strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice. State VR agencies provide a wide range of services designed to enable individuals with disabilities to prepare for, obtain, and retain, gainful employment. Individuals with a physical or mental impairment that results in a substantial barrier to employment and who can benefit from and require VR services to prepare for, secure, retain, or regain employment are eligible to receive VR services. However, State VR agencies must give priority to individuals with the most significant disabilities if they cannot provide services to all eligible individuals.

Program services are tailored to the specific needs of the individual through an individualized plan for employment (IPE) in order to achieve his or her employment outcome. The VR Program may provide a variety of services, including, but not limited to, counseling, assessment, career development that includes job readiness training, vocational training, job coaching, on-the-job training and supports, assistive technology, transportation, and job placement.

In FY 2013, $3.029 billion in Federal funds were allocated to State VR agencies to administer the VR Program. Nationally, there are about 1 million individuals in various phases of the VR process within the VR system and about 580,000 individuals exit the program annually. Of the approximately 323,300 who exited the program after receiving services under an IPE in FY 2012, 180,216 exited with an employment outcome, 91 percent of whom were individuals with significant disabilities. The extent to which programs and services lead to effective results is important both in terms of improving employment outcomes for individuals with disabilities and justifying current and future investments.

Return-on-investment (ROI) is a performance measure used to evaluate the efficiency of an investment program, and it is calculated by dividing the benefits by the costs of the investment. Models investigating Federal and State investments and results are important given current and future budget conditions. Over the years, ROI studies have examined outcomes of the VR Program in relation to expended Federal and State funds. However, there are limitations in the use of findings from previous studies on VR Program effectiveness because they did not take into account all of the factors that may have an impact on ROI results. For example, previous studies did not account for specific services and disability subpopulations, potential selection bias (e.g., limiting the analysis to individuals who received services rather than all who enter the VR system), long-term outcomes and employment retention, recurring episodes of VR participation, and relevant demographic, service, and benefit program factors. In addition, the full range of costs, including Federal administrative costs, have not been taken into account in most VR ROI models. Changing economic conditions and their relative impacts on VR Program effectiveness are also not reflected in current ROI research.

While recent methodological research has included some of the important elements missing from earlier studies (Dean, 2013a and 2013b), there is a need to build on these advances to improve ROI measurement of the VR Program and to create a standard approach for applying the ROI tool in VR settings. Expanding what is known about the effectiveness of the VR Program will provide policymakers, administrators, counselors, and consumers with information necessary to better allocate resources for individuals within specific disability subpopulations. The proposed priority aims at addressing this need.

References

Dean, D., Schmidt, R., Pepper, J., and Stern, S. (2013a). The effects of Vocational Rehabilitation on people with mental illness. Retrieved from: *http://people.virginia.edu/~sns5r/resint/vocrehstf/vocrehmi.pdf.*

Dean, D., Schmidt, R., Pepper, J., and Stern, S. (2013b). The effects of Vocational Rehabilitation on people with cognitive disabilities. Retrieved from: *http://people.virginia.edu/~sns5r/resint/vocrehstf/vocrehci.pdf.*

Hollenbeck, Kevin and Wei-Jang Huang (2006). Net Impact and Benefit Cost Estimates of the Workforce Development System in Washington State. MI: W.E. Upjohn Institute for Employment Research. Retrieved from *http://research.upjohn.org/cgi/viewcontent.cgi?article=1023&context=up_technicalreports.*

Kisker, E., G. Strech, J. Vetter, and C. Foote (2008). Evaluating Rehabilitation Services in Oklahoma: An Analysis of Program Impacts and of Benefits/Costs. Oklahoma Department of Rehabilitative Services.

Wilhelm, S. and J. Robinson (2010). Utah State Office of Rehabilitation Economic Impact Study. The University of Utah Center for Public Policy and Administration.

Proposed Priority

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority under NIDRR's Disability and Rehabilitation Research Projects (DRRPs) program on Improving Methods of Evaluating Return on Investment for the State VR Services Program.

The DRRP must contribute to improving the ROI methodologies available to assess the impact of the VR Program on employment outcomes of individuals with disabilities by:

(a) Developing or expanding valid, innovative, and replicable ROI model(s) for assessing the VR Program and the services it provides. These model(s) must include variables such as costs associated with individuals who enter the agency but leave without receiving services, costs related to specific services so VR agencies can better consider ROI when determining services that lead to better outcomes, estimates of State and Federal expenditures incurred as part of the VR Program administration and service delivery system, characteristics of disability subpopulations, long-term outcomes extending years after exit from the VR Program, and information on general economic conditions. These models must use rigorous methods, including the use of a comparison group to determine the effect of the VR program.

(b) Testing the model(s) in at least eight State VR agencies with varying characteristics (e.g., urban/rural, with/without waitlists) to determine its replicability, including determining what data are necessary to make the model(s) successful and evaluating the data quality and data availability in selected sites. The final number of sites must be approved by NIDRR. In carrying out this requirement, we want the successful applicant to clarify a process for ensuring access to Social Security data and earnings data as required to assess long-term impact of the VR program.

(c) Developing and disseminating recommended standards for conducting ROI studies of the VR Program.

(d) Producing and disseminating training materials to support the VR Program in using the model(s).

(e) Making the underlying data available so others can learn from and replicate the findings, without compromising personally identifiable information. Data availability will conform to all security requirements of identified sources.

(f) Working with an advisory board made up of ROI, VR, and research methodology experts to ensure the findings are relevant, replicable, and sound.

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)).

Final Priority

We will announce the final priority in a notice in the **Federal Register**. We will determine the final priority 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 we choose to use this priority, 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 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 this proposed priority only upon a reasoned determination that its benefits justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this proposed priority 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 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 Program have been well established over the years. Projects similar to the new DRRP have been completed successfully, and the new DRRP, established consistently with the proposed priority, is expected to improve the lives of individuals with disabilities and generate through research and development, disseminate, and promote the use of new information that would improve our understanding of how VR services improve the employment outcomes of 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) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., Room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

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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.

Dated: May 20, 2014.

Michael K. Yudin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2014–12041 Filed 5–22–14; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2013–0823; FRL–9911–04-Region 9]

Approval of Air Quality Implementation Plan Revisions; State of California; South Coast VMT Emissions Offset Demonstrations

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of California to meet the vehicle miles traveled emissions offset requirement under the Clean Air Act for the 1-hour ozone and 1997 8-hour ozone national ambient air quality standards (NAAQS) in the Los Angeles-South Coast Air Basin. The EPA is proposing to approve this revision because it demonstrates that California has put in place specific enforceable transportation control strategies and transportation control measures to offset the growth in emissions from the growth in vehicle miles traveled and vehicle trips in the South Coast, and thereby meets the applicable requirements of the Clean Air Act. The EPA is taking comments on this proposal and plans to follow with a final action.

DATES: Any comments must be submitted by June 23, 2014.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2013–0823, by one of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.
- *Email: ungvarsky.john@epa.gov.*
- *Mail or Deliver:* John Ungvarsky, Air Planning Office (AIR–2), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Instructions: All comments 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, and the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to the EPA, your email address will be automatically captured and included as part of the public comment. If the EPA cannot read your comments due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment.

Docket: The index to the docket for this action is available electronically on the *www.regulations.gov* Web site and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California, 94105. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available at either location (e.g., 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 below.

FOR FURTHER INFORMATION CONTACT: John Ungvarsky, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX, (415) 972–3963, *ungvarsky.john@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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I. Regulatory Background

A. Ozone National Ambient Air Quality Standards

Ground-level ozone is formed when oxides of nitrogen (NO_X) and volatile organic compounds (VOC) react in the presence of sunlight. These two pollutants, referred to as ozone precursors, are emitted by many types of pollution sources, including on- and off-road motor vehicles and engines, power plants and industrial facilities, and smaller area sources such as lawn and garden equipment and paints.

Scientific evidence indicates that adverse public health effects occur following exposure to ozone, particularly in children and adults with lung disease. Breathing air containing ozone can reduce lung function and inflame airways, which can increase respiratory symptoms and aggravate asthma or other lung diseases. Ozone exposure also has been associated with increased susceptibility to respiratory infections, medication use, doctor visits, and emergency department visits and hospital admissions for individuals with lung disease. Ozone exposure also increases the risk of premature death from heart or lung disease. Children are at increased risk from exposure to ozone because their lungs are still developing and they are more likely to be active outdoors, which increases their exposure.

In 1979, under section 109 of the Clean Air Act (CAA or Act), the EPA established primary and secondary national ambient air quality standards (NAAQS, standards, or standard) for ozone at 0.12 parts per million (ppm) averaged over a 1-hour period (referred to herein as the ''1-hour ozone standard'' or ''1-hour ozone NAAQS''). See 44 FR 8202 (February 8, 1979).

In 1997, the EPA revised the ozone NAAQS to set the acceptable level of ozone in the ambient air at 0.08 ppm, averaged over an 8-hour period (referred to herein as the ''1997 8-hour ozone standard'' or ''1997 8-hour ozone NAAQS''). See 62 FR 38856 (July 18, 1997). The EPA set the 8-hour ozone standard based on scientific evidence demonstrating that ozone causes adverse health effects at lower concentrations and over longer periods of time than was understood when the previous 1-hour ozone standard was set. The EPA determined that the 8-hour ozone standard would be more protective of human health, especially children and adults who are active outdoors, and individuals with a pre-

existing respiratory disease, such as asthma.

In 2008 (73 FR 16436, March 27, 2008), the EPA revised and further strengthened the primary and secondary NAAQS for ozone by setting the acceptable level of ozone in the ambient air at 0.075 ppm, averaged over an 8-hour period (''2008 8-hour ozone standard''). Today's proposed action relates only to the 1-hour and 1997 8-hour ozone standards and does not relate to the 2008 8-hour ozone standard.

B. South Coast Ozone Designations and Classifications

Section 107 of the CAA requires the EPA to designate all areas of the country as nonattainment, attainment, or unclassifiable for each of the NAAQS, depending upon whether such areas experience violations of the NAAQS or contribute to violations in a nearby area. In the late 1970s, the EPA designated the Los Angeles-South Coast Air Basin Area (South Coast) [1] as nonattainment for the 1-hour ozone NAAQS. Under the 1990 CAA Amendments, ozone nonattainment areas were further classified, based on the severity of their nonattainment problem, as ''Marginal'', ''Moderate,'' ''Serious,'' ''Severe,'' [2] or ''Extreme,'' and the South Coast was classified as ''Extreme'' nonattainment for the 1-hour ozone standard. See 56 FR 56694 (November 6, 1991).

In 2004, the EPA designated areas of the country with respect to the 1997 8-hour ozone standard, 69 FR 23858 (April 30, 2004), and the EPA designated the South Coast as ''Severe-17'' [3] for the 1997 ozone standard, but later granted the State of California's request to reclassify the South Coast to ''Extreme'' for that standard. See 75 FR 24409 (May 5, 2010).

C. Previous South Coast VMT Emissions Offset Demonstrations

Once the EPA has promulgated a NAAQS, states are required to develop and submit plans that provide for the implementation, maintenance, and enforcement of the NAAQS under CAA section 110(a)(1). The content requirements for such plans, which are referred to as state implementation plans (SIPs) are found in CAA section 110(a)(2). The CAA further requires states with nonattainment areas to submit revisions to their SIPs that provide for, among other things, attainment of the relevant standard within certain prescribed periods.

In California, as a general matter, the California Air Resources Board (CARB) is responsible for adoption and submittal to the EPA of California SIPs and California SIP revisions and is the primary State agency responsible for regulation of mobile sources. Local and regional air pollution control districts are responsible for developing regional air quality plans and for regulation of stationary sources. For the South Coast, the South Coast Air Quality Management District (SCAQMD or District) develops and adopts air quality management plans (AQMPs) to address CAA SIP planning requirements applicable to that region. Generally, such AQMPs are then submitted to CARB for adoption and submittal to the EPA as revisions to the California SIP.

Under the CAA, as amended in 1990, the control requirements and date by which attainment of the 1-hour ozone standard was to be achieved varied with an area's classification. ''Extreme'' areas, such as the South Coast, were subject to the most stringent planning requirements but were provided the most time to attain the standard (i.e., until 2010). The various ozone planning requirements to which ''Extreme'' ozone nonattainment areas were subject are set forth in section 172(c) and section 182(a)–(e) of the CAA.

The specific ozone planning requirement that is relevant for the purposes of this action is CAA section 182(d)(1)(A), which, in relevant part, requires the state, if subject to its requirements, to ''submit a revision that identifies and adopts specific enforceable transportation control strategies and transportation control measures to offset any growth in emissions from growth in vehicle miles traveled or numbers of vehicle trips in such area.'' [4] Herein, we use ''VMT'' to refer to vehicle miles traveled and refer to the related SIP requirement as the ''VMT emissions offset requirement.'' In addition, we refer to the SIP revision intended to demonstrate compliance with the VMT emissions offset requirement as the ''VMT emissions offset demonstration.''

As described above, in 1997, the EPA revised the ozone NAAQS and established the 1997 8-hour ozone NAAQS. Under the EPA's Phase I rules governing the transition from the 1-hour ozone standard to the 1997 8-hour ozone standard, the EPA revoked the 1-hour ozone standard effective June 2005 but also established ''anti-backsliding'' provisions that, in effect, carried forward most of the SIP requirements that had applied to an area by virtue of its 1-hour ozone classification to areas designated as nonattainment for the 1997 8-hour ozone standard. See 69 FR 23951 (April 30, 2004); 40 CFR 51.905(a)(1); and 40 CFR 51.900(f). The VMT emission offset requirement is one of the requirements carried forward; thus, the South Coast, which is designated nonattainment for the 1997 8-hour ozone standard, remains subject to the VMT emissions offset requirement for the 1-hour ozone standard, notwithstanding the revocation of that standard in 2005. Moreover, the South Coast is also subject to the VMT emissions offset requirement for the 1997 8-hour ozone standard by virtue of its classification, initially as ''Severe-17'' and later as ''Extreme,'' for the 1997 ozone standard. See 69 FR 23858 (April 30, 2004); 70 FR 71612 (November 29, 2005); 75 FR 24409 (May 5, 2010); and 40 CFR 51.902(a).

In 2008, to comply with the VMT emissions offset requirement for the 1-hour ozone standard, the SCAQMD submitted a demonstration showing decreases in aggregate year-over-year motor vehicle emissions in the South Coast from a base year (1990) through the applicable attainment year (2010).[5] The following year, the EPA approved the South Coast 1-hour ozone VMT emissions offset demonstration as meeting the VMT emissions offset requirement of CAA section 182(d)(1)(A). See 74 FR 10176 (March 10, 2009). The EPA also approved the South Coast VMT emissions offset demonstration submitted in connection with the area's ''Extreme'' classification for the 1997 8-hour ozone standard. See 77 FR 12674 (March 1, 2012). Once again, the approved demonstration showed decreases in aggregate year-

[1] The South Coast includes Orange County, the southwestern two-thirds of Los Angeles County, southwestern San Bernardino County, and western Riverside County. The South Coast is home to approximately 17 million people, has a diverse economic base, and contains one of the highest-volume port areas in the world. For a precise description of the geographic boundaries of the South Coast, please see 40 CFR 81.305.

[2] In EPA's final rule to classify nonattainment areas for the 1-hour ozone standard, Severe areas were classified as either Severe-15 or Severe-17 based on their design value. See 56 FR 56694 (November 6, 1991).

[3] In EPA's final rule to classify nonattainment areas for the 1997 8-hour ozone standard, Severe areas were classified as either Severe-15 or Severe-17 based on their design value. See 69 FR 23858 (April 30, 2004).

[4] CAA section 182(d)(1)(A) includes three separate elements. Please see the related discussion in our proposed rule withdrawing our previous approvals of the South Coast VMT emissions offset demonstrations and disapproving the same at 77 FR 58067, at 58068 (September 19, 2012). This proposed action relates only to the first element of CAA section 182(d)(1)(A) (i.e., the VMT emissions offset requirement).

[5] Letter from Elaine Chang, Deputy Executive Officer, SCAQMD, dated September 10, 2008.

over-year motor vehicle emissions in the South Coast from a base year through the applicable attainment year.[6]

In approving the South Coast VMT emissions offset demonstrations in 2009 and 2012, the EPA applied its then-longstanding interpretation of the VMT emissions offset requirement, first explained in guidance in the General Preamble to Title I of the Clean Air Act (see 57 FR 13498, at 13521–13523, April 16, 1992), that no transportation control measures are necessary if aggregate motor vehicle emissions are projected to decline each year from the base year of the plan to the attainment year. See 74 FR 10176, at 10179–10180 (March 10, 2009); 76 FR 57872, at 57889 (September 16, 2011). However, in response to a legal challenge brought in the U.S. Court of Appeals for the Ninth Circuit, the Court ruled against the EPA's approval of the South Coast VMT emissions offset demonstration for the 1-hour ozone standard, determining that the EPA incorrectly interpreted the statutory phrase ''growth in emissions'' in section 182(d)(1)(A) as meaning a growth in ''aggregate motor vehicle emissions'' versus a growth solely from VMT. Essentially, the Court ruled that additional transportation control measures are required whenever vehicle emissions are projected to be higher than they would have been had VMT not increased, even when aggregate vehicle emissions are actually decreasing. However, the Court acknowledged that ''clean car technology'' advances could result in there being no increase in emissions even in the face of VMT growth, which would then allow VMT to increase without triggering the requirement to adopt offsetting transportation control measures. *Association of Irritated Residents* v. *EPA,* 632 F.3d. 584, at 596–597 (9th cir. 2011), reprinted as amended on January 27, 2012, 686 F.3d 668, further amended February 13, 2012.

Based on this reasoning, the Court remanded the approval of the South Coast VMT emissions offset demonstration for the 1-hour ozone standard back to the EPA for further proceedings consistent with the opinion. In response, we withdrew our approval of the South Coast VMT emissions offset demonstration for the 1-hour ozone standard and disapproved it. See 78 FR 18849 (March 28, 2013). Furthermore, because our approval of the South Coast VMT emissions offset demonstration for the 1997 8-hour ozone standard was predicated on the same rationale as the corresponding South Coast demonstration for the 1-hour ozone standard that was rejected by the Ninth Circuit, we withdrew our approval of the South Coast VMT emissions offset demonstration for the 1997 8-hour ozone standard and disapproved it as well. *Id.*

Specifically, we withdrew our previous approvals of the VMT emissions offset demonstrations and disapproved the same because we found that the submitted VMT emissions offset demonstrations were not consistent with the Court's ruling on the requirements of section 182(d)(1)(A) because they failed to identify, compared to a baseline assuming no VMT growth, the level of ''increased'' emissions, within the overall set of declining aggregate motor vehicle emissions, resulting solely from VMT growth and to show how such relatively higher emissions, compared to what they would have been had VMT held constant, have been offset through adoption and implementation of transportation control strategies and transportation control measures. See 77 FR 58067, at 58070 (September 19, 2012).[7]

II. Submittal of Revised South Coast VMT Emissions Offset Demonstrations

A. 2012 South Coast AQMP and CARB's Technical Supplement

As described above, in March 2013, the EPA finalized the withdrawal of its previous approvals of SIP revisions submitted by the State of California to meet the VMT emissions offset requirement under the CAA for the South Coast 1-hour and 1997 8-hour ozone nonattainment areas. See 78 FR 18849 (March 28, 2013). In response, CARB and the SCAQMD (''State'') prepared and adopted revised South Coast VMT emissions offset demonstrations to show compliance with the VMT emissions offset requirement under section 182(d)(1)(A) for the 1-hour and 1997 8-hour ozone standards consistent with the Court's opinion in the *Association of Irritated Residents* case discussed above.

On February 13, 2013, CARB submitted, as a revision to the California SIP, the *Final 2012 Air Quality Management Plan* (December 2012) (''2012 South Coast AQMP'') for the South Coast Air Basin (''2012 South Coast AQMP''), adopted by SCAQMD on December 21, 2012 and by CARB on January 25, 2013.[8] The revised South Coast VMT emissions offset demonstrations, which are the subject of today's proposed action, are included in the February 13, 2013 SIP revision submittal as appendix VIII, titled ''Vehicle Miles Traveled Emissions Offset Demonstration'' (February 2013), to the 2012 South Coast AQMP. In this document, we are proposing action only on the revised South Coast VMT emissions offset demonstrations contained in appendix VIII of the 2012 South Coast AQMP. The EPA will take action on the other portions of the 2012 South Coast AQMP, including the revised South Coast 1-hour ozone attainment demonstration found in appendix VII to 2012 South Coast AQMP, in separate rulemakings.

The revised South Coast VMT emissions offset demonstrations address the requirement under CAA section 182(d)(1)(A) for a state with ozone nonattainment areas classified as ''Severe'' or ''Extreme'' to identify and adopt specific enforceable transportation control strategies and transportation control measures to offset any growth in emissions from growth in VMT or the numbers of vehicle trips. The demonstrations include analyses for the 1-hour ozone and 1997 8-hour ozone standards.

On April 3, 2014, CARB submitted a technical supplement to the revised South Coast VMT emissions offset demonstration submitted on February 13, 2013 (''technical supplement''). See letter and enclosures from Lynn Terry, Deputy Executive Officer, CARB, to Deborah Jordan, Director, Air Division, EPA Region 9. CARB's technical supplement includes a revised set of motor vehicle emissions estimates reflecting technical changes to the inputs used to develop the original set of calculations.[9] While the vehicle

[6] See the SCAQMD's *Final 2007 Air Quality Management Plan* (June 2007) for the South Coast Air Basin, chapter 6, table 6–12.

[7] For a more detailed discussion of the regulatory and SIP submittal history of the South Coast Air Basin 1-hour and 8-hour nonattainment areas with respect to the VMT emissions offset requirement under CAA section 182(d)(1)(A), the South Coast VMT emissions offset demonstrations, the related EPA actions, and the ensuing litigation and Court decision, please see our rule proposing to disapprove our previous approvals of the South Coast emissions offset demonstrations and disapproval of the same at 77 FR 58067, at 58068–58070 (September 19, 2012).

[8] See CARB Resolution 13–3 (January 25, 2013) and letter from James N. Goldstene, Executive Officer, CARB, to Jared Blumenfeld, Regional Administrator, EPA Region 9, letter with enclosures (February 13, 2013).

[9] The principal difference between the two sets of calculations is that CARB's technical supplement includes running exhaust, start exhaust, hot soak, and running loss emissions of VOCs in all of the emissions scenarios. These processes are directly related to VMT and vehicle trips. The revised calculation excludes diurnal and resting loss emissions of VOCs from all of the emissions scenarios because such evaporative emissions are related to vehicle population rather than to VMT or vehicle trips.

emissions estimates in CARB's technical supplement differ from those contained in the demonstration as submitted on February 13, 2013, the conclusions of the analysis remain the same.

B. CAA Procedural Requirements for Submittals of SIPs and SIP Revisions

CAA section 110(a)(1) and (2) and CAA section 110(l) require a state to provide reasonable public notice and opportunity for public hearing prior to the adoption and submission of a SIP or SIP revision. To meet this requirement, every SIP submittal should include evidence that adequate public notice was given and an opportunity for a public hearing was provided consistent with the EPA's implementing regulations in 40 CFR 51.102.

CARB and the District have satisfied applicable statutory and regulatory requirements for reasonable public notice and hearing prior to adoption and submittal of the 2012 South Coast AQMP, which as noted above, included the revised South Coast VMT emissions offset demonstrations as appendix VIII to the plan. The District provided a public comment period and held a public hearing prior to the adoption of the 2012 South Coast AQMP on December 7, 2012.[10] CARB provided the required public notice and opportunity for public comment prior to its January 25, 2013 public hearing on the plan.[11]

The SIP submittal includes notices of the District and CARB public hearings as evidence that all hearings were properly noticed. We therefore find that the submittals meet the procedural requirements of CAA sections 110(a) and 110(l).

III. Evaluation of Revised South Coast VMT Emissions Offset Demonstrations

A. Section 182(d)(1)(A) and the EPA's August 2012 VMT Emissions Offset Demonstration Guidance

As noted previously, the first element of CAA section 182(d)(1)(A) requires that areas classified as ''Severe'' or ''Extreme'' submit a SIP revision that identifies and adopts transportation control strategies and transportation control measures sufficient to offset any growth in emissions from growth in VMT or the number of vehicle trips. In response to the Court's decision in *Association of Irritated Residents* v. *EPA,* also discussed above, the EPA issued a memorandum titled *Guidance on Implementing Clean Air Act Section 182(d)(1)(A): Transportation Control Measures and Transportation Control Strategies to Offset Growth in Emissions Due to Growth in Vehicle Miles Travelled* (herein referred to as the ''August 2012 guidance'').[12]

The August 2012 Guidance discusses the meaning of the terms, ''transportation control strategies'' (TCSs) and ''transportation control measures'' (TCMs), and recommends that both TCSs and TCMs be included in the calculations made for the purpose of determining the degree to which any hypothetical growth in emissions due to growth in VMT should be offset. Generally, TCSs is a broad term that encompasses many types of controls including, for example, motor vehicle emission limitations, inspection and maintenance (I/M) programs, alternative fuel programs, other technology-based measures, and TCMs, that would fit within the regulatory definition of ''control strategy.'' See, e.g., 40 CFR 51.100(n). TCMs are defined at 40 CFR 51.100(r) as meaning ''any measure that is directed toward reducing emissions of air pollutants from transportation sources. Such measures include, but are not limited to those listed in section 108(f) of the Clean Air Act[,]'' and generally refer to programs intended to reduce the VMT, the number of vehicle trips, or traffic congestion, such as programs for improved public transit, designation of certain lanes for passenger buses and high-occupancy vehicles (HOVs), trip reduction ordinances, and the like.

The August 2012 guidance explains how states may demonstrate that the VMT emissions offset requirement is satisfied in conformance with the Court's ruling. States are recommended to estimate emissions for the nonattainment area's base year and the attainment year. One emission inventory is developed for the base year, and three different emissions inventory scenarios are developed for the attainment year. For the attainment year, the state would present three emissions estimates, two of which would represent hypothetical emissions scenarios that would provide the basis to identify the ''growth in emissions'' due solely to the growth in VMT, and one that would represent projected actual motor vehicle emissions after fully accounting for projected VMT growth and offsetting emissions reductions obtained by all creditable TCSs and TCMs. See the August 2012 guidance for specific details on how states might conduct the calculations.

The base year on-road VOC emissions should be based on VMT in that year and it should reflect all enforceable TCSs and TCMs in place in the base year. This would include vehicle emissions standards, state and local control programs such as I/M programs or fuel rules, and any additional implemented TCSs and TCMs that were already required by or credited in the SIP as of that base year.

The first of the emissions calculations for the attainment year would be based on the projected VMT and trips for that year, and assume that no new TCSs or TCMs beyond those already credited in the base year inventory have been put in place since the base year. This calculation demonstrates how emissions would hypothetically change if no new TCSs or TCMs were implemented, and VMT and trips were allowed to grow at the projected rate from the base year. This estimate would show the potential for an increase in emissions due solely to growth in VMT and trips. This represents a ''no action'' taken scenario. Emissions in the attainment year in this scenario may be lower than those in the base year due to the fleet that was on the road in the base year gradually being replaced through fleet turnover; however, provided VMT and/or numbers of vehicle trips will in fact increase by the attainment year, they would still likely be higher than they would have been assuming VMT had held constant.

The second of the attainment year's emissions calculations would also assume that no new TCSs or TCMs beyond those already credited have been put in place since the base year, but would also assume that there was no growth in VMT and trips between the base year and attainment year. This estimate reflects the hypothetical emissions level that would have occurred if no further TCMs or TCSs had been put in place and if VMT and trip levels had held constant since the base year. Like the ''no action'' attainment year estimate described above, emissions in the attainment year may be lower than those in the base year due to the fleet that was on the road in the base year gradually being replaced by cleaner vehicles through fleet turnover, but in this case they would not be influenced by any growth in VMT or trips. This emissions estimate would reflect a ceiling on the attainment emissions that should be allowed to occur under the statute as interpreted by the Court because it shows what would happen under a scenario in which no offsetting TCSs or TCMs have yet been

[10] See SCAQMD Governing Board Resolution No. 12–19.

[11] See CARB Board Resolution No. 13–3.

[12] Memorandum from Karl Simon, Director, Transportation and Climate Division, Office of Transportation and Air Quality, to Carl Edland, Director, Multimedia Planning and Permitting Division, EPA Region 6, and Deborah Jordan, Director, Air Division, EPA Region 9, August 30, 2012.

put in place and VMT and trips are held constant during the period from the area's base year to its attainment year. This represents a ''VMT offset ceiling'' scenario. These two hypothetical status quo estimates are necessary steps in identifying the target level of emissions from which states would determine whether further TCMs or TCSs, beyond those that have been adopted and implemented in reality, would need to be adopted and implemented in order to fully offset any increase in emissions due solely to VMT and trips identified in the ''no action'' scenario.

Finally, the state would present the emissions that are actually expected to occur in the area's attainment year after taking into account reductions from all enforceable TCSs and TCMs that in reality were put in place after the baseline year. This estimate would be based on the VMT and trip levels expected to occur in the attainment year (i.e., the VMT and trip levels from the first estimate) and all of the TCSs and TCMs expected to be in place and for which the SIP will take credit in the area's attainment year, including any TCMs and TCSs put in place since the base year. This represents the ''projected actual'' attainment year scenario. If this emissions estimate is less than or equal to the emissions ceiling that was established in the second of the attainment year calculations, the TCSs or TCMs for the attainment year would be sufficient to fully offset the identified hypothetical growth in emissions.

If, instead, the estimated projected actual attainment year emissions are still greater than the ceiling which was established in the second of the attainment year emissions calculations, even after accounting for post-baseline year TCSs and TCMs, the state would need to adopt and implement additional TCSs or TCMs to further offset the growth in emissions and bring the actual emissions down to at least the ''had VMT and trips held constant'' ceiling estimated in the second of the attainment year calculations, in order to meet the VMT offset requirement of section 182(d)(1)(A) as interpreted by the Court.

B. Revised South Coast VMT Emissions Offset Demonstrations

For the revised South Coast VMT emissions offset demonstrations, the State used EMFAC2011, the latest EPA-approved motor vehicle emissions model for California.[13] The EMFAC2011 model estimates the on-road emissions from two combustion processes (i.e., running exhaust and start exhaust) and four evaporative processes (i.e., hot soak, running losses, diurnal losses, and resting losses). The EMFAC2011 model combines trip-based VMT data from the regional transportation planning agencies (i.e., Southern California Association of Governments), starts data based on household travel surveys, and vehicle population data from the California Department of Motor Vehicles. These sets of data are combined with corresponding emission rates to calculate emissions.

Emissions from running exhaust, start exhaust, hot soak, and running losses are a function of how much a vehicle is driven. As such, emissions from these processes are directly related to VMT and vehicle trips, and the State included emissions from them in the calculations that provide the basis for the revised South Coast VMT emissions offset demonstrations. The State did not include emissions from resting loss and diurnal loss processes in the analysis because such emissions are related to vehicle population, not to VMT or vehicle trips, and thus are not part of ''any growth in emissions from growth in vehicle miles traveled or numbers of vehicle trips in such area'' (emphasis added) under CAA section 182(d)(1)(A).

The revised South Coast VMT emissions offset demonstrations address both the 1-hour ozone standard and the 1997 8-hour ozone standard and include two different ''base year'' scenarios: 1990, for the purposes of the VMT emissions offset demonstration for the 1-hour ozone standard, and 2002, for the purposes of the VMT emissions offset demonstration for the 1997 8-hour ozone standard. The ''base year'' for VMT emissions offset demonstration purposes should generally be the same ''base year'' used for nonattainment planning purposes. In 2012, the EPA approved the 2002 base year inventory for the South Coast for the purposes of the 1997 8-hour ozone standard, 77 FR 12674, at 12693 (March 1, 2012), and thus, the State's selection of 2002 as the base year for the revised South Coast VMT emissions offset demonstration for the 1997 8-hour ozone standard is appropriate. With respect to the 1-hour ozone standard, the revised South Coast attainment demonstration, submitted to the EPA on February 13, 2013, relies on a base year of 2008, rather than 1990; however, the State's selection of 1990 as the base year for the VMT offset demonstration is appropriate because 1990 was used as the base year for 1-hour ozone SIP planning purposes under the CAA Amendments of 1990, which established, among other requirements, the VMT emissions offset requirement in section 182(d)(1)(A).

The demonstrations also include the previously described three different attainment year scenarios (i.e., no action, VMT offset ceiling, and projected actual) but the attainment year differs between the two demonstrations. Year 2022 was selected as the attainment year for the revised VMT emissions offset demonstration for the 1-hour ozone standard, and year 2023 was selected as the attainment year for the revised demonstration for the 1997 8-hour ozone standard. For the 1997 8-hour ozone standard, the State's selection of 2023 is appropriate given that the approved South Coast 1997 8-hour ozone plan demonstrates attainment by the applicable attainment date of June 15, 2024 based on the 2023 controlled emissions inventory. See 76 FR 57872, at 57885 (September 16, 2011) and 77 FR 12674, at 12693 (March 1, 2012).

For the 1-hour ozone standard, in 2013, the EPA found the California SIP for the South Coast to be substantially inadequate to comply with the obligation to adopt and implement a plan providing for attainment of the 1-hour ozone standard. 78 FR 889 (January 7, 2013). Under this ''SIP call,'' effective February 6, 2013, the State was required to develop a revised South Coast plan demonstrating attainment of the 1-hour ozone standard as expeditiously as practicable, but no later than five years from the effective date of the SIP call, or, in this case, no later than February 6, 2018, unless the State can demonstrate that it needs up to an additional five years, i.e., up to February 6, 2023, to attain the standard in light of the severity of the nonattainment problem and the availability and feasibility of control measures.

The revised South Coast 1-hour ozone attainment demonstration, which was submitted along with the revised VMT emissions offset demonstrations and the rest of the 2012 South Coast AQMP on February 13, 2013, provides a justification for the full five years beyond the statutory five-year attainment date. The revised South Coast 1-hour ozone attainment demonstration thus provides a demonstration of attainment of the 1-hour ozone standard in the South Coast by 2023 based on the controlled 2022 emissions inventory. In a separate rulemaking action published elsewhere

[13] See 78 FR 14533 (March 6, 2013) regarding the EPA's approval of the 2011 version of the California EMFAC model (short for EMissionFACtor) and announcement of its availability. The software and detailed information on the EMFAC vehicle emission model can be found on the following CARB Web site: *http://www.arb.ca.gov/msei/msei.htm*.

in today's **Federal Register**, EPA is proposing to approve 2022 as the attainment year for the 1-hour ozone standard in the South Coast.[14] Based on the proposed approval of 2022 as the attainment year for the South Coast for the 1-hour ozone standard, we find CARB's selection of Year 2022 as the attainment year for the revised VMT emissions offset demonstration for the 1-hour ozone standard to be acceptable. For additional background and justification regarding the 2022 attainment year, please see the separate rulemaking action published elsewhere in today's **Federal Register**.

Tables 1 and 2 summarize the relevant distinguishing parameters for each of the emissions scenarios and show the State's corresponding VOC emissions estimates. Table 1 provides the parameters and emissions estimates for the revised VMT emissions offset demonstration for the 1-hour ozone standard, and table 2 provides the corresponding values for the revised demonstration for the 1997 8-hour ozone standard.

TABLE 1—VMT EMISSIONS OFFSET INVENTORY SCENARIOS AND RESULTS FOR 1-HOUR OZONE STANDARD

Scenario	VMT		Starts		Controls	VOC emissions
	Year	1000/day	Year	1000/day	Year	tpd
Base Year	1990	257,490	1990	46,060	1990	873
No Action	2022	394,838	2022	72,531	1990	488
VMT Offset Ceiling	1990	257,490	1990	46,060	1990	312
Projected Actual	2022	394,838	2022	72,531	2022	65

Source: CARB's Technical Supplement, April 3, 2014.

TABLE 2—VMT EMISSIONS OFFSET INVENTORY SCENARIOS AND RESULTS FOR 1997 8-HOUR OZONE STANDARD

Scenario	VMT		Starts		Controls	VOC emissions
	Year	1000/day	Year	1000/day	Year	tpd
Base Year	2002	330,268	2002	58,039	2002	280
No Action	2023	395,750	2023	72,730	2002	115
VMT Offset Ceiling	2002	330,268	2002	58,039	2002	89
Projected Actual	2023	395,750	2023	72,730	2023	62

Source: CARB's Technical Supplement, April 3, 2014.

For the two ''base year'' scenarios, the State ran the EMFAC2011 model for the applicable base year (i.e., 1990 for the 1-hour ozone standard and 2002 for the 1997 8-hour ozone standard) using VMT and starts data corresponding to those years. As shown in tables 1 and 2, the State estimates South Coast VOC emissions at 873 tons per day (tpd) in 1990 and 280 tpd in 2002.

For the two ''no action'' scenarios, the State first identified the on-road motor vehicle control programs (i.e., TCSs or TCMs) put in place since the base years and incorporated into EMFAC2011 and then ran EMFAC2011 with the VMT and starts data corresponding to the applicable attainment year (i.e., 2022 for the 1-hour ozone standard and 2023 for the 1997 8-hour ozone standard) without the emissions reductions from the on-road motor vehicle control programs put in place after the base year. Thus, the ''no action'' scenarios reflect the hypothetical VOC emissions that would occur in the attainment years in the South Coast if the State had not put in place any additional TCSs or TCMs after 1990 (for the 1-hour ozone VMT emissions offset demonstration) or after 2002 (for the 8-hour ozone demonstration). As shown in tables 1 and 2, the State estimates ''no action'' South Coast VOC emissions at 488 tons per day (tpd) in 2022 and 115 tpd in 2023. The principal difference between the two estimates is that the latter value (used for the revised VMT emissions offset demonstration for the 8-hour ozone standard) reflects the emissions reductions from TCSs and TCMs put in place by the end of 2002 whereas the former value (used for the revised demonstration for the 1-hour ozone standard) reflects only the emissions reductions from TCSs and TCMs put in place by the end of 1990. The most significant of the measures adopted since 1990 and relied upon for the 1-hour ozone VMT emissions offset demonstration include tiered (series of increasingly stringent limits) emissions standards for new motor vehicles (i.e., Low Emissions Vehicles I, II, and III standards), content specifications for gasoline (i.e., California Reformulated Gasoline Phases 1, 2, and 3), and enhancements to the State's I/M program (i.e., Smog Check II). See attachments 1 and 2 of Appendix VIII to the 2012 South Coast AQMP (i.e., the revised South Coast VMT emissions offset demonstrations) for the entire list of TCSs and TCMs adopted by the State since 1990.[15]

For the ''VMT offset ceiling'' scenarios, the State ran the EMFAC2011 model for the attainment years but with VMT and starts data corresponding to base year values. Like the ''no action'' scenarios, the EMFAC2011 model was adjusted to reflect the VOC emissions levels in the attainment years without the benefits of the post-base-year on-road motor vehicle control programs. Thus, the ''VMT offset ceiling'' scenarios reflect hypothetical VOC emissions in the South Coast if the State had not put in place any TCSs or TCMs after the base years and if there had been no growth in VMT or vehicle trips between the base years and the attainment years.

[14] In this context, ''attainment year'' refers to the ozone season immediately preceding a nonattainment area's attainment date. In the case of the South Coast for the 1-hour ozone standard, the proposed applicable attainment date is February 6, 2023, and the ozone season immediately preceding that date will occur in year 2022.

[15] The docket for today's action includes an updated list of the post-1990 transportation control strategies in attachment 1 of Appendix VIII to the South Coast AQMP.

The hypothetical growth in emissions due to growth in VMT and trips can be determined from the difference between the VOC emissions estimates under the ''no action'' scenarios and the corresponding estimates under the ''VMT offset ceiling'' scenarios. Based on the values in tables 1 and 2, the hypothetical growth in emissions due to growth in VMT and trips in the South Coast would have been 176 tpd (i.e., 488 tpd minus 312 tpd) for the purposes of the revised VMT emissions offset demonstration for the 1-hour ozone standard, and 26 tpd (i.e., 115 tpd minus 89 tpd) for the purposes of the corresponding demonstration for the 8-hour ozone standard. These hypothetical differences establish the levels of VMT growth-caused emissions that need to be offset by the combination of post-baseline year TCMs and TCSs and any necessary additional TCMs and TCSs.

For the ''projected actual'' scenario calculations, the State ran the EMFAC2011 model for the attainment years with VMT and starts data at attainment year values and with the full benefits of the relevant post-baseline year motor vehicle control programs. For this scenario, the State included the emissions benefits from TCSs and TCMs put in place since the base year. The most significant measures put in place during the 2002 to 2023 time frame, relied upon for the 8-hour ozone demonstration, include Low Emission Vehicles II and III standards, Zero Emissions Vehicle standards, and California Reformulated Gasoline Phase 3. Again, see attachments 1 and 2 of the Appendix VIII to the 2012 South Coast AQMP. These measures are also relied upon in the approved South Coast 8-hour ozone attainment demonstration and the revised South Coast 1-hour ozone attainment demonstration.[16]

As shown in tables 1 and 2, the results from these calculations establish projected actual attainment-year VOC emissions of 65 tpd for the 1-hour standard demonstration and 62 tpd for the 1997 8-hour standard demonstration. The State then compared these values against the corresponding VMT offset ceiling values to determine whether additional TCMs or TCSs would need to be adopted and implemented in order to offset any increase in emissions due solely to VMT and trips. Because the ''projected actual'' emissions are less than the corresponding ''VMT Offset Ceiling'' emissions, the State concluded that the demonstration shows compliance with the VMT emissions offset requirement and that there are sufficient adopted TCSs and TCMs to offset the growth in emissions from the growth in VMT and vehicle trips in the South Coast for both the 1-hour and 1997 8-hour standards. In fact, taking into account of the creditable post-baseline year TCMs and TCSs, the State showed that they offset the hypothetical differences by 423 tpd for the 1-hour standard and by 53 tpd for the 1997 8-hour standards, rather than merely the required 176 tpd and 26 tpd, respectively.[17]

Based on our review of the State's submittal, including the technical supplement, we find the State's analysis to be acceptable and agree that the State has adopted sufficient TCSs and TCMs to offset the growth in emissions from growth in VMT and vehicle trips in the South Coast for the purposes of the 1-hour ozone and 1997 8-hour ozone standard. As such, we find that the revised South Coast VMT emissions offset demonstrations, comply with the VMT emissions offset requirement in CAA section 182(d)(1)(A), and therefore, we propose approval of the revised South Coast VMT emissions offset demonstrations for the 1-hour ozone and 1997 8-hour ozone standards as a revision to the California SIP.

IV. EPA's Proposed Action and Request for Public Comment

Under CAA section 110(k)(3), and for the reasons set forth above, EPA is proposing to approve CARB's submittal dated February 13, 2013 of the revised South Coast VMT emissions offset demonstrations for the 1-hour ozone and 1997 8-hour ozone standards, as supplemented by CARB on April 3, 2014, as a revision to the California SIP. We are proposing to approve this SIP revision because we believe that it demonstrates that California has put in place specific enforceable transportation control strategies and transportation control measures to offset the growth in emissions from the growth in VMT and vehicle trips in the South Coast for both the 1-hour ozone and 1997 8-hour ozone standards, and thereby meets the applicable requirements in section 182(d)(1)(A) of the Clean Air Act.

EPA is soliciting public comments on the issues discussed in this document or on other relevant matters. We will accept comments from the public on this proposal for the next 30 days. We will consider these comments before taking final action.

V. Statutory and Executive Order Reviews

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

[16] See 77 FR 12674 (March 1, 2012) for the EPA's approval or waiver/authorization of the TCSs and TCMs relied upon for the 1997 8-hour ozone attainment demonstration in the 2007 South Coast AQMP. Also see *Technical Support Document for the Final Rulemaking Action on the South Coast 2007 8-Hour Ozone Plan and the South Coast Portions of the Revised 2007 State Strategy,* USEPA Region 9, December 2011. Also see footnote 15. Per section 209 of the CAA, the EPA has previously waived (for control of emissions from new motor vehicles of new motor vehicle engines prior to March 30, 1966) or authorized (for control emissions of nonroad engines or vehicles) all such TCSs and TCMs.

[17] The offsetting VOC emissions reductions from the TCSs and TCMs put in place after the respective base year can be determined by subtracting the ''projected actual'' emissions estimates from the ''no action'' emissions estimates in tables 1 and 2. For the purposes of the 1-hour ozone demonstration, the offsetting emissions reductions, 423 tpd (488 tpd minus 65 tpd), exceed the growth in emissions from growth in VMT and vehicle trips (176 tpd). For the purposes of the 8-hour ozone demonstration, the offsetting emissions reductions, 53 tpd (115 tpd minus 62 tpd), exceed the growth in emissions from growth in VMT and vehicle trips (26 tpd).

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

List of Subjects in 40 CFR Part 52

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

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

Dated: May 5, 2014.

Jared Blumenfeld,

Regional Administrator, EPA Region 9.

[FR Doc. 2014–11511 Filed 5–22–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2014–0185; FRL–9911–03–Region 9]

Approval and Promulgation of Implementation Plans; California; South Coast 1-Hour and 8-Hour Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the portions of a State implementation plan (SIP) revision submitted by the State of California on February 13, 2013 that relate to attainment of the 1-hour and 1997 8-hour ozone national ambient air quality standards in the Los Angeles-South Coast area. Specifically, the EPA is proposing to approve the portions of the South Coast Air Quality Management District's *Final 2012 Air Quality Management Plan* that update the approved control strategy for the 1997 8-hour ozone standard and that provide a demonstration of attainment of the 1-hour ozone standard by December 31, 2022. In proposing approval, EPA finds that an attainment date of December 31, 2022 is appropriate in light of the severity of the 1-hour ozone problem in the South Coast and, given the extent to which emissions sources in the South Coast have already been controlled, the limited emissions remaining that can be regulated. EPA is proposing as part of this action to approve new commitments adopted by the South Coast Air Quality Management District, updated new technology measures, and a new commitment by the California Air Resources Board to submit contingency measures in 2019 as necessary to meet the emissions reductions targets for 2022 from implementation of new technology measures.

DATES: Any comments must arrive by June 23, 2014.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2014–0185, by one of the following methods:

• *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.

• *Email: tax.wienke@epa.gov.*

• *Mail or deliver:* Wienke Tax, Office of Air Planning (AIR–2), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Instructions: All comments 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comments due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: The index to the docket for this action is available electronically on the *www.regulations.gov* Web site and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material or large maps), and some may not be publicly available at either location (e.g., 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 below.

FOR FURTHER INFORMATION CONTACT: Wienke Tax, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX, (415) 947–4192, *tax.wienke@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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I. Background

Ground-level ozone is an oxidant that is formed from photochemical reactions in the atmosphere between volatile organic compounds (VOC) and oxides of nitrogen (NO_X) in the presence of sunlight. These two pollutants, referred to as ozone precursors, are emitted by many types of pollution sources including on-road motor vehicles (cars, trucks, and buses), nonroad vehicles and engines, power plants and industrial facilities, and smaller area sources such as lawn and garden equipment and paints.

Under section 109 of the Clean Air Act (CAA or Act), EPA promulgates national ambient air quality standards (NAAQS or standards) for pervasive air pollutants, such as ozone. The NAAQS are concentration levels that, the attainment and maintenance of which, EPA has determined to be requisite to protect public health and welfare. In 1979, EPA established the 1-hour ozone NAAQS of 0.12 parts per million (ppm).[1] Section 110 of the CAA requires States to develop and submit state implementation plans (SIPs) to implement, maintain, and enforce the NAAQS.

Under the Clean Air Act, as amended in 1977, EPA designated all areas of the country as ''nonattainment,'' ''attainment,'' or ''unclassifiable'' with respect to each NAAQS, and in so doing, designated the South Coast[2] as a nonattainment area for photochemical oxidant (later ozone). *See* 43 FR 8962 (March 3, 1978). States with nonattainment areas are required to submit revisions to their SIPs that include a control strategy necessary to demonstrate how the area will attain the NAAQS, and EPA took action on a number of related SIP revisions submitted by the California Air Resources Board (CARB) in the late 1970s and 1980s for the South Coast 1-hour ozone nonattainment area.[3] However, by 1990, like many other areas throughout the country, the South Coast had not attained the 1-hour ozone standard, and under the CAA Amendments of 1990, the South Coast was classified as an ''extreme'' nonattainment area for the 1-hour ozone standard with an attainment deadline of November 15, 2010 (56 FR 56694, November 6, 1991) and was subject to additional SIP planning requirements, including a revised attainment demonstration.

In the wake of the classification of the South Coast nonattainment area as ''extreme'' for the 1-hour ozone standard, CARB submitted a number of SIP revisions for the South Coast that contained attainment demonstrations for the 1-hour ozone standard and that relied on a combination of mobile source control measures adopted by CARB and stationary source control measures adopted by South Coast Air Quality Management District (SCAQMD). In connection with these submittals, EPA took the following actions:

- 1994 South Coast Air Quality Management Plan (AQMP) and related state strategy (''1994 AQMP'')—EPA approved the 1-hour ozone attainment demonstration at 62 FR 1150 (January 8, 1997);
- 1997 AQMP, as revised in 1999 (''1997/1999 AQMP'')—EPA approved the revised 1-hour ozone demonstration at 65 FR 18903 (April 10, 2000); and
- 2003 AQMP and related state strategy (''2003 AQMP'')—EPA disapproved the revised 1-hour ozone attainment demonstration at 74 FR 10176 (March 10, 2009).

Each of these plans rely on a regulatory foundation of regulations adopted and implemented by the SCAQMD, CARB, and EPA for stationary and mobile sources, and also include commitments for new or more stringent regulations to achieve additional emissions reductions necessary for attainment. Each subsequent ozone plan then builds upon the foundation of the new or strengthened regulations that were adopted to support the previous plan. While the emissions reduction measures implemented under these South Coast ozone plans have been successful in reducing ozone concentrations in the South Coast,[4] the South Coast failed to attain the 1-hour ozone standard by the applicable attainment date of 2010.[5]

Meanwhile, in 1997, EPA revised the NAAQS for ozone, setting it at 0.08 ppm averaged over an 8-hour timeframe (referred to herein as the ''1997 8-hour ozone standard'') to replace the existing 1-hour ozone standard of 0.12 ppm.[6] [7] In 2004, EPA designated and classified the South Coast area as a ''severe-17'' nonattainment area for the 1997 8-hour ozone standard but later granted CARB's request to reclassify the South Coast to ''extreme'' for the 1997 8-hour ozone standard.[8] The corresponding applicable attainment year for the 1997 8-hour ozone standard in the South Coast is 2023. In response to this designation, CARB submitted the 2007 South Coast AQMP and related 2007 State Strategy (''2007 AQMP''), and EPA took the following action:

- 2007 AQMP and 2007 State Strategy, as amended in 2009 and 2011—EPA approved the attainment demonstration for the 1997 8-hour ozone standard at 77 FR 12674 (March 1, 2012), amended at 77 FR 70707 (November 27, 2012).

The 8-hour ozone control strategy in the 2007 AQMP builds upon the control strategy established under the previous 1-hour ozone plans. In connection with EPA's 2012 approval of the South Coast attainment demonstration for the 1997 8-hour ozone standard in the 2007 AQMP, EPA approved a number of commitments by CARB and the SCAQMD as part of the California SIP, including commitments to bring certain defined measures before their respective boards by certain dates, commitments to achieve certain aggregate emissions reductions by certain milestone years, and a commitment to achieve emissions reductions from development and implementation of advanced control technologies under CAA section 182(e)(5). Of particular relevance for this proposed action, EPA approved CARB's commitment to achieve aggregate emissions reductions (beyond those already accounted for in the baseline) of 52 tons per day (tpd) of VOC and 144 tpd of NO_X in the South Coast by 2020, and CARB's commitment under section 182(e)(5) to achieve an additional 40 tpd of VOC and 241 tpd of NO_X in the South Coast by 2023.

As noted above, the last South Coast 1-hour ozone attainment demonstration on which EPA took action was the one included in the 2003 AQMP. The 2003 AQMP revised the 1-hour ozone attainment demonstration approved as part of the 1997/1999 AQMP in light of new modeling results that showed that the approved strategy from the 1997/1999 AQMP would not provide for attainment of the 1-hour ozone standard by the 2010 attainment deadline.

[1] See 44 FR 8202 (February 8, 1979).

[2] The South Coast includes Orange County, the southwestern two-thirds of Los Angeles County, southwestern San Bernardino County, and western Riverside County (see 40 CFR 81.305).

[3] Under California law, CARB is the state agency that is responsible for submitting SIPs and SIP revisions to EPA. CARB is also responsible for the regulation of mobile sources in California. Regional air quality management districts, such as the South Coast Air Quality Management District (SCAQMD or ''District''), are responsible for developing and adopting regional air quality plans and for regulating stationary sources. Once adopted, the plans developed by the regional air quality management districts are submitted to CARB for adoption as part of the California SIP and then submitted to EPA for approval or disapproval under section 110 of the CAA.

[4] For example, the annual number of days at any one monitoring station during which the 1-hour ozone standard was exceeded decreased from 103 days to 6 days between 1990 and 2010 despite significant increases in population, employment and vehicle travel. The maximum 1-hour ozone concentration measured in the South Coast decreased from 0.33 ppm to 0.14 ppm over the same period.

[5] 76 FR 82133 (December 30, 2011).

[6] 62 FR 33856 (July 18, 1997).

[7] On March 27, 2008 (73 FR 16436), EPA lowered the 8-hour ozone standard to 0.075 ppm (the 2008 8-hour ozone standard), and on May 21, 2012, EPA designated the South Coast as extreme nonattainment for the 2008 8-hour ozone standard (77 FR 30088). Today's proposed action relates to an attainment demonstration for the 1-hour ozone standard that relies heavily on the control strategy approved for attainment of the 1997 8-hour ozone standard. Attainment demonstrations for the more stringent 2008 8-hour ozone standard are not yet due.

[8] 69 FR 23858 (April 30, 2004); 75 FR 24409 (May 5, 2010).

EPA disapproved the revised 1-hour ozone attainment demonstration in the 2003 AQMP because a number of state control measures upon which the demonstration relied had been withdrawn from consideration. EPA's action on the 2003 AQMP was successfully challenged. In response to the court's decision [9] and in recognition of the fact that the South Coast had in fact failed to attain the 1-hour ozone standard by 2010, EPA issued a ''SIP call'' to California at 78 FR 889 (January 7, 2013) under CAA section 110(k)(5).[10] In our final SIP call, we explained that states remain obligated to adopt and implement an attainment demonstration plan for the 1-hour ozone standard, notwithstanding the revocation of the 1-hour ozone standard in 2005, under EPA's ''anti-backsliding'' regulations governing the transition from the 1-hour ozone standard to the 1997 8-hour ozone standard.[11] See 40 CFR 51.905(a)(1)(i).

Under our SIP call, California was required to submit a SIP revision that meets the requirements of CAA section 182(c)(2)(A) [12] and that demonstrates attainment of the 1-hour ozone standard as expeditiously as practicable but no later than five years from the effective date of the final SIP call, absent justification for a later date, not to exceed 10 years beyond the effective date of the final SIP call. In considering whether a period longer than five years is warranted, EPA must consider the severity of the remaining nonattainment problem in the South Coast and the availability and feasibility of pollution control measures. *See* CAA section 172(a)(2).

The subject of today's proposed action is a SIP revision that was submitted in part to respond to EPA's SIP call for a revised attainment demonstration for the 1-hour ozone standard. As discussed later in this document, the submitted 1-hour ozone attainment demonstration relies heavily on the approved control strategy for the 1997 8-hour ozone standard that is discussed above in connection with EPA's approval of the 2007 AQMP.

II. EPA's Review of California's Submittal

On December 7, 2012, SCAQMD adopted the *Final 2012 Air Quality Management Plan* (''2012 AQMP''), and later forwarded it to CARB for approval and submittal to EPA. The 2012 AQMP updates the approved 1997 8-hour ozone control strategy, includes attainment demonstrations for the 1-hour ozone standard and the 2006 $PM_{2.5}$ standard, and includes demonstrations intended to address the vehicle-miles-traveled emissions offset requirements of CAA section 182(d)(1)(A) [13] for the 1-hour ozone and 1997 8-hour ozone standards. With respect to the 1997 8-hour ozone standard, in adopting the 2012 AQMP, the SCAQMD indicated that, while the 2012 AQMP updates the approved 1997 8-hour ozone control strategy with new measures designed to reduce reliance on CAA section 182(e)(5) long-term (i.e., advanced control technologies) measures for VOC and NO_X reductions, it is not intended as an update to other elements of the approved 8-hour ozone control plan.[14]

On January 25, 2013, CARB adopted the 2012 AQMP as a revision to the California SIP. On February 13, 2013, CARB submitted the 2012 AQMP to EPA along with the relevant CARB and SCAQMD board resolutions and other supporting material. In adopting the 2012 AQMP, CARB committed to develop, adopt, and submit contingency measures by 2019 if advanced control technology measures do not achieve planned reductions as required by CAA section 182(e)(5).[15] As noted above, the 2012 AQMP contains a number of SIP elements for a number of pollutants. Today, we are proposing action on the portions of the 2012 AQMP that update the approved 1997 8-hour ozone control strategy from the 2007 AQMP and that provide an attainment demonstration for the 1-hour ozone standard. Specifically, the relevant elements of the 2012 AQMP covered by our proposed action include:

- CARB's resolution of adoption (Resolution 13–3);
- SCAQMD's resolution of adoption (Resolution 12–19);
- The ozone-related portions of chapter 4 of the 2012 AQMP (''Control Strategy and Implementation'');
- Appendices IV–A (''District's Stationary Source Control Measures''), IV–B (''Proposed Section 182(e)(5) Implementation Measures''), and IV–C (''Regional Transportation Strategy and Control Measures''); and
- Appendix VII (''South Coast 2012 1-hour ozone attainment demonstration''), which includes 4 attachments, one of which includes a demonstration of reasonably available control measures (RACM).

In addition, EPA requested clarification of the commitments made by SCAQMD and CARB in connection with the 1-hour ozone attainment demonstration in the 2012 AQMP, and the two agencies responded with the following letters clarifying their respective commitments:

- Letter from Barry R. Wallerstein, D.Env, SCAQMD Executive Officer, to Jared Blumenfeld, Regional Administrator, EPA Region IX, May 1, 2014 (''Wallerstein Letter''); and
- Letter from Richard W. Corey, Executive Officer, CARB, to Jared Blumenfeld, Regional Administrator, EPA Region IX, May 2, 2014 (''Corey Letter'').

For simplicity, in referring to the elements on which we are acting, we are using the term ''2012 AQMP'' even though we recognize that the 2012 AQMP includes other elements in addition to those covered in this proposed action.

The 1-hour ozone attainment demonstration includes base year and future year emissions inventory estimates, a control strategy and RACM demonstrations, and an attainment demonstration based on photochemical modeling. The control strategy for the revised 1-hour ozone demonstration relies on the same SCAQMD measures referred to by SCAQMD as new measures that update the approved 1997 8-hour ozone control strategy.

A. CAA Procedural and Administrative Requirements for SIP Submittals

CAA sections 110(a)(1) and (2) and 110(l) require a state to provide reasonable public notice and opportunity for public hearing prior to

[9] *See Association of Irritated Residents* v. *EPA,* 632 F.3d 584 (9th Cir. 2011), reprinted as amended on January 27, 2012, 686 F.3d 668, further amended February 13, 2012.

[10] Section 110(k)(5) provides, in relevant part, that: ''Whenever [EPA] finds that the [SIP] for any area is substantially inadequate to attain or maintain the relevant [NAAQS], . . . , or to otherwise comply with any requirement of this chapter, [EPA] shall require the State to revise the plan as necessary to correct such inadequacies.''

[11] Our finding of substantial inadequacy under CAA section 110(k)(5) for failure to ''adopt and implement'' a 1-hour ozone attainment demonstration is not intended as a finding of nonimplementation under CAA section 179(a)(4).

[12] Under CAA section 182(c)(2)(A), the State must submit a revision to the SIP that includes a demonstration that the plan, as revised, will provide for attainment of the ozone NAAQS. The attainment demonstration must be based on photochemical grid modeling or any other analytical method determined by EPA to be at least as effective. Section 182(c)(2)(A) applies within ozone nonattainment areas classified as ''serious,'' but as a general matter, areas classified as ''extreme'' for the ozone nonattainment area, such as the South Coast, are subject to the requirements for lower-classified areas, such as those for ''serious'' areas, as well as those prescribed specifically for ''extreme'' areas.

[13] Under CAA section 182(d)(1)(A), states with severe or extreme ozone nonattainment areas must submit SIP revisions that identify and adopt specific transportation control strategies and transportation control measures to offset any growth in emissions from growth in vehicle miles traveled or numbers of vehicle trips in such areas.

[14] See SCAQMD Governing Board Resolution No. 12–19 (December 7, 2012).

[15] See CARB Board Resolution No. 13–3 (January 25, 2013).

the adoption and submittal of a SIP or SIP revision. To meet this requirement, every SIP submittal should include evidence that adequate public notice was given and a public hearing was held consistent with EPA's implementing regulations in 40 CFR 51.102.

The SCAQMD provided a public comment period and held a public hearing prior to its December 7, 2012 adoption of the 2012 AQMP. CARB provided the required public notice and opportunity for public comment prior to its January 25, 2013 public hearing on the 2012 AQMP. CARB's February 13, 2013 SIP submittal package includes notices of the SCAQMD and CARB public hearings, as evidence that all hearings were properly noticed. We therefore find that CARB's February 13, 2013 SIP revision submittal meets the procedural requirements of CAA sections 110(a) and 110(l).

B. Attainment Demonstration Requirements

CAA section 182(c)(2)(A) requires states with ozone nonattainment areas classified as serious, severe or extreme to submit plans that demonstrate attainment of the 1-hour ozone standard as expeditiously as practicable but no later than the outside date established in the CAA. The attainment demonstration should include technical analyses that locate and identify sources of emissions that are contributing to violations of the 1-hour ozone standard within the nonattainment area and adopted measures with schedules for implementation and other means and techniques necessary and appropriate for attainment. In order to determine whether the area has demonstrated attainment ''as expeditiously as practicable,'' the area must provide a demonstration that all RACM are implemented. CAA 172(c)(1). In addition, the ''. . . attainment demonstration must be based on photochemical grid modeling or any other analytical method determined by the Administrator . . . to be at least as effective.'' CAA section 182(c)(2)(A).

1. Emissions Inventories

a. Requirements for Emissions Inventories

Attainment demonstrations rely upon emissions inventories that reflect different scenarios, including existing conditions (''base year'') and future ''baseline'' conditions. The base year emission inventory must be a comprehensive, accurate, current inventory of actual emissions from all sources of the relevant pollutant. Future baseline emissions inventories must reflect the most recent population, employment, travel and congestion estimates for the area. In this context, ''baseline'' emissions represent an estimate of the emissions that would occur in an area if no additional controls other than those already adopted are implemented.

b. Base Year and Future Baseline Emissions Inventories in the 2012 AQMP

The 2012 AQMP includes a 2008 base year and a 2022 baseline emissions inventory for the South Coast 1-hour nonattainment area. Documentation for these inventories is found in appendix III (''Base and Future Year Emission Inventory''), and section 3 of appendix VII, of the 2012 AQMP. The 2008 base year ozone precursor inventory provides the basis for the control measure analysis and the attainment demonstration in the South Coast 2012 1-hour ozone attainment demonstration.

VOC and NO_X emissions are grouped into two general categories, stationary sources and mobile sources. Stationary sources can be further divided into ''point'' and ''area'' sources. Point sources typically refer to permitted facilities and have one or more identified and fixed pieces of equipment and emissions points. Permitted facilities are required to report their emissions to the SCAQMD Annual Emissions Reporting Program. Area sources consist of widespread and numerous smaller emission sources, such as small permitted facilities, households, and road dust. The mobile sources category can be divided into two major subcategories, ''on-road'' and ''off-road'' mobile sources. On-road mobile sources include light-duty automobiles, light-, medium-, and heavy-duty trucks, and motorcycles. Off-road mobile sources include aircraft, locomotives, construction equipment, mobile equipment, and recreational vehicles.

The emissions inventories in the 2012 AQMP were developed using data provided by CARB, the California Department of Transportation, and SCAG. These agencies collect data (industry growth factors, socio-economic projections, travel activity levels, emission factors, emission speciation profiles, and emissions) and developing methodologies (for example, model and demographic forecast improvements) used to generate comprehensive emissions inventories. CARB maintains statewide inventories in its California Emissions Inventory Development and Reporting System (CEIDARS) and California Emission Forecasting and Planning Inventory (CEFIS).[16]

Area source inventories are developed by CARB and the District for approximately 400 area source categories. For the 2008 base year inventory, a number of area source category emissions inventories used existing methodologies with updated activity data such as fuel or sales data. Both CARB and the District are continuously updating and improving emissions inventory methodologies; for this plan, five new categories were added to the inventory, other methodologies were refined, and some area source categories were expanded.[17]

CARB prepares on-road and most of the off-road inventories from its Emission FACtor (EMFAC) 2011 model and 2011 In-Use Fleet Off-Road models.[18] Caltrans provides information on highway projects. SCAG uses these data to estimate and project vehicle miles travelled (VMT) and speeds. SCAG also provides socioeconomic projections and projections of transportation activity data for use in on-road inventory development.

Table 1 depicts a summary of the 2008 VOC and NO_X emissions inventory for the South Coast 1-hour ozone nonattainment area as presented in the 2012 AQMP. Emissions estimates in table 1 are broken down by the major source categories described above. Based on the inventory for 2008, stationary and area sources currently account for 40 percent of VOC emissions, and 10 percent of the NO_X emissions, in the South Coast while mobile sources account for 60 percent of the VOC emissions and 90 percent of the NO_X emissions.

[16] See 2012 AQMP, Appendix III.

[17] See 2012 AQMP, Appendix III, pages III–1–5, III–1–11, and III–1–14–15.

[18] EMFAC 2011 was approved by EPA for use in SIPs on March 6, 2013 (see 78 FR 14533).

TABLE 1—SUMMARY OF SOUTH COAST AIR BASIN 2008 VOC AND NO_X EMISSIONS INVENTORY

[Summer planning inventory, tpd]

Source category	VOC	NO_X
Fuel Combustion	14	41
Waste Disposal	12	2
Cleaning and Surface Coatings	43	0
Petroleum Production and Marketing	41	0
Industrial Processes	19	0
Solvent Processes	126	0
Miscellaneous Processes	9	44
Subtotal—Stationary and Area Sources	264	87
On-road Vehicles	213	426
Off-road Vehicles	162	208
Subtotal—Mobile Sources	375	634
Total—South Coast	639	721

Source: 2012 AQMP, appendix VII, table VII–3–1.

Table 2 presents a summary of future baseline emissions in the South Coast in 2022. In this instance, future baseline emissions reflect SCAQMD regulations adopted as of June 2012 and CARB rules adopted by August 2011 [19] as well as the latest forecasts of growth in population, employment, and vehicle travel. Generally, EPA will approve a State plan that takes emissions reduction credit for a control measure only where EPA has approved the measure as part of the SIP, or in the case of certain on-road and nonroad (or ''off-road'') measures, where EPA has issued the related waiver of preemption or authorization under CAA section 209(b) or section 209(e). Thus, to take credit for the emissions reductions from newly-adopted or amended SCAQMD rules for stationary sources, the related rules must be approved by EPA into the SIP.

Table 3 lists the SCAQMD regulations for which specific emissions reduction credit was taken in the future baseline emissions estimates for the 2012 AQMP. See 2012 AQMP, appendix III, table III–2–2B. As shown in table 3, EPA has approved all of these regulations into the SIP. Most of these regulations have been amended a number of times by SCAQMD, and, with three exceptions, EPA has approved the most recently amended versions of the regulations into the SIP. As to the three exceptions (Rules 1146, 1146.1, and 1147), EPA anticipates taking final action on the most recently amended versions of the regulations prior to taking final action on the revised 1-hour ozone attainment demonstration.

With respect to mobile sources, we have placed a table in the docket that shows, among other things, the CARB regulations adopted through August 2011. In general, CARB regulations adopted through August 2011 and included in the future baseline are approved into the SIP, waived or authorized and thus emissions reduction credit for them in the future baseline is warranted. For example, EPA approved CARB's Truck and Bus Rule at 77 FR 20308 (April 4, 2012); EPA authorized CARB's Cleaner In-Use Off-Road Equipment Regulation at 78 FR 58090 (September 20, 2013); EPA authorized CARB's At-Berth Regulation, which reduces emissions from diesel auxiliary engines on contained ships, passenger ships and refrigerated cargo ships while berthing at a California port, at 76 FR 77515 (December 13, 2011); and EPA waived preemption for CARB's Truck Idling Regulation at 77 FR 9239 (February 16, 2012). EPA is anticipating final action on CARB's amended Consumer Products Regulation prior to taking final action on the revised 1-hour ozone attainment demonstration.

TABLE 2—SUMMARY OF SOUTH COAST AIR BASIN 2022 VOC AND NO_X EMISSIONS INVENTORY

[Summer planning inventory, tpd]

Source category	VOC	NO_X
Fuel Combustion	14	28
Waste Disposal	14	2
Cleaning and Surface Coatings	55	0
Petroleum Production and Marketing	36	0
Industrial Processes	17	0
Solvent Processes	112	0
Miscellaneous Processes	9	40
Subtotal—Stationary and Area Sources	258	70
On-road Vehicles	73	131
Off-road Vehicles	109	137
Subtotal—Mobile Sources	182	267
Total—South Coast	440	337

Source: Interpolated for year 2022 from 2012 AQMP, Appendix III, tables B–4 and B–5.

[19] See 2012 AQMP, Appendix III, page III–1–1.

Emissions in table 2 are also broken down by the major source categories described above. A comparison between future baseline emissions in table 2 with the corresponding base year (2008) emissions in table 1 shows that, assuming current controls, there will be only modest changes in emissions from stationary and area sources but substantial decreases in emissions from mobile sources. However, even with the substantial decrease in mobile sources emissions relative to 2008, mobile sources will still account for 40 percent of the VOC, and 80 percent of the NO_X, basin-wide inventory in 2022.

TABLE 3—DISTRICT MEASURES INCLUDED IN THE FUTURE YEAR BASELINE EMISSIONS

Rule	Description	Date of SCAQMD adoption or most recent amendment	EPA Approval (unless otherwise noted)
Rule 1110.2	Emissions from Gaseous- and Liquid-Fueled Internal Combustion Engines.	February 1, 2008	74 FR 18995, April 27, 2009.
Rule 1111	Reduction of NO_X Emissions from Natural-Gas-Fired, Fan-Type Central Furnaces.	November 6, 2009	75 FR 46845, August 4, 2010.
Rule 1113	Architectural Coatings	June 3, 2011	78 FR 18244, March 26, 2013.
Rule 1118	Control of Emissions from Refinery Flares	November 4, 2005	72 FR 49196, August 28, 2007.
Rule 1121	Control of Nitrogen Oxides from Residential-Type Natural-Gas-fired Water Waters.	September 3, 2004	74 FR 20880, May 6, 2009.
Rule 1133.2	Emissions Reductions from Co-Composting Operations.	January 10, 2003	69 FR 43518, July 21, 2004.
Rule 1133.3	Emission Reductions from Greenwaste Composting Operations.	July 8, 2011	77 FR 71129, November 29, 2012.
Rule 1143	Consumer Paint Thinners and Multipurpose Solvents.	December 3, 2010	76 FR 70888, November 16, 2011.
Rule 1144	Metalworking Fluids and Direct Contact Lubricants.	July 9, 2010	76 FR 70888, November 16, 2011.
Rule 1146	Emissions of Oxides of Nitrogen from Industrial, Institutional, and Commercial Boilers, Steam Generators and Process Heaters.	September 5, 2008	Proposed limited approval/limited disapproval at 76 FR 40303 (July 8, 2011).
Rule 1146.1	Emissions of Oxides of Nitrogen from Small Industrial, Institutional, and Commercial Boilers, Steam Generators and Process Heaters.	September 5, 2008	Proposed limited approval/limited disapproval at 76 FR 40303 (July 8, 2011).
Rule 1146.2	Emissions of Oxides of Nitrogen from Large Water Heaters and Small Boilers and Process Heaters.	May 5, 2006	73 FR 74027, December 5, 2008.
Rule 1147	NO_X Reductions from Miscellaneous Sources	September 9, 2011	December 5, 2008 version of rule approved at 75 FR 46845, August 4, 2010.
Rule 1149	Storage Tank and Pipeline Cleaning and Degassing.	May 2, 2008	74 FR 67821, December 21, 2009.
Rule 1151	Motor Vehicle and Mobile Equipment Non-Assembly Line Coating Operations.	December 2, 2005	78 FR 58959, September 24, 2013.
Rule 1177	Liquefied Petroleum Gas Transfer and Dispensing.	June 1, 2012	79 FR 364, January 3, 2014.
Rule 1178	Further Reductions of VOC Emissions from Storage Tanks at Petroleum Facilities.	April 7, 2006	72 FR 49196, August 28, 2007.

We have reviewed the emissions inventories developed for the 2012 South Coast 1-hour ozone attainment demonstration, and the inventory methodologies used by the SCAQMD for consistency with CAA requirements and EPA's guidance. We find that the 2008 base year inventory is a comprehensive, accurate, and current inventory of ozone precursor emissions in the South Coast 1-hour ozone nonattainment area, and that 2008 is an appropriate base year for the revised 1-hour ozone attainment demonstration, and that the future baseline emissions projections for 2022 reflect appropriate emissions calculation methods and the latest planning assumptions. Therefore, we find the base year and future baseline emissions inventories to be acceptable for the purposes of developing a 1-hour ozone attainment demonstration.

2. South Coast 1-Hour Ozone Plan Control Strategy

a. Requirements for Control Strategies and RACM Demonstrations

EPA's SIP call required California to submit a SIP revision that meets the requirements of CAA section 182(c)(2)(A), which requires a demonstration that the SIP, as revised, will provide for attainment of the 1-hour ozone standard by the applicable attainment date. 78 FR 889, at 890 (January 7, 2013). In this case, the applicable attainment date is prescribed by CAA section 172(a)(2)(A), which is the date by which attainment can be achieved as expeditiously as practicable, but no later than February 6, 2018 (five years from the effective date of the SIP call). However, EPA may extend the attainment date to the extent EPA determines appropriate, for a period of no greater than February 6, 2023 (ten years from the effective date of the SIP call), considering the severity of nonattainment and the availability and feasibility of pollution control measures.

The 2012 AQMP includes a demonstration of attainment for the 1-hour ozone standard by December 31, 2022 and thus relies on an extension beyond the five-year deadline under CAA section 172(a)(2)(A). In section II.B.3 of this document, we provide our rationale for proposing approval of the extension in the attainment date to December 31, 2022. Our proposed approval of December 31, 2022 as the applicable attainment date depends in part upon California's showing that the 2012 AQMP provides for implementation of all RACM as

expeditiously as practicable (including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of reasonably available control technology (RACT)). See CAA section 172(c)(1).

In addition to RACM, to meet the requirements of CAA section 182(c)(2)(A), a 1-hour ozone attainment demonstration must include other ''enforceable emission limitations, and such other control measures, means or techniques * * *, as well as schedules and timetables for compliance, as may be necessary or appropriate to provide for attainment * * * by the applicable attainment date * * *.'' CAA section 172(c)(6). The CAA allows ozone nonattainment areas classified as ''extreme,'' such as the South Coast, to include ''provisions * * * which anticipate development of new control techniques or improvement of existing control technologies, * * * if the State demonstrates * * * that—(A) such provisions are not necessary to achieve the incremental emission reductions required during the first 10 years after the date of the enactment of the Clean Air Act Amendments of 1990; and (B) the State has submitted enforceable commitments to develop and adopt contingency measures to be implemented * * * if the anticipated technologies do not achieve planned reductions.'' CAA section 182(e)(5). The measures included in the plan that describe the mechanisms for developing and implementing new control techniques or improvements in existing control technologies and achieving the planned emissions reductions are referred to as ''new technology'' measures.

The control strategy for the 1-hour ozone attainment demonstration in the 2012 AQMP relies on all three types of strategies to reduce basin-wide emissions to the extent necessary to demonstrate attainment of the 1-hour ozone standard (i.e., reduce emissions to 410 tpd of VOC and 150 tpd of NO_X): implementation of RACM; other control measures, means or techniques; and new technology measures. In this case, the phrase, ''other control measures, means, or techniques'' refers to the commitments made by the SCAQMD and CARB to bring certain regulatory initiatives to their respective boards on a certain schedule and to meet certain aggregate emissions reductions in certain years. The overall control strategy and emissions reductions from the various components is presented in table 4.

TABLE 4—SUMMARY OF SOUTH COAST'S 1-HOUR OZONE ATTAINMENT DEMONSTRATION CONTROL STRATEGY

[Summer planning inventory (tpd)]

Emissions scenario	VOC	NO_X
Year 2008 Base Year [a]	593	754
Emission Reductions from Baseline Measures	153	419
Year 2022 Baseline	440	335
SCAQMD's New Aggregate Emissions Reduction Commitment	6	11
CARB's Existing Aggregate Emissions Reduction Commitment	7	24
New Technology Measures	17	150
Year 2022 With Fulfillment of Commitments	410	150

[a] The modeling runs that were used to demonstrate attainment of the 1-hour ozone standard in the 2012 AQMP were based on the base year (2008) summer planning inventories (see table 1 above) with adjustments made for weekly and daily temperature variations. See 2010 AQMP, appendix VII, page VII–51.

With respect to commitments, the 1-hour ozone attainment demonstration in the 2012 AQMP includes certain new commitments adopted by SCAQMD and relies on existing commitments by CARB that were approved by EPA through approval of the attainment demonstration for the 1997 8-hour ozone standard in the 2007 AQMP. The ''new technology'' provision in the 2012 AQMP updates the corresponding provision in the 2007 AQMP by proving greater specificity in the description of the actions that are or will be taken to achieve emissions reductions from development or deployment of advanced control technologies or techniques. The focus of the ''new technology'' provisions is the mobile source category of emissions in light of the extent to which such sources contribute to the overall inventory of ozone precursors.

b. 2012 AQMP RACM Demonstration

CAA section 172(c)(1) requires that each attainment plan ''provide for the implementation of all reasonably available control measures as expeditiously as practicable (including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of reasonably available control technology), and shall provide for attainment of the national primary ambient air quality standards.''

EPA has previously provided guidance interpreting the RACM requirement in the General Preamble at 13560 [20] and in a memorandum entitled ''Guidance on Reasonably Available Control Measures (RACM) Requirements and Attainment Demonstration Submissions for the Ozone NAAQS,'' John Seitz, November 30, 1999. (Seitz memo). In summary, EPA guidance provides that to address the requirement to adopt all RACM, states should consider all potentially reasonable control measures for source categories in the nonattainment area to determine whether they are reasonably available for implementation in that area and whether they would, if implemented individually or collectively, advance the area's attainment date by one year or more. *See* Seitz memo and General Preamble at 13560; *see also* ''State Implementation Plans; General Preamble for Proposed Rulemaking on Approval of Plan Revisions for Nonattainment Areas,'' 44 FR 20372 (April 4, 1979) and Memorandum dated December 14, 2000, from John S. Seitz, Director, Office of Air Quality Planning and Standards, ''Additional Submission on RACM from States with Severe One-Hour Ozone Nonattainment Area SIPs.'' In the following paragraphs, we discuss each element of the control strategy and provide a rationale for why we find it acceptable.

First, as noted above, EPA approved the 2007 AQMP for the 1997 8-hour ozone NAAQS in 2012. As part of that

[20] The ''General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' published at 57 FR 13498 on April 16, 1992, describes EPA's preliminary view on how we would interpret various SIP planning provisions in title I of the CAA as amended in 1990, including those planning provisions applicable to the 1-hour ozone standard.

action, EPA approved the related RACM demonstration. See 77 FR 12674, at 12694 (March 1, 2012). In so doing, we approved the individual stationary-source RACM demonstration from SCAQMD, the transportation-related RACM demonstration from SCAG, and the mobile and area source RACM demonstration from CARB. See 76 FR 57872, at 57877–57881 (September 16, 2011).

To update the RACM demonstration for the 2012 AQMP, the SCAQMD followed a similar process as it had used for the 2007 AQMP. That is, the SCAQMD conducted a process to identify RACM for the South Coast that involved public meetings to solicit input, evaluation of EPA's suggested RACM, and evaluation of other air agencies' regulations. See 2012 AQMP, appendix VII, attachment 4. As part of this process, the SCAQMD evaluated measures implemented in other nonattainment areas based on the severity of the nonattainment situation as well as attainment dates (including the San Joaquin Valley, the San Francisco Bay Area, Ventura, Dallas-Fort Worth, the New York Metro area, and the Houston-Galveston area) and measures identified by the Lake Michigan Air Directors Consortium (LADCO). The SCAQMD also held meetings with CARB, technical experts, local government representatives, and the public during development of the 2012 AQMP, and sponsored an air quality technology symposium in September of 2011, which generated additional potential control measures. In addition, the SCAQMD reevaluated existing SIP-approved SCAQMD rules and regulations.

From the set of identified potential controls, the SCAQMD then screened the identified measures and rejected those that would not individually or collectively advance attainment in the area, had already been adopted as rules, or were in the process of being adopted. The remaining measures were evaluated taking into account baseline inventories, available control technologies, and potential emission reductions as well as whether the measure could be implemented on a schedule that would advance attainment of the 1-hour ozone standard by at least a year, assuming a 2022 attainment deadline. In addition, to capture all improvements in innovative control technologies and identify areas for improvement in its regulations, SCAQMD staff reevaluated all the SCAQMD's source-specific rules and regulations and compared these requirements to more than 100 rules that had recently been adopted in four other California air districts (San Joaquin Valley, Sacramento, Ventura, and San Francisco Bay Area).[21]

Based on its RACM analysis summarized above, SCAQMD concluded that, in general, its existing rules and regulations are equivalent to, or more stringent than, other Districts' rules. In the few areas where this was not the case, SCAQMD staff have developed one or more control measures for inclusion in the 2012 AQMP. In adopting the 2012 AQMP, the SCAQMD committed to develop, adopt, submit and implement 15 new measures, including measures at least as stringent as those identified in other California districts' SIPs, and several innovative measures. Table 5 lists these measures along with the related adoption and implementation date, and estimated emissions reductions. For a detailed description of the measures to which the SCAQMD has committed, please see appendix VI–A of the 2012 AQMP.

TABLE 5—DISTRICT CONTROL MEASURES IN 2012 AQMP 1-HOUR OZONE ATTAINMENT DEMONSTRATION

Number and title	Adoption	Implementation period	Reduction (tons per day (tpd)) by 2023	
			VOC	NO_X
CTS–01—Further VOC Reductions from Architectural Coatings (Rule 1113).	2015–2016	2018–2020	2–4	
CTS–02—Further Emission Reduction from Miscellaneous Coatings, Adhesives, Solvents and Lubricants.	2013–2016	2015–2018	1–2	
CTS–03—Further VOC Reductions from Mold Release Products.	2014	2016	0.8–2	
CMB–01—Further NO_X Reductions from RECLAIM	2015	2020		3–5
CMB–02—NO_X Reductions from Biogas Flares	2015	Beginning 2017		TBD
CMB–03—Reductions from Commercial Space Heating	Phase I—2014 (Tech Assessment), Phase II—2016.	Beginning 2018		0.18
FUG–01—VOC Reductions from Vacuum Trucks	2014	2016	1	
FUG–02—Emission Reduction from LPG Transfer and Dispensing—Phase II.	2015	2017	1–2	
FUG–03—Further Reductions from Fugitive VOC Emissions.	2015–2016	2017–2018	1–2	
MCS–01—Application of All Feasible Measures	Ongoing	Ongoing	TBD	TBD
MCS–02—Further Emission Reductions from Green waste Processing (Chipping and Grinding Operations not associated with composting).	2015	2016	1	
MCS–03—Improved Start-up, Shutdown and Turnaround Procedures.	Phase I—2012 (Tech Assessment), Phase II—TBD.	Phase I—2013 (Tech Assessment), Phase II—TBD.	TBD	TBD
INC–01—Economic Incentive Programs to Adopt Zero and Near-Zero Technologies.	2014	Within 12 months after funding availability.		TBD
INC–02—Expedited Permitting and CEQA Preparation Facilitating the Manufacturing of Zero and Near-Zero Technologies.	2014–2015	Beginning 2015	N/A	N/A

[21] 2012 AQMP, appendix VII, attachment 4, page VII–10.

TABLE 5—DISTRICT CONTROL MEASURES IN 2012 AQMP 1-HOUR OZONE ATTAINMENT DEMONSTRATION—Continued

Number and title	Adoption	Implementation period	Reduction (tons per day (tpd)) by 2023	
			VOC	NO_X
EDU–01—Further Criteria Pollutant Reductions from Education, Outreach and Incentives.	Ongoing	Ongoing	N/A	N/A

Source: 2012 AQMP, table 4–4. Note: TBD = to be determined once the specific inventory and control approach for the measure are identified. N/A = not applicable given nature of the measure.

More specifically, the SCAQMD has committed to develop, adopt, submit and implement the 15 new measures listed in table 5 to achieve, in aggregate, emission reductions of 5.8 tpd of VOC and 10.7 tpd of NO_X by January 1, 2022 unless these measures or a portion thereof are found infeasible and substitute measures that can achieve equivalent reductions in the same implementation timeframes are adopted.[22] The 2012 AQMP describes a process for public review of findings of feasibility and the related measure substitution.

As to the few remaining measures that the SCAQMD rejected from its RACM analysis, the SCAQMD determined that these measures would not advance the attainment date due to the insignificant or unquantifiable emissions reductions they would potentially generate. See 2012 AQMP, appendix VII, attachment 2, page VII–10. Based on our review of the SCAQMD's latest RACM review process and the SCAQMD's proposed commitment to new measures (listed in table 5), we find that the 2012 AQMP demonstrates RACM for stationary sources in the South Coast.

With respect to transportation sources, SCAG's RACM analysis focused on transportation control measures (TCMs). TCMs are, in general, measures designed to reduce emissions from on-road motor vehicles through reductions in vehicle miles traveled or traffic congestion. SCAG's analysis is described in appendix VII, pages VII–20 to VII–23 of the 2012 AQMP. The TCMs in the 2012 AQMP are derived from TCM projects in the 2012–2035 SCAG Regional Transportation Plan/Sustainable Communities Strategy (RTP/SCS).[23] SCAG's evaluation, described beginning on page VII–20 of appendix VII of the 2012 AQMP, resulted in extensive local government commitments to implement programs to reduce auto travel and improve traffic flow. Attachment 2 to appendix VIII (''Vehicle Miles Traveled Emissions Offset Demonstration'') to the 2012 AQMP contains the list of TCMs under development and newly scheduled TCMs. See also 2012 AQMP, appendix IV–C.

In so doing, SCAG evaluated a wide variety of TCMs, including those measures listed in CAA section 108(f) and relevant measures adopted in other nonattainment areas in the country, and determined that there was no combinations of reasonable measures that would advance attainment of the 1-hour ozone standard in the South Coast. See 2012 AQMP, appendix VII and appendix IV–C. Based on our review of appendix IV–C of the 2012 AQMP, we agree with the conclusion in the 2012 AQMP that the TCMs being implemented in the South Coast are inclusive of all TCM RACM for the area.

As to the mobile source component of the RACM demonstration, in 2007, CARB adopted the ''California Air Resources Board's Proposed State Strategy for California's 2007 State Implementation Plan'' (''2007 State Strategy'') through which CARB identified and committed to propose new defined measures for on-road and off-road sources and the fuels that power them.

Given the need for significant emissions reductions in California nonattainment areas, CARB has been a leader in the development and adoption of stringent mobile source control measures nationwide and has unique authority under CAA section 209 (subject to a waiver or authorization by EPA) to adopt and implement new emission standards for many categories of on-road vehicles and engines and new and in-use off-road vehicles and engines. We have also noted that many if not most of these particular measures are being proposed for adoption for the first time anywhere in the nation. Like the 2007 AQMP, the 2012 AQMP relies on the defined measures adopted by CARB in the 2007 State Strategy approved by EPA in 2012, and we agree with the 2012 AQMP's conclusion that CARB's mobile source program, approved as RACM in connection with the 2007 AQMP, continues to be RACM as it expands and further reduces emissions.

Therefore, for the reasons discussed above, we conclude that the 2012 AQMP provides for RACM for ozone precursor emissions from stationary, transportation, and mobile sources in the South Coast.

c. 2012 AQMP Aggregate Emissions Reductions Commitments

As described in the previous section of this document, through adoption of the 2012 AQMP, the SCAQMD has committed to achieve specific aggregate emissions reductions from VOC and NO_X sources in the South Coast area. Specifically, the SCAQMD has committed to develop, adopt, submit and implement measures that will achieve the following additional emissions reductions by January 1, 2022: 5.8 tpd of VOC and 10.7 tpd of NO_X. The SCAQMD expects to meet its emissions reductions commitments for VOC and NO_X through implementation of the 15 measures in table 5, and through implementation of the Surplus Off-road Option for NO_X (SOON) provision for construction/industrial equipment, but reserves the right to substitute measures as described in the previous section of this document.[24] CARB has made no new aggregate emissions reduction commitment for the purposes of demonstrating attainment of the 1-hour ozone standard by December 31, 2022 in the South Coast, but the 2012 AQMP estimates that CARB's existing, EPA-approved aggregate emissions reduction commitment under the 2007 AQMP will provide 7 tpd of VOC and 24 tpd of NO_X reductions by 2022. Considered together, the SCAQMD's new aggregate emissions reductions commitment and CARB's

[22] See 2012 AQMP, pages 4–41 through 4–46, and Wallerstein Letter.

[23] The Sustainable Communities Strategy is new to this RTP cycle and is required by California Senate Bill 375. While the focus of the SCS is greenhouse gases, concurrent criteria pollutant reductions occur. The emissions benefits associated with the RTP/SCS are reflected in the projected baseline emissions inventories in the 2012 AQMP. 2012 AQMP, appendix VII, page VII–23.

[24] SCAQMD estimates that extension of the SOON provision will achieve 7.5 tpd of NO_X reductions by 2022.

existing aggregate emissions reductions commitment under the 2007 AQMP amount to 13 tpd of VOC and 35 tpd of NO_X for the purposes of 1-hour attainment in the South Coast by December 31, 2022.

EPA believes that, with respect to the 2012 AQMP 1-hour ozone attainment demonstration, circumstances warrant the consideration of enforceable commitments as part of the attainment demonstration for the South Coast. As shown in table 4 above, the majority of the VOC reductions and a substantial portion of NO_X emissions reductions needed to demonstrate attainment in the South Coast come from SCAQMD regulations that were adopted prior to June 2012, and CARB regulations that were adopted prior to August 2011, i.e., baseline measures that have been or will be approved into the SIP (or issued waivers or authorizations) prior to a final approval of the attainment demonstration. As a result of these State and District efforts, most sources in the South Coast nonattainment area are currently subject to stringent rules adopted and approved by EPA (or for which EPA has issued waivers or authorization in the case of CARB regulations) prior to the development of the 2012 AQMP, leaving few opportunities (and generally more technologically and economically challenging ones) to further reduce emissions.

In the 2012 AQMP, the SCAQMD identified potential control measures that could provide many of the additional emissions reductions needed for attainment. See 2012 1-hour ozone attainment demonstration, appendix VII, section 4. However, the timeline needed to develop, adopt, and implement these measures went beyond the February 2013 submittal date of the South Coast 2012 1-hour ozone attainment demonstration. These circumstances warrant the SCAQMD's and CARB's reliance on enforceable commitments as part of the attainment demonstration in the South Coast 2012 1-hour ozone attainment demonstration.

Given the State's demonstrated need for reliance on enforceable commitments, we now consider the three factors EPA uses to determine whether the use of enforceable commitments in lieu of adopted measures to meet a CAA planning requirements is approvable: (1) Does the commitment address a limited portion of the statutorily-required program; (2) is the state capable of fulfilling its commitment; and (3) is the commitment for a reasonable and appropriate period of time.

For the first factor, we look to see if the commitment addresses a limited portion of a statutory requirement, such as the amount of emissions reductions needed to demonstrate attainment in a nonattainment area. For this calculation, reductions assigned to the new technology provision (CAA section 182(e)(5)) are not counted as commitments.[25]

As shown in table 4 above, the remaining portions of the emission reductions needed to demonstrate attainment of the 1-hour ozone standard in the South Coast nonattainment area (*i.e.,* of the State's total enforceable commitments), after accounting for baseline measures and emissions reduction commitments assigned to CAA section 182(e)(5) measures, amount to 13 tpd VOC and 35 tpd NO_X. When compared to the total reductions needed to demonstrate attainment (not including the CAA section 182(e)(5) reductions in the attainment demonstration), the remaining portion of the enforceable commitments represents approximately 7 percent of the needed VOC reductions and approximately 6 percent of the needed NO_X reductions. These percentage reductions are consistent with other SIPs for which EPA has approved enforceable commitments. See our approval of the SJV PM_{10} Plan at 69 FR 30005 (May 26, 2004), the SJV 1-hour ozone plan at 75 FR 10420 (March 8, 2010), the Houston-Galveston 1-hour ozone plan at 66 FR 57160 (November 14, 2001), approval of the SJV 2007 $PM_{2.5}$ SIP at 76 FR 41338 (November 9, 2011), and approval of the South Coast $PM_{2.5}$ SIP at 76 FR 41562 (November 9, 2011). We believe the State's commitment meets the first factor because it addresses a limited proportion of the required emission reductions.

For the second factor, we consider whether the SCAQMD and CARB are capable of fulfilling their commitments. The 2012 AQMP includes a specific list of regulatory initiatives from which emissions reductions are estimated to fulfill that agency's aggregate emissions reduction commitment. See table VII–4–2, and control measure OFFRD–01 (i.e., extension of the SOON provision) in table VII–4–4 of appendix VII of the 2012 AQMP. With respect to CARB's existing aggregate commitment from the 2007 AQMP, table VII–4–1 of the 2012 AQMP lists the types of measures included in the 2007 AQMP that the State of California could implement to meet CARB's existing 2020 aggregate commitment and thereby provide the planned emissions reductions for 1-hour ozone attainment purposes in 2022. Given the State's and SCAQMD's efforts to date to reduce emissions and the proposed stationary and mobile source strategies found in the 2012 AQMP, we believe that the State and SCAQMD are capable of fulfilling their aggregate emissions reductions commitments.

For the third and last factor, we consider whether the commitment is for a reasonable and appropriate period of time. First, we note SCAQMD's commitment is to achieve the specified aggregate emission reductions by January 1, 2022 (see Wallerstein Letter), for the purpose of providing for attainment of the 1-hour ozone standard by December 31, 2022, an attainment date that we are proposing to approve herein. Second, to meet the aggregate reduction commitment by January 1, 2022, SCAQMD is relying on emissions reductions from the SOON program. Reductions from the SOON program involve accelerating fleet turnover of off-road diesel engines through equipment replacement and engine repowers that in turn rely on available funds. The SCAQMD's expectation of emissions reductions from the SOON program by January 1, 2022 is based on the reasonable assumption of continued funding at current levels to achieve similar annual reductions in the emissions as have been achieved over the past four years. As such, we find that SCAQMD's aggregate emissions reduction commitment is for a reasonable and appropriate period of time. CARB's emissions reduction commitment from the 2007 AQMP is for year 2020, and so long as the commitment is fulfilled by January 1, 2022, it will provide the necessary reductions to attain the 1-hour ozone standard in the South Coast by December 31, 2022. Thus, SCAQMD's new commitment and CARB's existing commitment are for a reasonable and appropriate period of time.

d. CAA Section 182(e)(5) New or Improved Technology Measures

For ozone nonattainment areas classified as extreme, the CAA recognizes that an attainment demonstration may need to rely to a certain extent on new or evolving technologies (referred to herein as ''new

[25] CAA section 182(e)(5) specifically allows EPA to approve an attainment demonstration that relies on reductions from new technologies. This provision is separate from the requirement in CAA section 172(c)(6) for enforceable emissions limitations under which enforceable commitments are considered. As a result, reductions attributed in the attainment demonstration to new technologies are not considered part of the State's enforceable commitments for purposes of determining the percentage of reductions needed for attainment that remain as commitments.

technology'' measures), given the relatively long time between developing the initial plan and attaining the standard and the degree of emissions reductions needed to attain. To address these needs, CAA section 182(e)(5) authorizes EPA to approve provisions in an extreme area plan which ''anticipate development of new control techniques or improvement of existing control technologies,'' and to approve an attainment demonstration based on such provisions, if the State demonstrates that: (1) Such provisions are not necessary to achieve the incremental emission reductions required during the first 10 years after November 15, 1990; and (2) the State has submitted enforceable commitments to develop and adopt contingency measures to be implemented if the anticipated technologies do not achieve the planned reductions. CAA 182(e)(5). The State must submit these contingency measures to EPA no later than three years before proposed implementation of these long-term measures, and the contingency measures must be ''adequate to produce emissions reductions sufficient, in conjunction with other approved plan provisions, to achieve the periodic emissions reductions required by [CAA sections 182(b)(1) or (c)(2)] and attainment by the applicable dates.'' *Id.*

The General Preamble further provides that the new technology measures contemplated by section 182(e)(5) may include those that anticipate future technological developments as well as those that require complex analyses, decision making and coordination among a number of government agencies. *See* General Preamble at 13524. An attainment demonstration that relies on long-term new technology measures under section 182(e)(5) must identify any such measures and contain a schedule outlining the steps leading to final development and adoption of the measures. *Id.*

SCAQMD and CARB have demonstrated a clear need for emissions reductions from new and improved control technologies to reduce air pollution in the South Coast. As shown in table 4, above, baseline measures, and enforceable commitments provide the majority, but not all, of the emissions reductions needed by 2022 to attain the emissions target for 1-hour ozone attainment in the South Coast of 410 tpd of VOC and 150 tpd of NO_X.

To cover the difference, which amounts to 17 tpd of VOC and 150 tpd of NO_X, the 2012 AQMP includes 10 measures to reduce mobile source emissions for 1-hour ozone and 1997 8-hour ozone planning purposes and seven additional measures to accelerate the development and deployment of near-zero and zero-emission technology for goods movement related sources and off-road equipment to achieve additional emissions reductions over the longer-term for 2008 8-hour ozone planning purposes as well. These ''new technology'' measures are intended to provide the emissions reductions necessary to attain the 1-hour ozone standard and also represent the updated ''new technology'' provisions for attainment of the 1997 8-hour ozone standard in the South Coast. The ''new technology'' measures are identical for both the 1-hour ozone and 1997 8-hour ozone standards. The differences in the new technology provisions between the 1-hour ozone and 1997 8-hour ozone attainment demonstrations lie in the extent to which the attainment demonstrations rely on such measures, and the timing. The emissions reductions that are needed from new technology measures to demonstrate attainment of the 1-hour ozone standard in the South Coast are 17 tpd of VOC and 150 tpd of NO_X by January 1, 2022. The corresponding emissions reductions and timing from new technology measures for 1997 8-hour ozone attainment purposes is 40 tpd of VOC and 241 tpd of NO_X by January 1, 2023.

Table 6 below lists the 2012 AQMP's new technology measures along with a brief summary of each measure. See 2012 AQMP, appendix IV–B for a detailed description of the measures. In support of these measures, CARB adopted a commitment to ''develop, adopt, and submit contingency measures by 2019 if advanced technology measures do not achieve planned reductions as required by section 182(e)(5)(B).'' CARB Resolution 13–3, page 9.

TABLE 6—SCAQMD AND CARB NEW TECHNOLOGY MEASURES IN 2012 AQMP

2012 AQMP measure identifier	Title	Description
ONRD–01	Accelerated Penetration of Partial Zero-Emission and Zero Emission Vehicles.	This measure continues implementation of CARB's Clean Vehicle Rebate Project (CVRP) through 2023 with a minimum number of 1,000 vehicles per year to be incentivized through the CVRP, which provides individual vehicle incentives of up to certain amounts (e.g., $2,500 for full zero-emission vehicles) for clean vehicles.
ONRD–02	Accelerated Retirement of Older Light-Duty and Medium Duty Vehicles.	This measure calls for retirement of, at a minimum, 2,000 light and medium-duty vehicles per year to 2023, and gives first priority to pre-1992 model year vehicles identified as high emitter and that are off-cycle to California's Smog Check Program. Incentives are up to $2,500 per vehicle which could include a replacement voucher under CARB's Enhanced Fleet Modernization Program.
ONRD–03	Accelerated Penetration of Partial Zero-Emission and Zero Emission Light-Heavy- and Medium-Heavy-Duty Vehicles.	This measure seeks additional emissions reductions through the early introduction of electric hybrid vehicles and continues the state hybrid truck and bus voucher incentive project (HVIP). Incentives of up to $25,000 per vehicle are part of this measure. The measure's goal is to fund 1,000 hybrid and zero-emission vehicles each year to 2023.
ONRD–04	Accelerated Retirement of Older On-Road Heavy-Duty Vehicles.	This measure seeks additional emissions reductions from older, pre-2010 heavy-duty vehicles beyond the emission reductions targeted in CARB's Truck and Bus Regulation. A significant number of heavy-duty trucks have been replaced through Proposition 1B Goods Movement Emission Reduction Program funding, the Carl Moyer Program, and other local incentives programs. This measure continues these programs through 2023.
ONRD–05	Further Emission Reductions from Heavy-Duty Vehicles Serving Near-Dock Railyards.	This measure calls for CARB to adopt a regulation or other enforceable mechanism to further reduce emissions from near-dock railyard drayage trucks. The regulation or other enforcement mechanism would require, by 2020, all containers transported between the marine ports and the near-dock railyards to use zero-emission technologies.

TABLE 6—SCAQMD AND CARB NEW TECHNOLOGY MEASURES IN 2012 AQMP—Continued

2012 AQMP measure identifier	Title	Description
OFFRD–01	Extension of the SOON Provision for Construction/Industrial Equipment.	This measure seeks to reduce emissions from older, high-emitting off-road diesel engines. Under this measure, incentive programs, such as the Carl Moyer Program and the SOON Provision of CARB's Off-Road rule, would continue to be used to fund equipment replacement and engine repower projects. This measure would extend the current SOON program beyond 2014 to 2023.
OFFRD–02	Further Emission Reductions from Freight Locomotives.	This measure carries forward the freight locomotive new technology measures from the 2007 AQMP and calls for replacing existing locomotive engines with Tier 4 engines beginning in 2015 such that by 2023, there will be at least 95% Tier 4 locomotives operating the South Coast.
OFFRD–03	Further Emission Reductions from Passenger Locomotives.	Metrolink's Board has adopted a locomotive replacement plan which includes the procurement of Tier 4 locomotive engines to replace its 30 Tier 0 locomotives over a three-year period. In addition, the replacement plans call for repowering the existing Tier 2 locomotives to Tier 4 emission levels, resulting in 100% Tier 4 locomotives by 2023.
OFFRD–04	Further Emission Reductions from Ocean-Going Marine Vessels While at Berth.	This measure focuses on ocean-going vessels not subject to CARB's shorepower regulation and seeks to deploy shorepower technologies for an additional 25 percent of the calls not subject to CARB's shorepower regulation.
OFFRD–05	Emission Reductions from Ocean-Going Marine Vessels.	This measure calls for incentives to be used to maximize the early introduction and preferential deployment of vessels to the San Pedro Bay Ports with cleaner/new engines meeting the new Tier 2 and Tier 3 IMO NO_X standards.
ADV–01	Actions for the Deployment of Zero and Near-Zero Emission On-Road Heavy-Duty Vehicles.	This measure includes two sets of actions. The first set involves the establishment of an optional NO_X exhaust emission standard that is at least 95 percent lower than the current 2010 on-road exhaust emissions standard. The second set is to develop zero-emission technologies for heavy-duty vehicles that can be deployed in the 2015 to 2035 timeframe.
ADV–02	Actions for the Deployment of Zero-Emission and Near-Zero Locomotives.	This measure describes actions needed to commercialize advanced zero-emission and near-zero emission technologies for locomotives that could be deployed in the 2020 to 2030 timeframe.
ADV–03	Actions for the Deployment of Zero-Emission and Near-Zero Cargo Handling Equipment.	This measure describes actions to demonstrate and commercialize advanced zero-emission and near-zero emission technologies for cargo handling equipment operated at marine ports, intermodal freight facilities, and warehouse distribution centers that could be deployed in the 2020 to 2030 timeframe.
ADV–04	Actions for the Deployment of Cleaner Commercial Harbor Craft.	This measure describes actions needed to commercialize advanced engine control technologies and hybrid systems for commercial harbor craft that could be deployed in the 2020 to 2030 timeframe.
ADV–05	Actions for Deployment of Cleaner Ocean-Going Marine Vessels.	This measure describes the actions needed to deploy retrofit technologies on existing Category 3 marine engines to achieve Tier 3 marine engine emissions standards.
ADV–06	Actions for the Deployment of Cleaner Off-Road Equipment.	This measure describes the actions needed to commercialize advanced zero-emission and near-zero emission technologies of off-road equipment that could be deployed in the 2020 to 2030 timeframe.
ADV–07	Actions for the Deployment of Cleaner Aircraft Engines.	This measure describes the actions needed to develop, demonstrate, and commercialize advanced technologies, procedures, and sustainable alternative jet fuels that could be deployed in the 2020 to 2030 timeframe.

We have evaluated the reliance on the new technology provision of section 182(e)(5) in the 2012 AQMP and have found it to be acceptable. First, the SIP call to which the 2012 AQMP responds is for an attainment demonstration plan for an area classified as ''extreme'' for the 1-hour ozone standard. As such, the attainment demonstration can rely on the new technology provision under CAA section 182(e)(5) if attainment cannot be demonstrated through implementation of RACM and enforceable commitments and if the specific criteria and requirements of section 182(e)(5) are met. As noted above, attainment by meeting the emissions targets for the 1-hour ozone standard in the South Coast (410 tpd of VOC and 150 tpd of NO_X) cannot be met through RACM and enforceable commitments. Second, with respect to the specific criteria and requirements, we find the 2012 AQMP's reliance on new technologies to be acceptable because:

- The 2012 AQMP relies on new technology measures for reductions from a base year of 2008 to an attainment year of 2022, a period of 14 years, and thus does not rely on new technologies to achieve incremental emission reductions required during the first 10 years of the plan; and
- CARB has submitted an enforceable commitment to develop, adopt, and submit contingency measures by 2019 [26] (three years before the 1-hour ozone attainment year) to be implemented if the anticipated technologies do not achieve the planned reductions.[27]

In addition, we note the progress to date that has been made toward implementing the new technology measures. For example, CARB reports that, in January 2012, CARB adopted the Advanced Clean Cars Program, which combines the control of smog, soot causing pollutants and greenhouse gas emissions into a single coordinated

[26] We interpret CARB's contingency measure commitment to be for January 1, 2019 based on the statutory requirement for such measures to be submitted (''no later than 3 years before proposed implementation of the [advanced control technologies measures]''), CAA section 182(e)(5), and the implementation date for implementation of the advanced control technologies measures in the 2012 AQMP by January 1, 2022.

[27] We also note that the State has committed to meet annually with EPA and to provide annual updates on the status of the 182(e)(5) commitments. See letter from James Goldstene, Executive Officer, CARB to Jared Blumenfeld, Regional Administrator, EPA Region 9, dated August 29, 2011 and letter from Richard Corey, Executive Officer, CARB to Jared Blumenfeld, Regional Administrator, EPA Region 9, dated March 6, 2014.

package of requirements for model years 2015 through 2025. In 2013, the California Legislature extended to 2023 two successful incentive programs, the Carl Moyer Program and the Air Quality Improvement Program, that otherwise would have sunset in 2014 and 2015, and provided nearly $65 million in additional funds. In December 2013, CARB adopted the new optional low-NO_X standards for on-road heavy-duty engines that are one of the actions called for in the 2012 AQMP's new technology measure ADV–01, listed above in table 6.

Thus, based on the above discussion and evaluation, we find that the reliance on new technology measures as part of the attainment demonstration for the 1-hour ozone standard in the 2012 AQMP satisfies the requirements of CAA section 182(e)(5). As such, we are proposing to approve the new technology measures summarized in table 6 and further described in the 2012 AQMP, appendix IV–B, for 1-hour ozone attainment demonstration purposes and as an update to the new technology provision in the 2007 AQMP for the 1997 8-hour ozone standard.

3. Applicable Attainment Date

As noted previously, in our final SIP call, we indicated that the applicable attainment date for the 1-hour ozone standard in the South Coast is as expeditiously as practicable, but no later than 5 years from the effective date of the final SIP call (i.e., February 6, 2018) but that EPA is authorized to extend the applicable attainment date for a period no greater than 10 years from the effective date of the SIP call (i.e., February 6, 2023) if appropriate given the severity of nonattainment and the availability and feasibility of pollution control measures.

The 2012 AQMP demonstrates attainment of the 1-hour ozone standard by December 31, 2022. To evaluate whether to approve an attainment date of December 31, 2022 for the 1-hour ozone standard in the South Coast, we reviewed the severity of nonattainment and the availability and feasibility of pollution control measures.

First, despite significant progress over the years, for urban areas nationwide, the South Coast nonattainment area has both the highest 1-hour ozone design value concentration and the highest annual maximum ozone concentrations in the United States. For instance, while the 1-hour design value has decreased from over 0.30 ppm in 1990 to less than 0.15 ppm in 2011 (see figure VII–2–2 in appendix VII of the 2012 AQMP), maximum ozone concentrations still are significantly higher than other metropolitan areas of the United States (see figures VII–2–3 and VII–2–4 in appendix VII) and remain over 20% higher than the standard. The 1-hour ozone problem in the South Coast is complex, the design value monitor has shifted over time, and the problem is compounded by the topographical and meteorological conditions for the area that are very conducive to the formation and concentration of ozone. 2012 AQMP, appendix VII, section 5.

As discussed in the section of this document on control strategies and RACM, the South Coast nonattainment area needs significant reductions in VOC and NO_X to demonstrate attainment, on the order of 31 percent for VOC and 80 percent for NO_X from 2008 base year emissions. EPA believes that further reduction of these pollutants is challenging, because the State and local air pollution regulations already in place include most of the readily available VOC and NO_X control measures. Moreover, attainment in the South Coast nonattainment area must also mitigate the emissions increases associated with the projected increases in population and emissions levels for this high growth area.

The SCAQMD has a long history of adopting new measures and revising existing measures that provide emissions reductions of VOC and to a lesser extent, NO_X. These measures provide ongoing reductions that contribute towards attainment of the 1-hour ozone standard. The SCAQMD's VOC reductions are achieved primarily from rules governing the petroleum industry, as well as consumer products rules at both the State and local level. These types of control measures present special implementation challenges (e.g., the large number of individuals subject to regulation and the difficulty of applying conventional technological control solutions). NO_X reductions come largely from SCAQMD rules for fuel combustion sources, NO_X RECLAIM, and from CARB's mobile source rules.

As provided above, EPA agrees that the implementation schedule for enhanced stationary source controls is expeditious, taking into account the time necessary for purchase and installation of the required control technologies. We believe that it is not feasible at this time to accelerate the emission reduction schedule for the state and federal mobile source requirements, which set aggressive compliance dates for new emission standards and which must rely on fleet turnover over the years to deliver the ultimate emission reductions. In addition, the State has adopted standards for many categories of on-road and off-road vehicles and engines, and gasoline and diesel fuels, and is relying on existing, approved commitments to continue developing rules for Smog Check Improvements, Expanded Passenger Vehicle Retirement Program, Cleaner Main Ship Engines and Fuel, Cleaner Line-Haul Locomotives, and Off-Road Recreational Vehicle Equipment. EPA believes that the SCAQMD and CARB are implementing these rules and programs as expeditiously as practicable. EPA also expects that SCAQMD and CARB will continue to investigate opportunities to accelerate progress as new control opportunities arise, and that the agencies will promptly adopt and expeditiously implement any new measures found to be feasible in the future. For these reasons and also the need to conduct significant public outreach if applicable control approaches are to be effective, EPA agrees with the SCAQMD and CARB that a December 31, 2022 attainment date for the South Coast for the 1-hour ozone standard is as expeditious as practicable.

4. Air Quality Modeling for the South Coast 2012 1-Hour Ozone Attainment Demonstration

In this section of the document, we discuss the applicable statutory and regulatory requirements for modeled attainment demonstrations, EPA guidance on air quality modeling for ozone standards, the air quality modeling analysis supporting the attainment demonstration in the State's submittal, and our evaluation of these modeling analyses as part of the attainment demonstration SIP.

a. CAA and Regulatory Requirements for 1-Hour Ozone Air Quality Modeling and EPA Guidance

For any ozone nonattainment area classified as serious or above, section 182(c)(2)(A) of the CAA specifically requires the State to submit a modeled attainment demonstration based on a photochemical grid modeling evaluation or any other analytical method determined by the Administrator to be at least as effective as photochemical modeling. In addition, 40 CFR section 51.112 requires that attainment must be demonstrated using applicable air quality models, data bases, and other requirements specified in Appendix W to 40 CFR part 51, as interpreted in EPA guidance. *See, e.g.,* Guideline for Regulatory Application of the Urban Airshed Model, EPA–450/4–91–013 (July 1991); ''Guidance on Use of Modeled Results to Demonstrate Attainment of the Ozone NAAQS,''

EPA–454/B–95–007 (June 1996); ''Guidance for the 1-hour Ozone Nonattainment Areas that Rely on Weight-of-Evidence for Attainment Demonstrations, Mid-Course Review Guidance'' (March 28, 2002); ''Guidance for Improving Weight-of-Evidence Through Identification of Additional Emission Reduction Not Modeled (Nov 1999); ''Guidance on the Use of Models and Other Analyses for Air Quality Goals in Attainment Demonstrations for Ozone, $PM_{2.5}$, and Regional Haze,'' April 2007. These guidance documents describe the criteria that an air quality model and its application should meet to qualify for use in an ozone attainment demonstration. For more detail on EPA's evaluation of the modeling in the South Coast 1-hour ozone attainment demonstration, see the ''Modeling and Other Analyses Attainment Demonstration'' memorandum in the docket for today's proposal.[28] The modeling document in the docket also includes a complete list of applicable modeling guidance documents. These documents describe the components of the attainment demonstration, explain how the modeling and other analyses should be conducted, and provide overall guidance on the technical analyses for attainment demonstrations.

As with any predictive tool, inherent uncertainties are associated with photochemical grid modeling. EPA's guidance recognizes these limitations and provides recommended approaches for considering other analytical evidence to help assess whether attainment of the NAAQS is likely. This process is called a weight of evidence (WOE) analysis. EPA's modeling guidance (updated in 1996, 1999, and 2002) discusses various WOE analyses. This guidance recommends that all attainment demonstrations include supplemental analyses beyond the recommended modeling. These supplemental analyses provide additional information such as data analyses, and emissions and air quality trends, which would help strengthen the conclusion based on the photochemical grid modeling.

b. 1-Hour Attainment Demonstration Modeling and Weight of Evidence

i. Modeling Approaches for the SCAQMD Attainment Demonstration

a. Photochemical Grid Model. The model selected for the 20121-hour ozone attainment demonstration was developed using the U.S. EPA supported Community Multiscale Air Quality (CMAQ) (version 4.7) air quality modeling platform with Statewide Air Pollution Research Center-99 (SAPRC99) chemistry, and the Weather Research and Forecasting (WRF) model (version 3.3) meteorological fields. The modeling system (including the photochemical model, meteorological inputs, and chemical mechanism) is consistent with the previous advice of outside peer reviewers. CMAQ is a state-of-the-art air quality model that can simulate ozone and $PM_{2.5}$ concentrations together in a ''one-atmosphere'' approach for attainment demonstrations.

b. Episode Selection. The attainment demonstration modeling focuses on 92 days of ozone air quality observed during June through August of the base year 2008. Overall, the 92 day period provides a robust description of the 2008 ozone meteorological season. During this period, seven well defined multi-day ozone episodes occurred in the Basin with 16 days having daily 1-hour maximum ozone concentrations of 125 ppb or higher at the site with the maximum number of exceedances. When assessed for a normalized meteorological ozone episode potential using a regression based weighting covering 30 years of data (1998–2010), the June 18–22, 2008 period was ranked in the 99th percentile. This episode contained the top four daily ozone maximum concentrations for 2008 in the South Coast and was selected as the focus of the attainment demonstration.

c. Model Performance. Model performance was evaluated in three zones in the South Coast Basin: The San Fernando Valley; the eastern San Gabriel, Riverside and San Bernardino Valleys; and Los Angeles and Orange County. Normalized Gross Bias, Normalized Gross Error, and Peak Prediction Accuracy were determined for each area. Although not a requirement for determining acceptable model performance, the performance statistics were compared to the EPA performance goals presented in guidance documents. The performance goals for Normalized Gross Error and Peak Prediction Accuracy were met in the eastern San Gabriel, Riverside and San Bernardino Valleys. The statistic for bias (Normalized Gross Bias) tends to be negative, indicating that the model tends to slightly under-predict ozone. Both June 18th and June 20th failed to meet the model acceptance criteria for the unpaired peak analysis. As a result, the attainment demonstration focused on June 19th and 21st, days with observed peak concentrations that closely matched the design values. Based on their analysis, SCAQMD concludes and EPA agrees that model performance is acceptable for this application.

ii. Results of SCAQMD Modeling

Photochemical model simulations were conducted for the base year 2008 emissions and future-year 2022 baseline and controlled emissions. The 1-hour ozone attainment demonstration was based on the deterministic approach outlined in the ''Guidance on Use of Modeled Results to Demonstrate Attainment of the Ozone NAAQS,'' EPA–454/B–95–007 (June 1996). In addition, the weight of evidence analysis uses the model in a relative sense, using the relative response factor (RRF) technique described in the ''Guidance on the Use of Models and Other Analyses for Air Quality Goals in Attainment Demonstrations for Ozone, $PM_{2.5}$, and Regional Haze,'' April 2007.

a. Modeled Attainment. The model predicted a maximum 1-hour ozone concentration for 2022 of 125 parts per billion (ppb) on June 19th at the Pasadena monitor.[29] All other predicted concentrations during the five-day episode are projected to be below 124 ppb. The results of the attainment demonstration for 2022 indicate that, allowing for one day per year above the standard, the 1-hour ozone standard would be attained by 2022 at all monitors with the controlled emissions inventory. The attainment targets (410 tpd VOC and 150 tpd NO_X) are based on both short-term and long-term (i.e., new technology) measures. With the related emissions reductions in place, it is expected that all stations in the South Coast ozone nonattainment area will meet the 1-hour ozone standard during the 2022 ozone season.

b. Weight of Evidence Analysis. The weight of evidence analysis for the ozone attainment demonstration relies on the use of site-specific RRFs being applied to the 2008 weighted design values. The RRFs are determined from the future year controlled and the 2008 base year simulations. The results of the RRF analysis supports the deterministic attainment demonstration and the level of emission reductions needed for attainment. The selection criteria for the episode days and the process of applying the RRFs to the CAMX modeling are discussed in more detail in the modeling document in the docket for today's action.

[28] Memorandum to Docket EPA–R09–OAR–2014–0185 from Carol Bohnenkamp, Air Quality Analysis Office, EPA Region 9, ''Review of the Modeling for the Attainment Demonstration for the Proposed Rulemaking Action on the South Coast 2012 AQMP for the One Hour Ozone Standard'', dated May 1, 2014.

[29] The national 1-hour ozone standard is 0.12 ppm. Values of 124 ppb or less are not considered exceedances of the standard.

c. EPA's Evaluation of the Modeling Demonstration

Our evaluation of the air quality modeling analyses and supporting information provided in the South Coast 2012 1-hour ozone attainment demonstration indicate that the South Coast area will attain the 1-hour ozone standard by its December 31, 2022. In addition to the attainment demonstration provided in the South Coast 2012 1-hour ozone attainment demonstration, we have considered supplemental technical information, including ambient air quality monitoring data, which was not available at the time the attainment modeling was performed by SCAQMD. This information is discussed in more detail in the ''Review of the Modeling for the Attainment Demonstration for the Proposed Rulemaking Action on the South Coast 2012 AQMP for the One Hour Ozone Standard'' memorandum in the docket. The most recent ambient air quality data that we have reviewed indicate that the area is on track to attain the 1-hour ozone standard by December 31, 2022. The 1-hour ozone design value has decreased from 23.4 expected exceedance days in 2000–2002 (average each year) to 5.5 expected exceedance days in 2010–2012. The peak 1-hour concentration has decreased from 0.169 ppm in 2002 to 0.147 ppm in 2012.

Based on the analysis above and in the technical memorandum in the docket, EPA proposes to find that the air quality modeling provides an adequate basis for the 1-hour ozone attainment demonstration in the 2012 AQMP.

III. Proposed Action and Request for Public Comment

For the reasons discussed above, under section 110(k) of the CAA, the EPA is proposing to approve certain ozone-related portions of the 2012 South Coast AQMP as a revision to the California SIP. The relevant portions of the 2012 AQMP that are proposed for approval include the updated control strategy for the 1997 8-hour ozone standard and the demonstration of attainment of the 1-hour ozone standard in the South Coast by December 31, 2022. In so doing, we are proposing to approve the following commitments or measures upon which the 1-hour ozone attainment demonstration relies and that support update the approved control strategy for the 1997 8-hour ozone standard:

- SCAQMD's commitments to develop, adopt, submit and implement the measures as listed in table 5, above, subject to findings of infeasibility and measure substitution, and a commitment to meet aggregate emissions reductions targets of 5.8 tpd of VOC and 10.7 tpd of NO_X by January 1, 2022;
- The new technology measures listed in table 6, above to achieve emissions reductions of 17 tpd of VOC and 150 tpd of NO_X; in the South Coast by January 1, 2022; and
- CARB's commitment to submit contingency measures by January 1, 2019 as necessary to ensure that the emissions reductions from new technology measures are achieved.

In proposing approval, EPA finds that an attainment date of December 31, 2022 is appropriate in light of the severity of the 1-hour ozone problem in the South Coast and given the extent to which emissions sources in the South Coast have already been controlled and the difficulty of developing regulations and controlling additional emissions. EPA also finds that the South Coast 1-hour ozone attainment demonstration is based on reasonable estimates and forecasts of ozone precursor emissions and appropriate photochemical modeling techniques and assumptions and an acceptable control strategy.

We are taking public comments for thirty days following the publication of this proposed rule in the **Federal Register**. We will take all comments into consideration in our final rule.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submittal that complies with the provisions of the Actand 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 proposed action merely approves a state plan as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed 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, October 7, 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 proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: May 5, 2014.

Jared Blumenfeld,

Regional Administrator,EPA Region IX.

[FR Doc. 2014–11510 Filed 5–22–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2013–0400; FRL–9911–40–Region 6]

Approval and Promulgation of Implementation Plans; Texas; Control of Air Pollution From Nitrogen Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Texas State Implementation Plan (SIP) submitted by the Texas Commission on Environmental Quality (TCEQ) for Control of Air Pollution from Nitrogen Compounds. Specifically, three separate revisions were submitted to EPA with letters dated April 13, 2012, May 8, 2013, and May 14, 2013, respectively. We are proposing to approve these three submittals in accordance with the federal Clean Air Act (the Act, CAA).

DATES: Comments must be received on or before June 23, 2014.

ADDRESSES: Submit your comments identified by Docket No. EPA–R06–OAR–2013–0400 by one of the following methods:

- *www.regulations.gov.* Follow the on-line instructions.
- *Email:* Mr. Alan Shar at *shar.alan@epa.gov.*
- *Mail or delivery:* Air Planning Section Chief (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.

Instructions: Direct your comments to Docket ID No. EPA–R06–OAR–2013–0400. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information through *www.regulations.gov* or email, if you believe that it is CBI or otherwise protected from disclosure. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means that 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 along with any disk or CD–ROM submitted. 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 and any form of encryption and should be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *www.epa.gov/epahome/dockets.htm.*

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available at either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment with the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below.

FOR FURTHER INFORMATION CONTACT: Mr. Alan Shar (6PD–L), Air Planning Section, (214) 665–6691, *shar.alan@epa.gov.*

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

Outline

I. Background
A. What actions are we proposing?
1. The April 13, 2012 Submittal
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I. Background

A. What actions are we proposing?

We are proposing to approve three separate revisions to the Texas SIP submitted to EPA for review and evaluation with three letters dated April 13, 2012, May 8, 2013, and May 14, 2013, from the TCEQ. These three separate submittals are described below.

1. The April 13, 2012 Submittal

In a letter dated October 25, 2010, EPA requested that the TCEQ withdraw and revise its System Cap Trading (SCT) rules under 30 TAC Chapter 101 from SIP consideration. The EPA proposed disapproval of the TCEQ's SCT program on November 18, 2010, (75 FR 70654); and consequently, the TCEQ repealed and withdrew its SCT program rules from EPA's consideration as a SIP revision. Because of the TCEQ's repeal and withdrawal of the SCT program rule from the Texas SIP, on April 8, 2011, (76 FR 19739) EPA withdrew its proposed disapproval of the Texas SCT program rules. The 30 TAC Chapter 117 rules of NO_X cross-reference the SCT program rules of 30 TAC Chapter 101. Given the cross-reference linkage between the two rules, later, on April 13, 2012, the TCEQ submitted revisions to the 30 TAC Chapter 117 rule to EPA for review and evaluation.

The revisions to 30 TAC Chapter 117 remove references to the term ''system cap trading'' for utility electric generation sources operating in major ozone nonattainment areas and the East and Central Texas Counties. The revisions concern sections 117.1020, 117.1120, 117.1220, 117.3020, and 117.9800. The State's adopted rule was published on April 13, 2012, at 37 Texas Register 2655.

The intended effect of this removal is that the April 13, 2012, revisions to 30 TAC Chapter 117 and their corresponding provisions of 30 TAC Chapter 101 will become consistent. See section 1 of the Technical Support Document (TSD) prepared in conjunction with this rulemaking action for more information.

2. The May 8, 2013 Submittal

With a letter dated May 8, 2013, the TCEQ submitted revisions to the 30 TAC Chapter 117, Subchapter D, Division 2, Dallas Fort Worth (DFW) Eight-Hour Ozone Nonattainment Area, Minor Sources. The revisions specifically concern sections 117.2103, 117.2130, 117.2135, and 117.2145. Halliburton Energy Services, Inc., located in Carrollton, Texas 75006 petitioned the TCEQ to be allowed an additional exemption in the rules in 30 TAC Chapter 117, Subchapter D, Division 2 that limit NO_X emissions from minor sources in the DFW 8-Hour ozone nonattainment area. The TCEQ approved the petition, and initiated the rulemaking process. The State's adopted rule was published on April 26, 2013, at 38 Texas Register 2634. See section 2 of the TSD for more information. On May 8, 2013, the TCEQ submitted their adopted rule revisions to EPA, requesting EPA's evaluation and approval.

3. The May 14, 2013 Submittal

With a letter dated May 14, 2013, the TCEQ submitted revisions to the 30 TAC Chapter 117 to update references to Electric Reliability Council of Texas, Incorporated (ERCOT) protocols and reflect changes to ERCOT's new Emergency Service Response (ERS) program. The ERCOT manages the electrical grid within the ERCOT region of Texas, with oversight by the Public Utility Commission of Texas.

Specifically, the May 14, 2013, submittal concerns revisions to the definition of emergency situation in section 117.10 Definitions. The State's adopted rule was published on April 26, 2013, at 38 Texas Register 2623. See section 3 of the TSD for more information. On May 14, 2013, the TCEQ submitted their adopted rule revisions to EPA, requesting EPA's evaluation and approval.

II. Evaluation

Our evaluation of these three submittals is as follows:

A. What is our evaluation of the April 13, 2012, submittal?

The SCT program was created to provide additional flexibility to facilities subject to emission limits specified in 30 TAC Chapter 117. Through use of emission credits generated from each affected source one could determine the compliance of these sources with their applicable NO_X control requirements. See section 117.9800.

The TCEQ later repealed and withdrew its SCT program rules from 30 TAC Chapter 101. The April 13, 2012, revisions to Chapter 117 remove references to SCT from sections 117.1020, 117.1120, 117.1220, 117.3020, and 117.9800. The removal of references to SCT from Chapter 117 rules will make both the trading rules of Chapter 101 and the NO_X control rules of Chapter 117 consistent, and will clarify the available compliance options for electric generating units in Texas. See EPA's November 1, 2011, letter to the TCEQ. The revision is administrative in nature. Therefore, we are proposing to approve the April 13, 2012, revisions to Chapter 117 into the Texas SIP.

B. What is our evaluation of the May 8, 2013, submittal?

In response to a petition from Haliburton, the TCEQ adopted a revision to their SIP that exempts stationary diesel engines that are used exclusively for product testing and personnel training, operate less than 1,000 hours per year on a rolling 12-month basis, and meet applicable EPA's Tier emission standards for non-road engines listed in 40 CFR 89.112(a), Table 1 (October 23, 1998) in effect at the time of installation, modification, reconstruction, or relocation. In addition, they have included monitoring and recordkeeping requirements for demonstrating compliance. We have included a section by section review of the affected provisions of Chapter 117 (sections 117.2103, 117.2130, 117.2135, 117.2145) of the May 8, 2013, submittal in the TSD. See section 2, and Appendix A of the TSD.

Halliburton operates a stationary, reciprocating internal combustion engine (the drawworks engine) for the purposes of employee training and product testing at its Carrollton, Texas Plant. The drawworks engine is used for lifting and lowering casing into the test well at this plant. The test well is used solely for purposes of employee training and down-hole product testing, and is not associated with the actual oil or gas production operations. Engines used to raise and lower down-hole equipment in actual oil and gas operations in the field, which the drawworks engine is designed to simulate, are typically not subject to similar Chapter 117 testing requirements because they are not installed at one location long enough to trigger the definition of a stationary internal combustion engine in section 117.10. According to the records, the drawworks engine was installed in 2010, and the emissions testing results are compliant with the federal Tier 3 emission standards for non-road engines listed in 40 CFR 89.112(a), Table 1.

According to section 110(l) of the Act, each revision to an implementation plan submitted by a State under this chapter shall be adopted by such State after reasonable notice and public hearing. The Administrator shall not approve a revision of a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of this chapter. The TCEQ submitted a 110(l) analysis and additional information as a part of the May 8, 2013, submittal. Also, see the April 26, 2013, issue of Texas Register at 38 TexReg 2634.

As a part of this analysis we are considering the following factors: (a) The engine has been shown to meet the Tier 3 emission standards for non-road engines listed in 40 CFR 89.112(a), Table 1; (b) NO_X emissions reductions from the engine were not relied upon in the DFW attainment demonstration SIP revision for creditable reductions; (c) this unit operates less than 1,000 hours per year; (d) actual NO_X emissions from the engine is calculated to be 0.87 tons per year (tpy) which is substantially below the 50 tpy threshold; (e) the engine is dedicated exclusively to employee training and product testing activities, and is not used for the actual oil and gas production operations; (f) section 117.2135(e) states that engine's operating time must be monitored with a non-resettable elapsed run time meter to demonstrate compliance with the operating restrictions in 117.2103(10); and (g) section 117.2145(b) requires that the records be maintained for at least five years and must be made available upon request to the State, EPA, or any local air pollution control agency having jurisdiction. Furthermore, the adopted exemption is narrow in scope and consistent with the similar existing exemptions for stationary diesel engines located at minor sources, such as stationary engines used in research and testing and stationary engines used for purposes of performance verification and testing. See sections 117.2003(a)(2)(B) and 117.2003(a)(2)(C). Therefore, we are proposing to agree with the TCEQ's explanation and the reasons as to why expansion of this partial exemption, in itself, does not adversely impact the status of the Texas' progress towards attainment of the 1997 eight-hour ozone standard, will not interfere with control measures, and will not prevent reasonable further progress toward attainment of the ozone standard. For these reasons, we find their 110(l) analysis adequate for the purpose of evaluation of the proposed revisions to 30 TAC Chapter 117. Therefore, we are proposing to approve the May 8, 2013, revisions to Chapter 117 into Texas SIP.

C. What is our evaluation of the May 14, 2013, submittal?

The May 14, 2013, revisions to the 30 TAC Chapter 117 update references to ERCOT's definition of ''emergency situation'' and its new ERS program that replaced the former Emergency Interruptible Load Service Program. The changes made by ERCOT are intended to promote electric power reliability during energy emergencies by allowing operation of generators for the purpose of selling power to the electric grid under limited circumstances. The revision to the definition of ''emergency situation'' in section 117.10(15) will make the 30 TAC Chapter 117 definitions of ''emergency situation'' consistent with the ERCOT's Nodal Protocols Section 2 (Definitions and Acronyms) of June 1, 2012. The adopted amendment does not increase the number of sources that could qualify for exemption under the Chapter 117 rules, or increase the frequency or duration of the operation during an emergency situation as compared to the approved SIP. Therefore, the adopted rulemaking will not contribute to nonattainment with the ozone NAAQS and is therefore consistent with section 110(l) of the Act. Therefore, we are proposing to approve the May 14, 2013 revisions to Chapter 117 into Texas SIP.

III. Proposed Action

Today, we are proposing to approve the April 13, 2012, revisions to 30 TAC Chapter 117 sections 117.1020, 117.1120, 117.1220, 117.3020, and 117.9800 to remove reference to SCT program rule from these sections. We are proposing to approve the May 8, 2013, revisions to 30 TAC Chapter 117 sections 117.2103, 117.2130, 117.2135, and 117.2145, to allow for partial exemption of oil and gas drawworks engines used for personnel training and product testing from NO_X control requirements. We are also proposing to approve the May 14, 2013, revisions to 30 TAC Chapter 117 section 117.10(15), to update the definition of emergency. We are proposing to approve these revisions to 30 TAC Chapter 117 into Texas 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. If a portion of the plan revision meets all the applicable requirements of this chapter and Federal regulations, the Administrator may approve the plan revision in part. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices that meet the criteria of the Act, and to disapprove state choices that do not meet the criteria of the Act. Accordingly, this proposed action approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed 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;
- 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); and
- 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.

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Reporting and recordkeeping requirements.

Dated: May 13, 2014.

Ron Curry,

Regional Administrator, Region 6.

[FR Doc. 2014–12024 Filed 5–22–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0008; FRL–9910–29]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before June 23, 2014.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed at the end of the pesticide petition summary of interest.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that

you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), (21 U.S.C. 346a), requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available online at *http://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), (21 U.S.C. 346a(d)(3)), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

New Tolerance

1. *PP 3E8178.* (EPA–HQ–OPP–2014–0297). PHARMAQ AS, P.O. Box 267 Skoyen, N–0213 Oslo, Norway c/o Center for Regulatory Services Inc., PHARMAQ AS, 5200 Wolf Run Shoals Road, Woodbridge, VA 22192, requests to establish an import tolerance in 40 CFR part 180 for residues of the insecticide deltamethrin, [(1R, 3R)-3(2,2-dibromovinyl)-2,2-dimethylcyclopropane-carboxylic acid (S)-alpha-cyano-3-phenoxybenzyl ester] and its major metabolites trans-deltamethrin [(s)-alpha-cyano-3-phenoxybenzyl-(1R, 3S) -3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and alpha-R-deltamethrin [(R)-alphacyano-3-phenoxybenzyl-(1R, 3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate], in or on Fin fish at 0.01 parts per million (ppm). A gas chromatography-mass spectrometry (GC–MS) method for determination of deltamethrin in Fish has been submitted to the EPA.

2. *PP 3E8226.* (EPA–HQ–OPP–2014–0207). Cheminova A/S, 1600 Wilson Blvd., Suite 700, Arlington, VA 22209–2510, requests to establish import tolerances in 40 CFR part 180 for residues of the insecticide gamma-cyhalothrin, in or on Fruit, citrus, group 10–10 at 0.07 ppm; Citrus, dried pulp at 0.2 ppm; and Citrus, oil at 3.5 ppm. An adequate analytical method for determining lambda-cyhalothrin in plant matrices has been previously submitted and accepted by EPA. (**Note:** The analytical enforcement methods for lambda-cyhalothrin are applicable for determination of gamma-cyhalothrin residues.)

3. *PP 3E8228.* (EPA–HQ–OPP–2014–0248). Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419–8300, requests to establish import tolerances in 40 CFR part 180 for residues of the fungicide azoxystrobin, (methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) and the Z isomer of azoxystrobin, (methyl (Z)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]pheny1}-3-methoxyacrylate) in or on the agricultural commodities, in or on Coffee, bean, green at 0.03 ppm; Pear, Asian at 0.07 ppm; and Tea at 10 ppm. An adequate analytical method, GC with nitrogen-phosphorus detection (GC–NPD) or in mobile phase by high performance liquid chromatography with ultra-violet detection (HPLC–UV), is available for enforcement purposes with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. The Analytical Chemistry section of the EPA concluded that the method(s) are adequate for enforcement. Analytical methods are also available for analyzing Meat, Milk, Poultry and Eggs which also underwent successful independent laboratory validations.

4. *PP 4E8239.* (EPA–HQ–OPP–2014–0161). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to establish tolerances in 40 CFR part 180 for combined residues of the herbicide sethoxydim, 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one, and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide), in or on the following raw agricultural commodities: Berry, low growing,

subgroup 13–07H, except strawberry at 2.5 ppm; Bushberry, subgroup 13–07B at 5.0 ppm; Caneberry subgroup 13–07A at 5.0 ppm; Fescue, forage at 6.0 ppm; Fescue, hay at 4.0 ppm; Fruit, citrus, group 10–10 at 0.5 ppm; Fruit, pome, group 11–10 at 0.2 ppm; Fruit, small, vine climbing, subgroup 13–07F, except fuzzy kiwifruit at 1.0 ppm; Rapeseed subgroup 20A at 35 ppm; Sunflower subgroup 20B, except safflower, seed at 7.0 ppm; Cottonseed subgroup 20C at 5.0 ppm; Vegetable, bulb, group 3–07 at 1.0 ppm; and Vegetable, fruiting, group 8–10 at 4.0 ppm. Analytical methods for detecting levels of sethoxydim and its metabolites in or on food with a limit of detection (LOD) that allows monitoring of food with residues at or above the level in these tolerances were submitted to EPA. The proposed analytical method involves extraction, partition, and clean-up. Samples are then analyzed by GC with sulfur-specific flame photometric detection. The limit of quantitation (LOQ) is 0.05 ppm.

5. *PP 4E8244.* (EPA–HQ–OPP–2014–0230). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to establish tolerances in 40 CFR part 180 for residues of the residues of fungicide metconazole, 5-[(4-chlorophenyl)-methyl]-2, 2-dimethyl-1-(1H–1,2,4-triazol-1-ylmethyl) cyclopentanol, measured as the sum of *cis*- and *trans*- isomers in or on the following raw agricultural commodities: Fruit, stone, group 12–12 at 0.2 ppm; Nut, tree, group 14–12 at 0.04 ppm; Pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm; Rapeseed subgroup 20A at 0.08 ppm; and Sunflower subgroup 20B at 0.9 ppm. Independently validated analytical methods have been submitted for analyzing parent metconazole residues with appropriate sensitivity for crops and processed commodities for which a tolerance is being requested.

6. *PP 3F8164.* (EPA–HQ–OPP–2013–0644). Gowan Company, P.O. Box 5569, Yuma, AZ 85366, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide, zoxamide (3, 5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide) and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH–1455 and RH–141455) and 3,5-dichloro-4-hydroxymethylbenzoic acid (RH–1452 and RH–141452) calculated as the stoichiometric equivalent of zoxamide, in or on Onion, bulb, subgroup 3–07A at 0.7 ppm. A GC with electron capture detection (GC/ECD) and GC with mass selective detection (GC/MSD) are available for tolerance enforcement for plant commodities as primary and confirmatory methods, respectively. Adequate multiresidue methods are available for enforcement of tolerances for zoxamide only.

7. *PP 3F8187.* (EPA–HQ–OPP–2013–0255). BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709, requests to establish a tolerance in 40 CFR part 180 for residues of the metrafenone, (3-bromo-6-methoxy-2-methylphenyl)(2,3,4-trimethoxy-6-methylphenyl)methanone in or on Vegetables, fruiting, group 8–10 at 1.0 ppm. The residues of parent metrafenone in/on Tomato and Pepper RAC samples were quantitated using an LC/MS/MS multi-residue QuEChERS method (BASF Study No. 398340). The method was successfully validated on Tomatoes and Peppers in conjunction with these studies prior to analysis of the field samples. Acceptable concurrent method recovery data for Tomato and Pepper RAC samples were also obtained for metrafenone. The validated limit of quantitation (LOQ) for residues of metrafenone in/on Tomato and Pepper RAC samples was 0.01 ppm. The method LOD was 0.001 ppm, or approximately 10% of the LOQ. An independent laboratory validation demonstrated good performance of the QuEChERS method.

8. *PP 3F8190.* (EPA–HQ–OPP–2013–0662). Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide, fluopyram (*N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide), in or on Soybean, seed at 0.04 ppm; Cotton, seed at 0.01 ppm; Cotton, gin by-products at 0.80 ppm; Peanut at 0.09 ppm; Grain, cereal, group 15 except rice at 0.03 ppm; Grain, cereal, forage, group 16 at 1.5 ppm; and Grain, cereal, fodder, hay, and straw, group 16, at 2.0 ppm; and for residues of fluopyram and its metabolite 2-(trifluoromethyl)benzamide, expressed in parent equivalents in or on Milk at 0.10 ppm; Beef, fat at 0.10 ppm; Beef, byproducts at 0.70 ppm; Beef, meat at 0.10 ppm; Egg at 0.15 ppm; Poultry, fat at 0.10 ppm; Poultry, meat at 0.10 ppm; Poultry, meat byproducts at 0.20 ppm; Hog, fat at 0.05 ppm; Hog meat at 0.10 ppm; and Hog, meat byproducts at 0.70 ppm. Fluopyram is the residue of concern for enforcement in plant commodities required for analysis based on the metabolic profile. In animal commodities, the residue of concern is fluopyram and fluopyram-benzamide. The analytical methods involve solvent extraction, filtration and addition of an isotopically labeled internal standards followed by solid phase extraction. Quantitation is by LC–MS/MS.

9. *PP 3F8220.* (EPA–HQ–OPP–2014–0114). E.I. du Pont de Nemours & Company (''DuPont''), 1007 Market Street, Wilmington, DE 19898, requests to establish tolerances in 40 CFR part 180 for residues of the fungicide oxathiapiprolin, 1-(4-{4-[(5RS)-5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}-1-piperidyl)-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl] ethanone, in or on the following commodities: Grapes (import tolerance) at 0.9 ppm; Vegetable, root and tuber vegetables, tuberous and corm vegetables (crop subgroup 1C) at 0.01 ppm; Bulb vegetables, onion, bulb (crop subgroup 3–07A) at 0.04 ppm; Bulb vegetables, onion, green (crop subgroup 3–07B) at 2 ppm; Fruiting vegetables (crop group 8–10) at 0.2 ppm; Cucurbit vegetables (crop group 9) at 0.2 ppm; *Brassica* (cole) leafy vegetables, head and stem *Brassica* (crop subgroup 5A) at 1.5 ppm; Leafy vegetables (except *Brassica* vegetables), Leafy greens (crop subgroup 4A) at 15 ppm; Peas, edible podded at 1 ppm; Peas, succulent, shelled at 0.05 ppm; and Ginseng root at 0.4 ppm. Adequate analytical methodology, HPLC–MS/MS detection, is available for enforcement purposes.

10. *PP 3F8227.* (EPA–HQ–OPP–2014–0153). ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio 44077, requests to establish tolerances in 40 CFR part 180 for residues of the fungicide pyriofenone, (5-chloro-2-methoxy-4-methyl-3-pyridinyl)(2,3,4-trimethoxy-6-methylphenyl)methanone, including its metabolites and degradates, in or on Cucurbit Vegetables, (Crop Group 9) at 0.3 ppm; and Berry and Small Fruit (Crop Group 13–07), except Large shrub/tree berry subgroup 13–07C at 0.9 ppm. A practical analytical method for pyriofenone using liquid chromatography-mass spectrometry/MS (LC/MS/MS) is available for analysis of grapes. This method has been confirmed through independent laboratory validation and is available for enforcement purposes.

Amended Tolerance

1. *PP 4E8239.* (EPA–HQ–OPP–2014–0161). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to remove the existing tolerances in 40 CFR 180.412 for combined residues of the herbicide sethoxydim, 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one, and its metabolites

containing the 2-cyclohexen-1-one moiety (calculated as the herbicide), in or on the following commodities are removed, including: Blueberry at 4.0 ppm; Borage, seed at 6.0 ppm; Caneberry subgroup 13A at 5.0 ppm; Canola, seed at 35.0 ppm; Cotton, undelinted seed at 5.0 ppm; Crambe, seed at 35.0 ppm; Cranberry at 2.5 ppm; Cuphea, seed at 35.0 ppm; Echium, seed at 35.0 ppm; Flax, seed at 5.0 ppm; Fruit, citrus, group 10 at 0.5 ppm; Fruit, pome, group 11 at 0.2 ppm; Gold of pleasure, seed at 35.0 ppm; Grape at 1.0 ppm; Hare's ear mustard, seed at 35.0 ppm; Juneberry at 5.0 ppm; Lesquerella, seed at 35.0 ppm; Lingonberry at 5.0 ppm; Lunaria, seed at 35.0 ppm; Meadowfoam, seed at 35.0 ppm; Milkweed, seed at 35.0 ppm; Mustard, seed at 35.0 ppm; Oil radish, seed at 35.0 ppm; Poppy, seed at 35.0 ppm; Rapeseed, seed at 35.0 ppm; Salal at 5.0 ppm; Sesame, seed at 35.0 ppm; Sunflower, seed at 7.0 ppm; Sweet rocket, seed at 35.0 ppm; Vegetable, bulb, group 3 at 1.0 ppm; and Vegetable, fruiting, group 8 at 4.0 ppm, upon establishment of the proposed tolerances listed in 4. under ''New Tolerance''.

2. *PP 4E8244.* (EPA–HQ–OPP–2014–0230). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540, proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.617 by removing tolerances for residues of the fungicide metconazole, 5-[(4-chlorophenyl)-methyl]-2, 2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl) cyclopentanol, measured as the sum of *cis*- and *trans*-isomers in or on the following raw agricultural commodities: Canola seed at 0.04 ppm; Fruit, stone, group 12 at 0.2 ppm; Pistachio at 0.04 ppm; and Nut, Tree, Group 14 at 0.04 ppm. Upon establishment of the proposed tolerances listed in 5. under ''New Tolerance'', these previously established tolerances will be superseded by inclusion in crop group or subgroup tolerances established by this action.

3. *PP 3F8191.* (EPA–HQ–OPP–2014–0225). Valent USA Corporation, 1101 14th Street, NW., Suite 1050, Washington, DC 20005, requests to amend the tolerances in 40 CFR 180.627 for residues of the fungicide fluopicolide, [2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide], including its metabolites and degradates, in or on Vegetable, tuberous and corm subgroup 1C from 0.02 ppm to 0.3 ppm; and Potato, processed waste from 0.05 ppm to 0.3 ppm. Compliance with the tolerance levels specified below is to be determined by measuring only fluopicolide [2,6-dichloro-*N*-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide] in or on the commodity. The Valent method RM-43C-1 by LC/MS/MS is used to measure and evaluate the chemical fluopicolide.

4. *PP 3F8214.* (EPA–HQ–OPP–2014–0210). FMC Corporation, 1735 Market Street, Philadelphia, PA 19103, requests to amend the tolerances in 40 CFR 180.418 for the residues of the insecticide zeta-cypermethrin, in or on Alfalfa, forage from 5.0 ppm to 15.0 ppm; and Alfalfa, hay from 15.0 ppm to 30.0 ppm. There is a practical analytical method (gas chromatography with Electron Capture Detection) (GC/ECD) for detecting and measuring levels of cypermethrin and zeta-cypermethrin in or on food with a limit of detection (LOD) that allows monitoring of food with residues at or above the levels set in these tolerances.

List of Subjects in 40 CFR Part 180

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 15, 2014.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2014–11904 Filed 5–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 495

[CMS–0052–P]

RIN 0938–AS30

Office of the Secretary

45 CFR Part 170

RIN 0991–AB97

Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record Incentive Programs for 2014; and Health Information Technology: Revisions to the Certified EHR Technology Definition

AGENCY: Centers for Medicare & Medicaid Services (CMS), and Office of the National Coordinator for Health Information Technology (ONC), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would change the meaningful use stage timeline and the definition of certified electronic health record technology (CEHRT). It would also change the requirements for the reporting of clinical quality measures for 2014.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 21, 2014.

ADDRESSES: In commenting, please refer to file code CMS–0052–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0052–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0052–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and

Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Holland, (410) 786–1309.

Elisabeth Myers, (410) 786–4751.

Steven Posnack, (202) 690–7151.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Statutory Basis for the Medicare and Medicaid EHR Incentive Programs

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) amended Titles XVIII and XIX of the Social Security Act (the Act) to authorize incentive payments to eligible professionals (EPs), eligible hospitals, critical access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of certified electronic health record (EHR) technology. Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to meaningful EHR users. These statutory provisions govern EPs, MA organizations (for certain qualifying EPs and hospitals that meaningfully use certified EHR technology (CEHRT), subsection (d) hospitals, and CAHs, respectively. Sections 1848(a)(7), 1853(l) and (m), 1886(b)(3)(B), and 1814(l) of the Act also establish downward payment adjustments, beginning with calendar or fiscal year 2015, for EPs, MA organizations, subsection (d) hospitals, and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for Medicaid incentive payments.

B. Considerations in Defining Meaningful Use and CEHRT

In sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act, the Congress identified the broad goal of expanding the use of EHRs through the concept of meaningful use. Section 1903(t)(6)(C) of the Act also requires that Medicaid providers adopt, implement, upgrade, or meaningfully use CEHRT if they are to receive incentives under Title XIX of the Act. CEHRT used in a meaningful way is one piece of the broader health information technology (HIT) infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. This vision of reforming the health care system and improving health care quality, efficiency, and patient safety should inform the definition of meaningful use.

Certified EHR technology is defined for the Medicare and Medicaid EHR Incentive Programs at 42 CFR 495.4, which references the Office of the National Coordinator for Health Information Technology's (ONC) definition of CEHRT under 45 CFR 170.102. For Stages 1 and 2 of meaningful use, CMS and ONC worked closely to ensure that the definition of meaningful use of CEHRT and the standards and certification criteria for CEHRT were coordinated. The definition of CEHRT under 45 CFR 170.102 requires, beginning with Federal fiscal year (FY) and calendar year (CY) 2014, EHR technology certified to the 2014 Edition EHR certification criteria. Therefore, all EPs, eligible hospitals, and CAHs must use 2014 Edition CEHRT to meet meaningful use under the Medicare and Medicaid EHR Incentive Programs beginning with FY 2014 and CY 2014.

On September 4, 2012, we published in the **Federal Register** (77 FR 53968 through 54162) a final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2,'' that established, among other final policies, the timeline for the stages of meaningful use through 2021 and the EHR reporting periods in 2014, as shown in Table 1 (77 FR 53973 through 53975).

TABLE 1—STAGE OF MEANINGFUL USE CRITERIA BY FIRST PAYMENT YEAR

First payment year	Stage of meaningful use										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2011	1	1	1	*2	2	3	3	TBD	TBD	TBD	TBD
2012	.....	1	1	*2	2	3	3	TBD	TBD	TBD	TBD
2013	.....	.....	1	*1	2	2	3	3	TBD	TBD	TBD
2014	.....	.....	.....	*1	1	2	2	3	3	TBD	TBD
2015	.....	.....	.....	.....	1	1	2	2	3	3	TBD
2016	.....	.....	.....	.....	.....	1	1	2	2	3	3
2017	.....	.....	.....	.....	.....	.....	1	1	2	2	3

*3-month quarter EHR reporting period for Medicare and continuous 90-day EHR reporting period (or 3 months at state option) for Medicaid EPs. All providers in their first year in 2014 use any continuous 90-day EHR reporting period.

EPs, eligible hospitals, and CAHs that attest to meaningful use for 2014 for their first year of Stage 2 or their second year of Stage 1 have a 3-month quarter EHR reporting period in CY 2014 (EPs) or FY 2014 (eligible hospitals and CAHs). For the Medicaid incentive payments for meaningful use, EPs have an EHR reporting period of any continuous 90-day period in CY 2014 as defined by the State Medicaid program, or, if the State so chooses, any 3-month

CY quarter in 2014. EPs, eligible hospitals, and CAHs that demonstrate meaningful use for the first time in 2014 have an EHR reporting period of any continuous 90-day period in CY 2014 or FY 2014, respectively.

II. Provisions of the Proposed Regulations

A. Proposed Changes to Meaningful Use Stage Timeline and the Use of CEHRT

1. Reporting in 2014

We are revisiting some of the requirements for the Medicare and Medicaid EHR Incentive Programs for 2014. Many EHR vendors have indicated, through letters to CMS, public forums and listening sessions, survey data, and information related to the certification and testing process, that the amount of time available after the publication of the Stage 2 final rule in which to make the required coding changes to enable their EHR products to be certified to the 2014 Edition of EHR certification criteria was much too short. We understand, based on information gained from EHR technology developers and ONC-Authorized Certification Bodies on timing, backlogs, and the certification case load, many EHR products were certified later than anticipated, which has impacted the corresponding time available to providers—especially hospitals—to effectively deploy 2014 Edition CEHRT and to make the necessary patient safety, staff training, and workflow investments in order to be prepared to demonstrate meaningful use in 2014. The availability of 2014 Edition CEHRT is further limited by the large number of providers needing to upgrade to 2014 Edition CEHRT. By the end of February 2014, over 350,000 providers had received an EHR incentive payment for adopting, implementing, or upgrading, or for successfully demonstrating meaningful use using 2011 Edition CEHRT. All providers need 2014 Edition CEHRT to adopt, implement, or upgrade, or to successfully demonstrate meaningful use for Stage 1 or Stage 2 in 2014. Through letters to CMS, public forums, listening sessions, and public comment at CMS meetings, many provider associations have expressed concern that, although 2014 Edition CEHRT may be available for adoption, there is a backlog of many months for the updated version to be installed and implemented so that providers can successfully attest for 2014. We also understand that the delay in availability may limit a provider's ability to fully implement 2014 Edition CEHRT across the facility. For example, (1) a hospital may have different systems in multiple settings, which all require an update and integration or (2) a provider may have certain 2014 Edition CEHRT functionality that, once implemented in a live setting, requires software patches or workflow changes.

In an effort to grant more flexibility to providers who have experienced 2014 Edition CEHRT product availability issues that impact the ability to fully implement 2014 Edition CEHRT to attest to meaningful use using 2014 Edition CEHRT, we are proposing the following changes for the Medicare and Medicaid EHR Incentive Programs for 2014 for providers that are not able to fully implement 2014 Edition CEHRT for a full EHR reporting period in 2014. We are proposing to allow these EPs, eligible hospitals, and CAHs that could not fully implement 2014 Edition CEHRT for the 2014 reporting year due to delays in 2014 Edition CEHRT availability to continue to use 2011 Edition CEHRT or a combination of 2011 Edition and 2014 Edition CEHRT for the EHR reporting periods in CY 2014 and FY 2014, respectively. These proposed alternatives are for providers that could not fully implement 2014 Edition CEHRT to meet meaningful use for the duration of an EHR reporting period in 2014 due to delays in 2014 Edition CEHRT availability.

We are proposing this change for 2014 only. We will maintain the existing policy that all providers must use 2014 Edition CEHRT for the EHR reporting periods in CY 2015, FY 2015, and in subsequent years or until new certification requirements are adopted in subsequent rulemaking.

We strongly recommend eligible professionals, eligible hospitals, and CAHs that have not yet purchased EHR technology to obtain 2014 Edition CEHRT as these providers will still need to use 2014 Edition CEHRT for their EHR reporting period in 2015 as stated earlier.

In order to avoid inadvertently incentivizing the purchase of an outdated product that cannot be used to demonstrate meaningful use in a subsequent year, we are proposing that to qualify for an incentive payment under Medicaid for 2014 for adopting, implementing, or upgrading CEHRT, a provider must adopt, implement, or upgrade to 2014 Edition CEHRT only. A provider would not be able to qualify for a Medicaid incentive payment for 2014 for adopting, implementing, or upgrading to 2011 Edition CEHRT or a combination of 2011 and 2014 Edition CEHRT. We are proposing to revise the definition of ''Adopt, Implement or Upgrade'' under 42 CFR 495.302 to reflect this proposal.

The edition of certified EHR technology which is available to a provider dictates the stage and version of the meaningful use objectives and measures to which the provider will be able to attest. For example, 2011 Edition CEHRT alone does not have the necessary functionality required to meet the Stage 2 objectives and measures. In addition, the edition of CEHRT determines which clinical quality measures a provider can calculate and report because the calculations are part of the software programming within the CEHRT system.

The three options for the use of CEHRT editions and the available Stage of meaningful use objectives and measures associated with each option are as follows:

a. Using 2011 Edition CEHRT Only

We are proposing that all EPs, eligible hospitals, and CAHs that use only 2011 Edition CEHRT for their EHR reporting period in 2014 must meet the meaningful use objectives and associated measures for Stage 1 under 42 CFR 495.6 that were applicable for the 2013 payment year, regardless of their current stage of meaningful use. We note that in the Stage 2 final rule (77 FR 53975 through 53979), we finalized certain changes to the Stage 1 objectives and associated measures, and some of those changes were applicable beginning with 2013 while other changes were applicable beginning with 2014. For ease of reference, we will refer to the Stage 1 objectives and associated measures under 42 CFR 495.6 that were applicable for 2013 as the ''2013 Stage 1 objectives and measures,'' and we will refer to the Stage 1 objectives and associated measures under 42 CFR 495.6 that are applicable for 2014 as the ''2014 Stage 1 objectives and measures.'' Providers who choose this option must attest that they are unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays when they attest to the meaningful use objectives and measures.

b. Using a Combination of 2011 and 2014 Edition CEHRT

We are proposing that all EPs, eligible hospitals, and CAHs using a combination of 2011 Edition CEHRT and 2014 Edition CEHRT for their EHR reporting period in 2014 may choose to meet the 2013 Stage 1 objectives and measures or the 2014 Stage 1 objectives and measures, or if they are scheduled to begin Stage 2 in 2014 under the timeline shown in Table 1, they may choose to meet the Stage 2 objectives and associated measures under 42 CFR

495.6. Providers who choose this option must attest that they are unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays when they attest to the meaningful use objectives and measures.

c. Using 2014 Edition CEHRT for 2014 Stage 1 Objectives and Measures in 2014 for Providers Scheduled To Begin Stage 2

A provider's ability to fully implement all of the functionality of 2014 Edition CEHRT may be limited by the availability and timing of product installation, deployment of new processes and workflows, and employee training. This effect is compounded for providers in Stage 2 as some providers may not be able to fully implement all of the functions included in 2014 Edition CEHRT that are necessary to meet the Stage 2 objectives and measures in time to complete their EHR reporting period in 2014. Therefore, under our proposal, providers who are scheduled to begin Stage 2 for the 2014 EHR reporting period but are unable to fully implement all the functions of their 2014 Edition CEHRT required for Stage 2 objectives and measures due to delays in 2014 Edition CEHRT availability would have the option of using 2014 Edition CEHRT to attest to the 2014 Stage 1 objectives and measures for the 2014 EHR reporting period. Providers who are scheduled to begin Stage 2 in 2014 who choose this option must attest that they are unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays when they attest to the meaningful use objectives and measures.

The EHR reporting periods in 2014 already have been established, and we are not proposing any changes. Under the current timeline shown in Table 1, providers that first demonstrated meaningful use Stage 1 in 2011 or 2012 are required to begin Stage 2 in 2014. We are proposing that the flexibility regarding use of the various editions of CEHRT as outlined earlier would apply only to the EHR reporting periods in 2014 for the EHR Incentive Program. Providers that were scheduled to begin Stage 2 in 2014 that instead meet the Stage 1 criteria in 2014 will be required to begin Stage 2 in 2015 as noted in Table 3. In 2015, all providers, except those in their first year of demonstrating meaningful use, are required to have a full year EHR reporting period. In addition, in 2015, all providers are required to have 2014 Edition CEHRT in order to successfully demonstrate meaningful use.

TABLE 2—PROPOSED CEHRT SYSTEMS AVAILABLE FOR USE IN 2014

If you were scheduled to demonstrate:	You would be able to attest for Meaningful Use:		
	Using 2011 Edition CEHRT to do:	Using 2011 & 2014 Edition CEHRT to do:	Using 2014 Edition CEHRT to do:
Stage 1 in 2014	2013 Stage 1 objectives and measures*.	2013 Stage 1 objectives and measures*. -OR- 2014 Stage 1 objectives and measures*.	2014 Stage 1 objectives and measures
Stage 2 in 2014	2013 Stage 1 objectives and measures*.	2013 Stage 1 objectives and measures*. -OR- 2014 Stage 1 objectives and measures*. -OR- Stage 2 objectives and measures*.	2014 Stage 1 objectives and measures* -OR- Stage 2 objectives and measures*

*Only providers that could not fully implement 2014 Edition CEHRT for the reporting period in 2014 due to delays in 2014 Edition CEHRT availability.

The following are example scenarios under our proposal.

Example A: An EP initiated participation in the Medicare EHR Incentive Program in 2011. The EP successfully demonstrated meaningful use and received incentive payments for 2011, 2012, and 2013. Based on the timeline in the Stage 2 final rule, the EP is required to use 2014 Edition CEHRT and demonstrate Stage 2 of meaningful use in 2014. Under our proposal, this EP who is scheduled to begin Stage 2 in 2014 would have the following options:

- Attest to the Stage 2 objectives and measures of meaningful use using 2014 Edition CEHRT in 2014 as scheduled.
- Attest to the Stage 2 objectives and measures of meaningful use using a combination of 2011 and 2014 Edition CEHRT in 2014 if they are unable to fully implement 2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability.
- Attest to the 2014 Stage 1 objectives and measures using 2014 Edition CEHRT or a combination of 2011 and 2014 Edition CEHRT in 2014 if they are unable to fully implement 2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability.
- Attest to the 2013 Stage 1 objectives and measures using 2011 Edition CEHRT or a combination of 2011 and 2014 Edition CEHRT in 2014 if they are unable to fully implement 2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability. Clinical quality measures must be submitted through attestation if attesting to the 2013 Stage 1 objectives and measures as discussed below in section B of this proposal.

Example B: An EP initiated participation in the Medicare EHR Incentive Program in 2013. The EP successfully demonstrated meaningful use and received an incentive payment for 2013. Based on the timeline in the Stage 2 final rule, the EP is required to use 2014 Edition CEHRT and demonstrate Stage 1 of meaningful use in 2014. Under our proposal, this EP would have one of the following options:

- Attest using 2014 Edition CEHRT to the 2014 Stage 1 objectives and measures of meaningful use in 2014 as scheduled.
- Attest using a combination of 2011 and 2014 Edition CEHRT and meet the 2014 Stage 1 objectives and measures of meaningful use in 2014 if they are unable to fully implement 2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability.
- Attest using 2011 Edition CEHRT or a combination of 2011 and 2014 Edition CEHRT and meet the 2013 Stage 1

objectives and measures of meaningful use in 2014 if they are unable to fully implement 2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability. Clinical quality measures must be submitted through attestation if attesting to the 2013 Stage 1 objectives and measures as discussed in section II.B. of this proposed rule.

2. Extension of Stage 2

Under the current timeline shown in Table 1, an EP, eligible hospital or CAH that first became a meaningful user in 2011 or 2012 would be required to begin Stage 3 on January 1, 2016 (the first day of CY 2016 for EPs) or October 1, 2015 (the first day of FY 2016 for eligible hospitals or CAHs), respectively. However, because we intend to analyze the meaningful use Stage 2 data to inform our development of the criteria for Stage 3 of meaningful use, we are proposing a 1-year extension of Stage 2 for those providers as is reflected in Table 3. We are proposing that Stage 3 would begin in CY 2017 for EPs and FY 2017 for eligible hospitals and CAHs that first became meaningful users in 2011 or 2012. The goal of this proposed change is two-fold: First, to allow CMS and ONC to focus efforts on the successful implementation of the enhanced patient engagement, interoperability, and health information exchange requirements in Stage 2; and second, to utilize data from Stage 2 participation to inform policy decisions for Stage 3.

This proposed change would allow EPs, eligible hospitals, and CAHs that first became meaningful users in 2011 or 2012 to begin Stage 3 on January 1, 2017 (EPs) and October 1, 2016 (eligible hospitals and CAHs). We will maintain the existing timeline for providers that first became meaningful users in 2013 and for those that begin in 2014 and subsequent years or until new certification requirements are adopted in subsequent rulemaking, as shown in Table 3.

TABLE 3—PROPOSED STAGE OF MEANINGFUL USE CRITERIA BY FIRST PAYMENT YEAR

First payment year	Stage of meaningful use										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2011	1	1	1	*1 or 2	2	2	3	3	TBD	TBD	TBD
2012	.....	1	1	*1 or 2	2	2	3	3	TBD	TBD	TBD
2013	.....	.....	1	*1	2	2	3	3	TBD	TBD	TBD
2014	.....	.....	.....	*1	1	2	2	3	3	TBD	TBD
2015	.....	.....	.....	.....	1	1	2	2	3	3	TBD
2016	.....	.....	.....	.....	.....	1	1	2	2	3	3
2017	.....	.....	.....	.....	.....	.....	1	1	2	2	3

*3-month quarter EHR reporting period for Medicare and continuous 90-day EHR reporting period (or 3 months at State option) for Medicaid EPs. All providers in their first year in 2014 use any continuous 90-day EHR reporting period.

We invite public comment on our proposals.

B. Clinical Quality Measure Submission in 2014

In 2014, as part of the definition of ''meaningful EHR user'' under 42 CFR 495.4, all providers are required to select and report on clinical quality measures (CQMs) from the relevant sets adopted in the Stage 2 final rule (77 FR 54069 through 54075, and 77 FR 54081 through 54089 and further specified as noted in the December 7, 2012 interim final rule with comment period (77 FR 72985) and published on the CMS eCQM Library [*http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*], regardless of their stage of meaningful use or year of participation in the EHR Incentive Program. We are proposing the following changes for reporting on clinical quality measures in 2014 for EPs, eligible hospitals, and CAHs for the Medicare and Medicaid EHR Incentive Programs. The method of CQM submission under this proposal would depend on the edition of CEHRT a provider uses to record, calculate, and report its clinical quality measures for the selected EHR reporting period in 2014.

Due to limitations in the Registration and Attestation System for the EHR Incentive Program and other CMS data systems, the reporting options and methods for CQMs for 2014 would depend upon the edition of CEHRT that a provider uses for its EHR reporting period in 2014. If a provider elects to use only 2011 Edition CEHRT for its EHR reporting period in 2014, the provider would be required to report CQMs by attestation as follows:

- EPs would report from the set of 44 measures and according to the reporting criteria finalized in the Stage 1 final rule (75 FR 44386 through 44411)—
  - ++ Three core/alternate core;
  - ++ Three additional measures; and
  - ++ The reporting period would be any continuous 90 days within CY 2014 for EPs that are demonstrating meaningful use for the first time or a 3-month CY quarter for EPs that have previously demonstrated meaningful use.
- Eligible hospitals and CAHs would report all 15 measures finalized in the Stage 1 final rule (75 FR 44411 through 44422).
- The reporting period would be any continuous 90 days within FY 2014 for hospitals that are demonstrating meaningful use for the first time or a 3-month FY quarter for hospitals that have previously demonstrated meaningful use.

If a provider elects to use a combination of 2011 Edition and 2014 Edition CEHRT and chooses to attest to the 2013 Stage 1 objectives and measures for its EHR reporting period in 2014, the provider would be required to report CQMs by attestation using the same measure sets and reporting criteria outlined earlier for providers who elect to use only 2011 Edition CEHRT for their EHR reporting periods in 2014. Because of the differences in how CQMs are calculated and tested between the 2011 and the 2014 Editions of CEHRT, we are further proposing that a provider may attest to data for the CQMs derived exclusively from the 2011 Edition CEHRT for the portion of the reporting period in which 2011 Edition CEHRT was in place.

If a provider elects to use a combination of 2011 Edition and 2014 Edition CEHRT and chooses to attest to the 2014 Stage 1 objectives and measures or the Stage 2 objectives and measures, the provider would be required to submit CQMs in accordance with the requirements and policies established for clinical quality measure reporting for 2014 in the Stage 2 final rule and subsequent rulemakings. For further explanation, we refer readers to

the following: For EPs—77 FR 54049 through 54089, 77 FR 72985 through 72991, 78 FR 74753 through 74757; and for eligible hospitals and CAHs—77 FR 54049 through 54089, 77 FR 72985 through 72991, 78 FR 50903 through 50906. We are also proposing that a provider must submit CQMs in accordance with the requirements and policies established for 2014 in those rulemakings if the provider elects to use only 2014 Edition CEHRT for the entire duration of its EHR reporting period in 2014, regardless of the stage of meaningful use that the provider chooses to meet.

For the Medicaid EHR Incentive Program, the method of reporting CQMs for EPs and eligible hospitals will continue to be at the state's discretion subject to our prior approval, as established in the Stage 2 final rule (77 FR 54075 through 54078, and 54087 through 54089).

We invite public comment on our proposal.

C. Revision to the CEHRT Definition for Additional Flexibility in 2014

To support the CMS proposals to provide additional flexibility in the Medicare and Medicaid EHR Incentive Programs during 2014, ONC is proposing to make a minor, but necessary, corresponding revision to the CEHRT definition at 45 CFR 170.102.

ONC is proposing to revise the CEHRT definition to change certain Federal fiscal year (FY)/calendar year (CY) cutoffs in paragraphs (1) and (2) of the CEHRT definition under 45 CFR 170.102. These FY/CY cutoffs were finalized in ONC's 2014 Edition final rule (77 FR 54257 through 54260). The policy in paragraph (1) of the definition applies to any fiscal year/calendar year up to and including 2013. The policy in paragraph (2) of the definition applies to FY 2014/CY 2014 and all subsequent years.

Paragraph (1) sets forth policy that permitted the use of 2011 Edition certified Complete EHRs and EHR Modules, a combination of 2011 and 2014 Edition certified Complete EHRs and EHR Modules, and 2014 Edition certified Complete EHRs and EHR Modules to be used to meet the CEHRT definition through the end of FY 2013/CY 2013. However, paragraph (2) establishes policy that, starting with FY 2014/CY 2014, only the use of 2014 Edition certified Complete EHRs and EHR Modules could be used to meet the CEHRT definition.

The following specific proposed revisions to the CEHRT definition are necessary to support the added flexibility we proposed for 2014. The effect of these proposed revisions would be to allow EPs, eligible hospitals, and CAHs to use either 2011 Edition or a combination of 2011 and 2014 Edition certified Complete EHRs and EHR Modules to meet the CEHRT definition and to demonstrate meaningful use Stage 1 for 2014.

Specifically, ONC is proposing to modify the CEHRT definition at 45 CFR 170.102 to replace the following

- ''2013'' with ''2014'' in the first sentence of paragraph (1).
- ''FY and CY 2014'' with ''FY and CY 2015'' in paragraph (1)(i) and (1)(iii).
- ''2014'' with ''2015'' in the first sentence of paragraph (2).

Overall, this proposed revision would make the first day of FY 2015 (for eligible hospitals and CAHs) and CY 2015 (for eligible professionals) the new required start date for exclusive use of 2014 Edition certified Complete EHRs and EHR Modules to meet the CEHRT definition.

We invite public comment on our proposals.

III. Collection of Information Requirements

This document does not impose any new information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, as defined under the Paperwork Reduction Act of 1995 (5 CFR 1320). However, it does make reference to the currently approved information collection request associated with the Electronic Health Record Incentive Program. The information collection requirements for the program are currently approved under OMB control number 0938–1158 with an expiration date of April 30, 2015.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.0 million to $35.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately

$141 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

CMS is proposing, for 2014 only, that EPs, eligible hospitals, and CAHs would be able to use either 2011 Edition, 2014 Edition or a combination of 2011 and 2014 Edition certified Complete EHRs and EHR Modules to meet the CEHRT definition and to demonstrate meaningful use during 2014.

To support the CMS proposals to provide added flexibility in the Medicare and Medicaid EHR Incentive Programs during 2014, ONC is proposing to make a minor, but necessary, corresponding revision to the CEHRT definition specified at 45 CFR 170.102, to change certain FY/CY cutoffs in paragraphs (1) and (2) of the CEHRT definition. These FY/CY cutoffs were finalized in ONC's 2014 Edition final rule (77 FR 54257 through 54260).

With respect to our proposal to allow the flexibility to use 2011 Edition Certified EHR Technology, a combination of 2011 Edition and 2014 Edition Certified EHR Technology, or solely 2014 Edition Certified EHR Technology in 2014, we do not believe that this proposal will have a significant impact as it merely gives providers the flexibility to choose to retain and use their 2011 Edition CEHRT, a combination of 2011 and 2014 Edition CEHRT, or 2014 Edition CEHRT in 2014. We are making this proposal in response to concerns that the availability of 2014 Edition CEHRT is quite limited. We refer readers to the impact analyses included in the final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2'' (77 FR 53698 through 54162). Similarly, the ONC proposal to revise the CEHRT definition merely provides additional flexibility in support of the CMS proposals and ONC does not believe that it will have a significant impact (see ''Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology'' (77 FR 54163 through 54292)).

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance, organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For the reasons stated in the preamble of this proposed rule, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR Part 495 and the Department is proposing to amend 45 CFR Part 170 as set forth below:

Title 42—Public Health

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 1. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 495.302 is amended by adding paragraph (4) to the definition of ''Adopt, implement or upgrade'' to read as follows:

§ 495.302 Definitions.

* * * * *

Adopt, implement or upgrade means—

* * * * *

(4) For payment year 2014, the references to ''certified EHR technology'' in paragraphs (1) through (3) of this definition are deemed to be references to paragraph (2) of the definition of ''Certified EHR Technology'' under 45 CFR 170.102 (that is, the definition of ''Certified EHR Technology'' for FY and CY 2015 and subsequent years).

* * * * *

Title 45—Public Health

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 3. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552.

§ 170.102 [Amended]

■ 4. In § 170.102, the definition of ''Certified EHR Technology'' is amended as follows:

■ A. In paragraph (1) introductory text, by removing the year ''2013'' and adding in its place the year ''2014''.

■ B. In paragraph (1)(i), by removing ''; or '' and adding in its place '';''.

■ C. In paragraph (1)(iii), by removing the phrase ''FY and CY 2014'' and adding in its place the phrase ''FY and CY 2015'' and by removing the cross-reference ''paragraph (2);'' and adding in its place the cross-reference ''paragraph (2) of this definition''.

■ D. In paragraph (2), by removing the phrase ''FY and CY 2014'' and adding in its place the phrase ''FY and CY 2015''.

Dated: May 12, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: May 13, 2014.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2014–11944 Filed 5–20–14; 4:15 pm]

BILLING CODE 4120–01–P

Notices

Federal Register
Vol. 79, No. 100
Friday, May 23, 2014

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

COMMISSION ON CIVIL RIGHTS

Meeting; Sunshine Act Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Amended Notice of Business Meeting.

DATE AND TIME: Friday, May 16, 2014; 9:30 a.m. E.S.T.

PLACE: 1331 Pennsylvania Ave. NW., Suite 1150, Washington, DC 20425.

Meeting Agenda

I. Approval of Agenda
II. Program Planning
- Discussion and Vote on Part A of the briefing report: Sex Trafficking: A Gender-Based Civil Rights Violation
- Discussion and Vote on Part A of the briefing report: Engagement with Arab and Muslim American Communities Post 9/11
- Consideration and Vote on Commission Resolution Commemorating the Anniversary of the Civil Rights Act of 1964
- Consideration and Vote on Press Release commemorating the 60th Anniversary of Brown v. Board of Education

III. Management and Operations
- Staff Director's Report

IV. State Advisory Committee (SAC) Appointments
- Kansas
- Utah

Motion & Vote to Close Meeting at 10:56 a.m.

Meeting Was Reopened at 11:17 a.m.

- Connecticut
- Vermont

V. Adjourn Meeting

CONTACT PERSON FOR FURTHER INFORMATION: Lenore Ostrowsky, Acting Chief, Public Affairs Unit (202) 376–8591.

Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact Pamela Dunston at (202) 376–8105 or at *signlanguage@usccr.gov* at least seven business days before the scheduled date of the meeting.

Dated: May 20, 2014.

Marlene Sallo,

Staff Director.

[FR Doc. 2014–12058 Filed 5–21–14; 11:15 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; Survey of Housing Starts, Sales, and Completions

AGENCY: U.S. Census Bureau, 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.

DATES: To ensure consideration, written comments must be submitted on or before July 22, 2014.

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(s) and instructions should be directed to Erica Filipek, U.S. Census Bureau, MCD, CENHQ Room 7K057, 4600 Silver Hill Road, Washington, DC 20233, telephone (301)763–5161 (or via the Internet at *Erica.Mary.Filipek@census.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

The U.S. Census Bureau plans to request a three-year extension of the current Office of Management and Budget (OMB) clearance of the Survey of Housing Starts, Sales and Completions, also known as the Survey of Construction (SOC). The SOC collects monthly data on new residential construction from a sample of owners or builders. The Census Bureau uses the Computer-Assisted Personal Interviewing (CAPI) electronic questionnaires SOC–QI/SF.1 and SOC–QI/MF.1 to collect data on start and completion dates of construction, physical characteristics of the structure (floor area, number of bathrooms, type of heating system, etc), and if applicable, date of sale, sales price, and type of financing. The SOC provides widely used measures of construction activity, including the economic indicators Housing Starts and Housing Completions, which are from the New Residential Construction series, and New Residential Sales.

The current clearance for this survey is scheduled to expire on October 31, 2014. No changes are planned to the questionnaire.

We sample about 1,700 new buildings each month (20,400 per year). We inquire about the progress of each building multiple times until it is completed (and a sales contract is signed, if it is a single-family house that is built for sale). For single-family buildings, we conduct an average of 8.17 interviews and for multifamily buildings, we conduct an average of 7.0 interviews. The total number of interviews conducted each year for single-family buildings is about 107,844 and for multifamily buildings is about 50,400. Each interview takes 5 minutes on average. Therefore, the total annual burden is 13,187 hours.

II. Method of Collection

The Census Bureau uses its field representatives to collect the data. The field representatives conduct interviews to obtain data.

III. Data

OMB Control Number: 0607–0110.

Form Number(s): SOC–QI/SF.1 and SOC–QI/MF.1.

Type of Review: Regular submission.

Affected Public: Individuals or households, business or other for-profit organizations.

Estimated Number of Respondents: 20,400.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 13,187.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Section 182.

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: May 20, 2014.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014–12001 Filed 5–22–14; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

Proposed Information Collection; Comment Request; SABIT Program: Applications and Questionnaires

AGENCY: International Trade Administration, 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.

DATES: Written comments must be submitted on or before July 22, 2014.

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 Tracy M. Rollins, SABIT, (202) 482–0073, *tracy.rollins@trade.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Special American Business Internship Training (SABIT) Program of the Department of Commerce's International Trade Administration (ITA), is a key element in the U.S. Government's efforts to support the economic transition of Eurasia (the former Soviet Union) and to support economic growth in other regions of the world, including Pakistan and the Middle East, et al. SABIT develops and implements two to three week training programs for groups of up to 20 business and government professionals from Eurasia and other regions. These professionals meet with U.S. government agencies, non-governmental organizations and companies in order to learn about various business practices and principles. This unique private sector-U.S. Government partnership was created in order to tap into the U.S. private sector's expertise and to assist developing regions in their transition to market-based economies while simultaneously boosting trade between the United States and other countries. Participant applications are needed to enable SABIT to find the most qualified participants for the training programs. Participant exit questionnaires provide insight as to what the participants have learned, and they are used to improve the content and administration of future programs. Alumni success story reports track the success of the program as regards to business ties between the U.S. and the countries SABIT covers.

The closing date for participant applications is based upon the starting date of the program and is published with the application, on the program's English-language Web site at *www.trade.gov/sabit,* and also on the Russian-language Web site at *www.sabitprogram.org,* if applicable. Pursuant to section 632(a) of the Foreign Assistance Act of 1961, as amended, funding for the programs will be provided by the Agency for International Development (AID).

The SABIT Program propose to revise the collection instruments. The instruments are very similar to those used by SABIT in past years. However, some wording has been changed to reflect the changing needs of SABIT over time. The changes are relatively minor and most of them are rephrasing of wording. Two questions have been added to the Participant Exit Questionnaire; and instructions for filling out the form, methods of submission, and the order of questions have been revised on the Participant Application. These revisions are not expected to increase the response time to complete the instruments.

II. Method of Collection

Participant applications are available for download from the SABIT English and Russian language Web sites at *www.trade.gov/sabit* and *www.sabitprogram.org.* Applications may be sent to program candidates via email, facsimile, or mail upon request. Applications are collected primarily via email, but are also accepted by mail or fax. Participant exit questionnaires are given to program participants at the completion of programs in person on paper or by email and are collected in paper format or by email. Alumni success story reports are used internally by SABIT staff to record success information, but at times they may be sent to alumni to fill out and submit via email or fax.

III. Data

OMB Control Number: 0625–0225.

Form Number(s): ITA–4143P–3.

Type of Review: Regular submission (revision of a currently approved information collection).

Affected Public: Individuals or households; Business or other for-profit organizations.

Estimated Number of Respondents: 2,000.

Estimated Time per Response: Participant application, 3 hours; participant exit questionnaire, 1 hour; alumni success story report, 1 hour.

Estimated Total Annual Burden Hours: 4,400.

Estimated Total Annual Cost to Public: $4,500 (mailed applications).

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: May 20, 2014.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014–11990 Filed 5–22–14; 8:45 am]

BILLING CODE 3510–HE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Non-commercial Permit and Reporting Requirements in the Main Hawaiian Islands Bottomfish Fishery

AGENCY: National Oceanic and Atmospheric Administration, 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.

DATES: Written comments must be submitted on or before July 22, 2014.

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 Walter Ikehara, (808) 725–5175, or *Walter.Ikehara@noaa.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

Regulations at 50 CFR 665, Subpart C, require that all participants (including vessel owners, operators, and crew) in the boat-based non-commercial bottomfish fishery in the Exclusive Economic Zone around the main Hawaiian Islands obtain a federal bottomfish permit. This collection of information is needed for permit issuance, to identify actual or potential participants in the fishery, determine qualifications for permits, and to help measure the impacts of management controls on the participants in the fishery. The permit program is also an effective tool in the enforcement of fishery regulations and serves as a link between the National Marine Fisheries Service (NMFS) and fishermen.

Regulations at 50 CFR 665 require that all vessel owners or operators in this fishery are required to submit a completed logbook form at the completion of each fishing trip. These logbook reporting sheets document the species and amount of species caught during the trip. The reporting requirements are crucial to ensure that NMFS and the Western Pacific Fishery Management Council (Council) will be able to monitor the fishery and have fishery-dependent information to develop an Annual Catch Limit for the fishery, evaluate the effectiveness of management measures, determine whether changes in fishery management programs are necessary, and estimate the impacts and implications of alternative management measures.

II. Method of Collection

Documents may be submitted by mail or online.

III. Data

OMB Control Number: 0648–0577.

Form Number: None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Individuals or small businesses.

Estimated Number of Respondents: 100.

Estimated Time per Response: 10 minutes per permit application; 2 hours per appeal of denied permit; 20 minutes per trip report logsheet.

Estimated Total Annual Burden Hours: 102.

Estimated Total Annual Cost to Public: $4,330.

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: May 20, 2014

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014–11997 Filed 5–22–14; 8:45 am]

BILLING CODE 3510–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD257

Fisheries of the Exclusive Economic Zone off Alaska; Application for an Exempted Fishing Permit

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

ACTION: Notice; public comment on an application for exempted fishing permit.

SUMMARY: This notice announces receipt of an application and the public comment period for an exempted fishing permit (EFP) from Mr. John Gauvin of Gauvin and Associates, LLC. If granted, this permit would allow the applicant to continue the development and testing of a salmon excluder device for the Bering Sea pollock trawl fishery. This activity is intended to promote the objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) by reducing salmon bycatch in the Bering Sea pollock trawl fishery.

DATES: Submit comments on or before June 23, 2014. Interested persons may comment on the EFP application and on the environmental assessment (EA) during the North Pacific Fishery Management Council (Council) meeting June 2 through June 10, 2014, in Nome, AK.

ADDRESSES: You may submit comments on this document, identified by FDMS Docket Number NOAA–NMFS–2014–0050, 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-2014-0050,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• Mail: Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

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), 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 Secretarial Review Draft Environmental Assessment For Issuing an Exempted Fishing Permit for the Purpose of Testing a Salmon Excluder Device in the Eastern Bering Sea Pollock Fishery, May 2014, prepared for this action are available from *http://www.regulations.gov* or from the NMFS Alaska Region Web site at *http://alaskafisheries.noaa.gov*.

FOR FURTHER INFORMATION CONTACT: Jeff Hartman, 907–586–7442.

SUPPLEMENTARY INFORMATION: NMFS manages the domestic groundfish fisheries in the Bering Sea and Aleutian Islands Management Area (BSAI) under the FMP. The Council prepared the FMP under the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing the groundfish fisheries of the BSAI appear at 50 CFR parts 600 and 679. The FMP and the implementing regulations at §§ 600.745(b) and 679.6 authorize issuance of EFPs to allow fishing that would otherwise be prohibited. Procedures for issuing EFPs are contained in the implementing regulations.

NMFS received an application for an EFP from Mr. Gauvin in December 2013. The purposes of the EFP project would be to improve the performance of the salmon excluder device developed under EFP 11–01 from 2011 to 2012, and to validate the performance of this device for pollock trawl gear used in the BSAI. The EFP project would focus on testing a redesigned excluder device to reduce chum salmon and Chinook salmon bycatch and refine the device for use on trawl vessels fishing for groundfish. The goal is to develop a device for pollock trawl gear that reduces salmon bycatch without significantly lowering pollock catch rates. Salmon are prohibited species that are incidentally caught in the pollock fishery (§ 679.21(e) and (f)).

The EFP would allow for testing of the salmon excluder device from January 2015 through June 2016, for several weeks in each pollock A and B season. Testing in each season would allow the device to be used under salmon occurrence and pollock fishing practices specific to each season. Testing in the A season would catch primarily Chinook salmon and roe-bearing pollock, while testing in the B season would catch Chinook and chum salmon and pollock that are not likely to be roe-bearing. EFP fishing would be conducted by one to two vessels in each season.

To test the salmon excluder device, exemptions would be necessary from regulations for salmon bycatch management, observer requirements, closure areas, total allowable catch amounts (TACs) for groundfish, and prohibited species catch (PSC) limits for the pollock fishery. Taking salmon during the experiment is crucial for determining the effectiveness of the device. Salmon taken during the experiment would not be counted toward the Chinook and chum salmon PSC limits under § 679.21(e)(1)(vii), (e)(3)(i)(A)(*3*), and (f)(2). The amount of chum salmon PSC taken by the pollock trawl industry during the EFP period could approach or exceed the chum salmon PSC limits under § 679.21(e)(7)(vii). If the EFP salmon were counted toward the salmon PSC limits, the EFP salmon may create an additional burden on the pollock trawl fishermen not participating in an intercooperative agreement for chum salmon or incentive plan agreement for Chinook salmon bycatch reduction by causing earlier closures of the Chum Salmon Savings Area or violating the plan agreement for Chinook salmon. More information regarding the intercooperative agreement for salmon bycatch reduction is at 72 FR 61070 (October 29, 2007). Information regarding the incentive plan agreements under Amendment 91 for Bering Sea Chinook salmon bycatch management is at 75 FR 53026 (August 30, 2010).

Approximately 2,500 chum salmon and 250 Chinook salmon for the 2015 B season and 500 chum salmon and 1,200 Chinook salmon for the 2015 and 2016 A seasons would be required to support the project. In total, the applicant would be limited to harvesting 3,000 chum salmon and 1,450 Chinook salmon during the EFP period. The experimental design requires this quantity of salmon to ensure statistically valid results.

The applicant also has requested an exemption from the Chum Salmon Savings Area (§§ 679.21(e)(7)(vii) and 679.22(a)(10)), the Bering Sea Pollock Restriction Area (§ 679.22(a)(7)(ii)), and the Steller Sea Lion Conservation Area (§ 679.22(a)(7)(vii)). These overlapping areas occur in locations of salmon concentration. The experiment must be conducted in areas of salmon concentration sufficient to ensure a statistically adequate sample size. These locations are ideal for conducting the experiment and ensuring that the vessel encounters sufficient concentrations of salmon and pollock for meeting the experimental design.

Groundfish taken under the EFP would be exempt from the TACs specified in the annual harvest specifications (§ 679.20). A total of 2,500 metric tons (mt) of groundfish (primarily pollock) would be taken during each A season of 2015 and 2016, and 2,500 mt of groundfish would be taken in the B season of 2016 for a total of 7,500 mt over the duration of the EFP. Approximately 96 percent of the groundfish harvested is expected to be pollock. The experimental design requires this quantity of pollock to ensure a statistically adequate sample size for measuring pollock escapement through the salmon excluder device.

The EFP groundfish harvest would not be included in the harvest applied against the Bering Sea groundfish TACs. The preliminary 2015 TAC for Bering Sea pollock is equal to the acceptable biological catch (ABC) at 1,258,000 mt, but the TAC is likely to be adjusted during the 2015/2016 harvest specifications process and may result in a TAC less than ABC (79 FR 12108, March 4, 2014). TAC and ABC have not been specified for the 2016 fishing year at this time. The EFP fishing will be permitted for this proposed action if the ABC for Bering Sea pollock exceeds the TAC by at least 5,000 mt in 2015 and 2,500 mt in 2016. Because of very little groundfish incidental catch in the pollock fishery, the harvest of other fish species during the EFP fishing is expected to be 50 mt to 80 mt per season. The majority of these other species harvested under the EFP likely would be Pacific cod, skates, flatfish, halibut, and jellyfish. The amount of groundfish harvest under the EFP and by the commercial groundfish fisheries is not expected to cause ABCs for groundfish species to be exceeded in either 2015 or 2016 because other BSAI

groundfish TACs are set with a sufficient difference between ABC and TAC to accommodate EFP fishing catch of groundfish species other than pollock.

The EFP is expected to take approximately 12 mt of halibut per season for a total of 12 mt of halibut in 2015 and 24 mt of halibut in 2016. The EFP would require an exemption from halibut PSC limits under § 679.21(e)(3)(ii)(C). The halibut taken under the EFP in combination with the groundfish fisheries is not expected to exceed the halibut PSC harvest specifications in 2015 or 2016.

Using a catcher/processor for the EFP study would require exemption from the Catcher Vessel Operational Area (CVOA) restriction (§ 679.22(a)(5)) because of the location of the Chinook salmon concentration in the CVOA. Catcher/processors are prohibited from operating in the CVOA during the B season. The EFP fishing may be done by either a catcher vessel or a catcher/processor. It may be necessary for the EFP applicant to use a catcher/processor to conduct tows in this area to ensure encountering sufficient pollock and salmon concentrations to meet the experimental design.

The EFP would exempt vessels that are EFP fishing from closures of the Chum Salmon Savings Area. This is necessary because the experimental design for this EFP is based on testing in areas with high incidental catch rates of salmon that may occur in the Chum Salmon Savings Area.

The EFP would include an exemption from selected observer requirements at §§ 679.50, 679.51, and 679.55. Participating vessels would use ''sea samplers'' who are NMFS-trained observers. They would not be deployed as NMFS observers, however, at the time of the EFP fishing. The ''sea samplers'' would conduct the EFP data collection and perform other observer duties that normally would be required for vessels directed fishing for pollock. EFP fishing trips also would be exempted from observer requirements for trip selection and fee collection.

The activities under the EFP are not expected to have a significant impact on the human environment as analyzed in the EA for this action (see **ADDRESSES**). The EFP would be subject to modifications pending any new relevant information regarding the 2015 and 2016 fishery, including the groundfish harvest specifications.

In accordance with 50 CFR 679.6 and 600 CFR 745(b)(3)(ii), NMFS has determined that the proposal warrants further consideration and has forwarded the application to the Council to initiate consultation. The Council will consider the EFP application during its meeting June 2 through June 10, 2014, which will be held at the Nome Mini Convention Center, 409 River St., Nome, AK. The applicant has been invited to appear in support of the application.

Public Comments

Public comments are being solicited on the application and the EA through the end of the comment period stated in this notice. To be considered, comments must be received on or before the last day of the comment period; that does not mean postmarked or otherwise transmitted by that date. Copies of the application and EA are available for review from NMFS (see **ADDRESSES**). Interested persons also may comment on the application and on the EA at the June 2014 Council meeting during public testimony.

Information regarding the meeting is available at the Council's Web site at *http://www.alaskafisheries.noaa.gov/npfmc/*.

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

Dated: May 20, 2014.

James P. Burgess,

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

[FR Doc. 2014–12021 Filed 5–22–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD266

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

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

ACTION: Notice; request for comments.

SUMMARY: NOAA Fisheries has made a preliminary determination that an exempted fishing permit application contains all of the required information and warrants further consideration. This request was submitted by the Gulf of Maine Research Institute and would allow commercial fishing vessels to evaluate if whiting can be caught in commercially viable quantities with minimal bycatch in the Gulf of Maine Grate Raised Footrope Trawl Exemption Area using a small-mesh trawl that has a standard cookie sweep, prior to the start of the current season that begins July 1. The exempted fishing permit would exempt the vessels from the Northeast multispecies minimum mesh size and seasonal restrictions at 50 CFR 648.80(a)(3) and 648.80 (a)(16).

Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed exempted fishing permits.

DATES: Comments must be received on or before June 9, 2014.

ADDRESSES: You may submit written comments by any of the following methods:

- *Email: NMFS.GAR.EFP@noaa.gov.* Include in the subject line ''Comments on GMRI Whiting EFP.''
- *Mail:* John K. Bullard, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on GMRI Whiting EFP.''
- *Fax:* (978) 281–9135.

FOR FURTHER INFORMATION CONTACT: Jason Berthiaume, Fishery Management Specialist, 978–281–9177, *Jason.Berthiaume@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Gulf of Maine Research Institute (GMRI) has submitted an application for an exempted fishing permit (EFP) to conduct commercial fishing activities that the regulations would otherwise restrict. The EFP would exempt three federally permitted commercial fishing vessels from the minimum mesh size requirements for the purpose of testing a small-mesh trawl fitted with an excluder grate for harvesting silver hake. The applicant states that there has been poor performance of the raised footrope trawl in this area due to the rocky habitat, and that removing the raised footrope could allow for increased catch rates while maintaining low bycatch rates. In addition, the applicant has requested authorization to test the trawl prior to the July 1–November 30 season in the Gulf of Maine Grate Raised Footrope Trawl Exemption Area.

The applicant would evaluate the performance of a small-mesh trawl that has a regulation compliant excluder grate and is fitted with a cookie sweep. The trawl would not have a raised footrope as required by the Gulf of Maine Grate Raised Footrope Trawl regulations. Participating vessels would complete up to 25 days of experimental fishing with five 1-hour tows per day with a target whiting catch of 5,000 lb (2,268 kg) per day. A research technician would accompany all trips under the EFP, and sort and weigh all

catch by species. Catch rates would be calculated for target and bycatch species and compared with historical and current catch rates. If it is determined that whiting catch rates are commercially viable, with minimal bycatch rates, GMRI would work on developing and obtaining funding to conduct more robust research in the future.

Whiting catch would be landed and sold and all catch of stocks allocated to Northeast multispecies sectors will be deducted from the sector's annual catch entitlement for each stock. Discards would be identified, weighed, measured, and returned to the sea as quickly as possible. The participating vessels would be required to comply with all other applicable requirements and restrictions specified at 50 CFR part 648, unless specifically exempted in this EFP.

If approved, the applicant may request minor modifications and extensions to the EFP throughout the year. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

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

Dated: May 20, 2014.

James P. Burgess,

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

[FR Doc. 2014–12022 Filed 5–22–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD302

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Groundfish Management Team (GMT) will hold a webinar to discuss items on the June Pacific Council meeting agenda (see *http://tinyurl.com/mg4p59h*). The meeting is open to the public, but is not intended as a public hearing.

DATES: The webinar will be held Tuesday, June 10, 2014 from 1 p.m. until 5 p.m., or when business for the day has been completed.

ADDRESSES: The meeting will be held via webinar. Join the meeting by visiting this link: *http://www.joinwebinar.com.* Enter the Webinar ID: 936–920–471. Please enter your name and email address (required). Once you have joined the webinar, choose either your computer's audio or select ''Use Telephone.'' If you do not select ''Use Telephone'' you will be connected to audio using your computer's microphone and speakers (VolP). It is recommended that you use a computer headset as GoToMeeting allows you to listen to the meeting using your computer headset and speakers. If you do not have a headset and speakers, you may use your telephone for the audio portion of the meeting by dialing this TOLL number 1–646–307–1722 (not a toll-free number); phone audio access code 694–418–350; audio phone pin shown after joining the webinar.

Pacific Council Address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384. A public listening station will also be provided at the Pacific Council office.

FOR FURTHER INFORMATION CONTACT: Ms. Kelly Ames, Staff Officer, Pacific Council; telephone: (503) 820–2426.

SUPPLEMENTARY INFORMATION: The GMT will hold a webinar to discuss items on the June Council meeting agenda (see *http://tinyurl.com/mg4p59h*) with specific focus on electronic monitoring regulatory development and exempted fishing permits. Public comments will be taken at the discretion of the GMT chair as time allows. The GMT is scheduled to report their recommendations to the Pacific Council at their June 2014 meeting in Garden Grove, CA.

Although non-emergency issues not contained in the meeting agenda may come before the GMT for discussion, those issues may not be the subject of formal GMT action during this meeting. GMT action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the GMT's intent to take final action to address the emergency.

Technical Information

PC-based attendees must use Windows 7, Vista, or XP. Mac-based attendees must use Mac OS X 10.5 or newer. Mobile attendees must use an iPhone, iPad, Android phone, or Android tablet. You may also send an email to Mr. Kris Kleinschmidt or contact him at (503) 820–2425 for technical assistance.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2425 at least 5 days prior to the meeting date.

Dated: May 20, 2014.

Tracey L. Thompson,

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

[FR Doc. 2014–11959 Filed 5–22–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD305

Mid-Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings.

DATES: The meeting will be held Tuesday, June 10, 2014 through Thursday, June 12, 2014. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meetings will be held at the Radisson Hotel Freehold, 50 Gibson Place, Freehold, NJ 07728; telephone: (732) 780–3400.

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:

Tuesday, June 10, 2014

10 a.m. until 12 p.m.—The Surfclam and Ocean Quahog Committee will meet.

1 p.m. until 4 p.m.—The Ecosystems and Ocean Planning Committee will meet.

Wednesday, June 11, 2014

8:30 a.m.—The Council will convene.
8:30 a.m. until 9:30 a.m.—Surfclam and Ocean Quahog Specifications will be discussed.
9:30 a.m. until 12 p.m.—The Demersal Committee will meet as a Committee of the Whole.
1 p.m. until 2 p.m.—A Framework to open the Recreational Black Sea Bass Fishery in Wave 1 (Framework Meeting 1) will be discussed.
2 p.m. until 3 p.m.—The River Herring & Shad Committee will meet as a Committee of the Whole.
3 p.m. until 5 p.m.—The Mackerel, Squid, and Butterfish Committee will meet as a Committee of the Whole.
5 p.m. until 6 p.m.—A Listening Session will be held.

Thursday, June 12, 2014

8 a.m.—The Council will convene.
8 a.m. until 9 a.m.—The Omnibus Allowable Biological Catch (ABC) Framework (Framework Meeting 2) will be discussed.
9 a.m. until 10 a.m.—The Research Set-Aside (RSA) Program Review will be discussed.
10 a.m. until 1 p.m.—The Council will hold its regular Business Session to receive Organizational Reports, the New England and South Atlantic Liaison Reports, 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, June 10- The Surfclam and Ocean Quahog Committee with review the most recent information to determine if adjustments are needed for the 2015–16 fishing year and review draft alternatives for Amendment 17 (Cost Recovery Amendment) and provide input to the Fishery Management Action Team for continued Amendment development. The Ecosystems and Ocean Planning Committee will receive presentations on National and Regional habitat initiatives and discuss developing/enhancing the role of the Committee under the 2014–18 Strategic Plan.

On Wednesday, June 11—Surfclam and Ocean Quahog Specifications will be reviewed for 2015–16. Framework Meeting 1 to open the recreational black sea bass fishery in Wave 1 options will be reviewed. The River Herring and Shad Committee will meet as a Committee of the Whole to review and develop recommendations for the river herring/shad cap and review the progress on river herring/shad conservation. The Mackerel, Squid, and Butterfish Committee will meet as a Committee of the Whole to review the Scientific and Statistical Committee recommendations for the 2015 specifications, develop 2015 specifications and related management measures, and review the slippage provisions in Framework 9 relative to the slippage provision in Framework 4 of the Herring Fishery Management Plan. The Listening Session will focus on NOAA Recreational Policy.

On Thursday, June 12—Framework Meeting 2 of the Omnibus ABC Framework will be held to review suggested modifications to the ABC Omnibus Framework and take action as appropriate (multiyear ABC's, assessment level designations, reference points). The Research Set-Aside Program Review will discuss the timing of RSA quota availability (potential for availability in January—March), progress on the implementation of Council recommendations to improve the RSA program, recent enforcement activities, and the future direction of the RSA Program. The Council will hold its regular Business Session to receive Organizational Reports, the New England and South Atlantic Council Liaison Reports, the Executive Director's Report, Science Report, Committee Reports, and conduct any continuing and/or new business.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are 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 5 days prior to the meeting date.

Dated: May 20, 2014.

Tracey L. Thompson,

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

[FR Doc. 2014–11945 Filed 5–22–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD297

Nominations to the Marine Fisheries Advisory Committee

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

ACTION: Notice; request for nominations.

SUMMARY: Nominations are being sought for appointment by the Secretary of Commerce to fill vacancies on the Marine Fisheries Advisory Committee (MAFAC or Committee) beginning in the fall of 2014. MAFAC is the only Federal advisory committee with the responsibility to advise the Secretary of Commerce (Secretary) on all matters concerning living marine resources that are the responsibility of the Department of Commerce. The Committee makes recommendations to the Secretary to assist in the development and implementation of Departmental regulations, policies, and programs critical to the mission and goals of NMFS. Nominations are encouraged from all interested parties involved with or representing interests affected by NMFS actions in managing living marine resources. Nominees should possess demonstrable expertise in a field related to the management of living marine resources and be able to fulfill the time commitments required for two annual meetings and subcommittee work. Individuals serve for a term of three years for no more than two consecutive terms if re-appointed. NMFS is seeking qualified nominees to fill upcoming vacancies being created by term limits.

DATES: Nominations must be postmarked or have an email date stamp on or before July 7, 2014.

ADDRESSES: Nominations should be sent to Heidi Lovett, Executive Director (Acting), MAFAC, Office of Policy, NMFS F–14438, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Heidi Lovett, MAFAC Executive Director (Acting); (301) 427–8004; email: *heidi.lovett@noaa.gov.*

SUPPLEMENTARY INFORMATION: The establishment of MAFAC was approved by the Secretary on December 28, 1970, and subsequently chartered under the Federal Advisory Committee Act, 5 U.S.C. App. 2, on February 17, 1971. The Committee meets twice a year with supplementary subcommittee meetings

as determined necessary by the Committee Chairperson. No less than 15 and no more than 21 individuals may serve on the Committee. Membership is comprised of highly qualified, diverse individuals representing commercial and recreational fisheries interests, environmental organizations, academic institutions, governmental, tribal and consumer groups, and other living marine resource interest groups from a balance of U.S. geographical regions, including the Western Pacific and Caribbean.

A MAFAC member cannot be a Federal employee, a member of a Regional Fishery Management Council, a registered Federal lobbyist, or a State employee. The selected candidate must pass a security check and submit a financial disclosure form. Membership is voluntary, and except for reimbursable travel and related expenses, service is without pay.

Each nomination submission should include the nominee's name, a cover letter describing the nominee's qualifications and interest in serving on the Committee, curriculum vitae or resume of the nominee, and no more than three supporting letters describing the nominee's qualifications and interest in serving on the Committee. Self-nominations are acceptable. The following contact information should accompany each nominee's submission: name, address, telephone number, fax number, and email address (if available).

Nominations should be sent to (see **ADDRESSES**) and must be received by July 7, 2014. The full text of the Committee Charter and its current membership can be viewed at the NMFS' Web page at *www.nmfs.noaa.gov/mafac.htm.*

Dated: May 19, 2014.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2014–11991 Filed 5–22–14; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Addition and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to and deletions from the Procurement List.

SUMMARY: This action adds a service to the Procurement List that will be provided by a nonprofit agency employing persons who are blind or have other severe disabilities, and deletes products from the Procurement List previously furnished by such agencies.

DATES: *Effective Date:* 6/23/2014.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 10800, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Addition

On 2/28/2014 (79 FR 11422–11423), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed addition to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agency to provide the service and impact of the addition on the current or most recent contractor, the Committee has determined that the service listed below is 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 provide the service to the Government.

2. The action will result in authorizing a small entity to provide the service 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 service proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service is added to the Procurement List:

Service

Service Type/Location: Furniture Design and Configuration Service, Maine National Guard, 194 Winthrop Street, Augusta, ME

NPA: Industries for the Blind, Inc., West Allis, WI

Contracting Activity: DEPT OF THE ARMY, W7NC USPFO ACTIVITY ME ARNG, AUGUSTA, ME

Deletions

On 3/28/2014 (79 FR 17509–17510) and 4/4/2014 (79 FR 18891–18892), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products 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 deleted from the Procurement List.

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

Binder, Loose-leaf, Presentation, Letter

NSN: 7510–00–582–5398—Blue, 3/8″

NSN: 7510–00–582–5399—Gray, 3/8″

NSN: 7510–00–582–5400—Tan, 3/8″

NPA: Vision Corps, Lancaster, PA

Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY

Portfolio, Clear Front Report Cover

NSN: 7510–01–411–7000—Dark Blue, 8 1/2″ x 11″

NSN: 7510–01–566–4140—Light Blue, 8 1/2″ x 11″

NSN: 7510–01–566–4141—Black, 8 1/2″ x 11″

NSN: 7510–01–566–4142—Red, 8 1/2″ x 11″

NSN: 7510–01–566–5060—Dark Green, 8 1/2″ x 11″

NPA: Vision Corps, Lancaster, PA

Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2014–11974 Filed 5–22–14; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products and a service to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products previously furnished by such agencies.

DATES: *Comments Must Be Received On Or Before:* 6/23/2014.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 10800, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products and service are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

NSN: MR 1189—Drying Mat, Microfiber, Holiday Themed
NPA: New York City Industries for the Blind, Inc., Brooklyn, NY
Contracting Activity: DEFENSE COMMISSARY AGENCY, FORT LEE, VA
COVERAGE: C-List for the requirements of military commissaries and exchanges as aggregated by the Defense Commissary Agency.
NSN: MR 1194—Bottle, Water, Reusable, 26oz
NPA: Industries for the Blind, Inc., West Allis, WI
Contracting Activity: DEFENSE COMMISSARY AGENCY, FORT LEE, VA
COVERAGE: C-List for the requirements of military commissaries and exchanges as aggregated by the Defense Commissary Agency.
Pen, Ergonomic, Low Viscosity Ink, Retractable, Wide body
NSN: 7520–00–NIB–2194—Black, 1mm
NSN: 7520–00–NIB–2196—Blue, 1mm
NPA: Industries for the Blind, Inc., West Allis, WI
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY
COVERAGE: A-List for the Total Government Requirement as aggregated by the General Services Administration.

Service

Service Type/Location: Laundry Service, Department of Veterans Affairs, Nebraska Western Iowa Health Care System and VA Central Iowa Health Care System, 2501 West 22nd Street, Sioux Falls, SD.
NPA: Goodwill Specialty Services, Inc., Omaha, NE
Contracting Activity: DEPARTMENT OF VETERANS AFFAIRS, 438–SIOUX FALLS VA MEDICAL CENTER, SIOUX FALLS, SD.

Deletions

The following products are proposed for deletion from the Procurement List:

Products

Cord Assembly, Elastic
NSN: 4020–01–072–4557
NSN: 4020–01–072–4558
NPA: Alpha Opportunities, Inc., Jamestown, ND
Contracting Activity: DEFENSE LOGISTICS AGENCY TROOP SUPPORT, PHILADELPHIA, PA
Powder Free, Latex and Polyisoprene
NSN: 6515–00–NIB–0555—Glove, Powder Free, Protegrity Smt
NSN: 6515–00–NIB–0556—Glove, Powder Free, Protegrity Smt
NSN: 6515–00–NIB–0557—Glove, Powder Free, Protegrity Smt
NSN: 6515–00–NIB–0558—Glove, Powder Free, Protegrity Smt
NSN: 6515–00–NIB–0559—Glove, Powder Free, Protegrity Smt
NSN: 6515–00–NIB–0560—Glove, Powder Free, Protegrity Smt
NSN: 6515–00–NIB–0561—Glove, Powder Free, Protegrity Smt
NSN: 6515–00–NIB–0562—Glove, Powder Free, Protegrity Smt
NSN: 6515–00–NIB–0563—Glove, Powder Free, Protegrity Micro Smt
NSN: 6515–00–NIB–0564—Glove, Powder Free, Protegrity Micro Smt
NSN: 6515–00–NIB–0565—Glove, Powder Free, Protegrity Micro Smt
NSN: 6515–00–NIB–0566—Glove, Powder Free, Protegrity Micro Smt
NSN: 6515–00–NIB–0567—Glove, Powder Free, Protegrity Micro Smt
NSN: 6515–00–NIB–0568—Glove, Powder Free, Protegrity Micro Smt
NSN: 6515–00–NIB–0569—Glove, Powder Free, Protegrity Micro Smt
NSN: 6515–00–NIB–0570—Glove, Powder Free, Protegrity Micro Smt
NPA: Bosma Industries for the Blind, Inc., Indianapolis, IN
Contracting Activity: DEPARTMENT OF VETERANS AFFAIRS, NAC, HINES, IL
Mattress, High Density Lumbar
NSN: 7210–00–NIB–0060
NSN: 7210–00–NIB–0061
NPA: RLCB, Raleigh, NC
Contracting Activity: W40M NORTHEREGION CONTRACT OFC, FORT BELVOIR, VA
Hydramax Hydration System
NSN: 8465–01–525–1559—Alpha, UCP, 120 oz
NSN: 8465–01–524–2144—Mustang, UCP, 120 oz
NSN: 8465–01–524–2764—Replacement Parts, Alpha and Mustang, 120 oz
NSN: 8465–01–524–2761—Mustang, Black, 120 oz
NPA: The Lighthouse for the Blind, Inc. (Seattle Lighthouse), Seattle, WA
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FORT WORTH, TX
Folder, File
NSN: 7530–00–NSH–0073
NSN: 7530–00–NSH–0074
NSN: 7530–00–NSH–0075
NSN: 7530–00–NSH–0076
NSN: 7530–00–NSH–0077
NSN: 7530–00–NSH–0078
NSN: 7530–00–NSH–0079
NSN: 7530–00–NSH–0080
NSN: 7530–00–NSH–0081
NSN: 7530–00–NSH–0082
NPA: Goodwill Industries of the Pioneer Valley, Inc., Springfield, MA
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2014–11973 Filed 5–22–14; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2014–OS–0032]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by June 23, 2014.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Nuclear Test Personnel Review Forms; DTRA Form 150, ''Information Request and Release'' and DTRA Forms 150–A, –B, –C, ''Nuclear Test Questionnaires,'' OMB Control No. 0704–0447.

Type of Request: Extension.

Number of Respondents: 370.

Responses per Respondent: 1.

Annual Responses: 370.

Average Burden per Response: 75 minutes.

Annual Burden Hours: 463.

Needs and Uses: The information collection requirement is necessary to collect irradiation scenario information from nuclear test participants to perform their radiation dose assessment. The DTRA radiation dose assessments are provided to the Department of Veterans Affairs in support of veteran radiogenic disease compensation claims. This information may also be used in approved veteran epidemiology studies that study the health impact of nuclear tests on U.S. veterans.

Affected Public: Veterans and civilian test participants, and their representatives who are filing radiogenic disease compensation claims with the Department of Veterans Affairs or Department of Justice and require information from the Department of Defense.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jasmeet Seehra at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD Information Management Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: May 19, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–11887 Filed 5–22–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2014–0008]

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to delete a System of Records.

SUMMARY: The Department of the Army is deleting a system of records notice in its existing inventory of record systems subject to the Privacy Act of 1974, as amended. The notice is A0350–1e TRADOC, Life Long Learning Center (November 15, 2010, 75 FR 69651).

DATES: Comments will be accepted on or before June 23, 2014. This proposed action will be effective the date following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. Leroy Jones, Department of the Army, Privacy Office, U.S. Army Records Management and Declassification Agency, 7701 Telegraph Road, Casey Building, Suite 144, Alexandria, VA 22325–3905 or by calling (703) 428–6185.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at *http://dpclo.defense.gov/.*

The Department of the Army proposes to delete a system of records notice from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: May 19, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

Deletion:

A0350–1e TRADOC, Life Long Learning Center (November 15, 2010, 75 FR 69651)

REASON:

The program using this system of records notice never implemented the collection of personally identifiable information; therefore, A0350–1e TRADOC, Life Long Learning Center can be deleted.

[FR Doc. 2014–11912 Filed 5–22–14; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Grants to States for School Emergency Management Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

Overview Information

Grants to States for School Emergency Management Program Notice inviting applications for new awards for fiscal year (FY) 2014.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.184Q.

DATES:

Applications Available: May 23, 2014.

Deadline for Transmittal of Applications: July 7, 2014.

Deadline for Intergovernmental Review: September 5, 2014.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The Grants to States for School Emergency Management Program provides grants to State educational agencies (SEAs) to increase their capacity to assist local educational agencies (LEAs) by providing training and technical assistance in the development and implementation of high-quality school emergency operations plans (EOPs).

Background

A 2007 report from the Government Accountability Office (GAO) notes that while 85 percent of LEAs have requirements for emergency management planning and 95 percent have written emergency management plans, the content within these plans varies.[1] For example, according to the GAO report, some LEA plans included federally recommended practices and procedures for all hazards, while other LEA plans did not. Also, according to the GAO report, many school district officials said that they experience challenges in planning for emergencies and some school districts face difficulties in communicating and coordinating with first responders.

In 2013, President Obama proposed a comprehensive plan, ''Now is the Time,'' to protect our children and communities by reducing gun violence, making schools safer, and increasing access to mental health services, including grants to States to help their school districts develop and implement emergency management plans.[2] The Grants to States for School Emergency Management Grant Program also was included in the President's FY 2014 budget request, and Congress provided funding for the new program in the Department of Education Appropriations Act, 2014.

The elements of the Now is the Time (NITT) plan to make our schools safer include a focus on improving emergency operations plans, to which this program responds, as well as proposals for new comprehensive school safety programs, more nurturing school climates, and new investments to help schools address pervasive violence. High-quality school EOPs make our schools safer by supporting efforts to prevent, protect against, mitigate, respond to, and recover from all hazards, both natural and man-made.

In order to develop and implement high-quality EOPs, LEA staff must have access to training and technical assistance on developing, implementing, and refining their plans. SEAs can play a critical role in providing the necessary training and technical assistance to LEAs.

Generally SEAs share with their LEAs information about applicable laws and mandates about school emergency management planning; and make resources available so that LEAs can fulfill their obligations. For example, SEAs may provide training, resources, tools, and information to support school safety and security, including emergency management planning. SEAs may also work with other State agencies or organizations to provide emergency management services to LEAs.

Priority and Requirements: We are establishing this priority and the application and program requirements for the FY 2014 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1).

Absolute Priority: This priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

Expand the capacity of State educational agencies (SEAs) to provide training and technical assistance to local educational agencies (LEAs) for the development and implementation of high-quality school emergency operations plans (EOPs).

Under this priority, those SEAs that currently have limited internal capacity regarding the development and implementation of high-quality EOPs must propose to first expand their internal SEA capacity before providing such training and technical assistance to LEAs.

SEAs that provide evidence of current internal capacity (e.g. currently have EOP subject matter experts on staff and comprehensive and up-to-date state EOP resources) may propose to immediately provide or expand such training and technical assistance to LEAs.

Program Requirements: If an applicant is awarded a grant under this program, it must meet the following requirements:

(1) Provide an established point of contact (e.g., person or office) for school emergency management issues and submit that information to the U.S. Department of Education (Department) no later than the project start date;

(2) Provide training and technical assistance to LEAs that result in adoption of best practices for developing and implementing school EOPs including, but not necessarily limited to, those provided in the Guide for Developing High-Quality School Emergency Operations Plans)[3];

(3) Provide training and technical assistance to LEAs on developing or enhancing memoranda of understanding with community partners (e.g., local government, law enforcement, public safety or emergency management, public health, and mental health agencies); and

(4) Provide training and technical assistance to LEAs on the implementation of the National Incident Management System (NIMS). Information about current NIMS requirements for States may be accessed at: *http://www.fema.gov/national-incident-management-system.*

Application Requirements: The following requirements apply to all applications submitted under this competition. The applicant must provide a plan that includes the following:

(1) Information on: (a) Training, technical assistance, and resources the applicant currently provides to LEAs on emergency management; and (b) the proposed number of LEAs, including rural LEAs that might not otherwise have full access to school emergency management training and resources, that would receive training and technical assistance resulting in the development and implementation of high-quality school EOPs under the applicant's proposal.

(2) A strategy for improving the applicant's: (a) Capacity to provide training and technical assistance to

[1] ''Most School Districts Have Developed Emergency Management Plans, but Would Benefit from Additional Federal Guidance,'' GA0–07–609, June 2007. Available at *http://www.gao.gov/new.items/d07609.pdf.*

[2] Available at: *http://www.whitehouse.gov/sites/default/files/docs/wh_now_is_the_time_full.pdf.*

[3] Available at: *http://rems.ed.gov/EOPGuides.* Plans must comply with the Americans with Disabilities Act (ADA), among other prohibitions on disability discrimination, across the spectrum of emergency management services, programs, and activities, including preparation, testing, notification and alerts, evacuation, transportation, sheltering, emergency medical care and services, transitioning back, recovery, and repairing and rebuilding. Plans should include students, staff, and parents with disabilities. Among other things, school emergency plans must address the provision of appropriate auxiliary aids and services to ensure effective communication with individuals with disabilities (e.g., interpreters, captioning, and accessible information technology); ensure individuals with disabilities are not separated from service animals and assistive devices, and can receive disability-related assistance throughout emergencies (e.g., assistance with activities of daily living, administration of medications); and comply with the law's architectural and other requirements. (Information and technical assistance about the ADA is available at *http://www.ada.gov.*)

LEAs, including rural LEAs that might not otherwise have full access to school emergency management training and resources, resulting in the development and implementation of high-quality school EOPs; and capacity to address the unique needs of students, staff, and visitors with disabilities and other access and functional needs; (b) existing training and technical assistance activities for LEAs; (c) availability of emergency management resources; and (d) alignment of emergency management training, technical assistance, and resources with emergency management planning at the Federal, State, and local levels.

(3) Identification of a process for the coordination and sustainability of support that will be provided to LEAs so that they can continue to improve their schools' EOPs beyond the period of Federal financial assistance.

Definitions: We are establishing the definitions for acceptable, adequate, complete, compliant, feasible, high-quality school emergency operations plan (EOP), mitigation, prevention, protection, recovery, response, rural LEA, technical assistance, and training in this notice for the FY 2014 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1). The remaining definitions are from 34 CFR 77.1(c), 20 U.S.C. 7801(30), and 48 U.S.C. 1921(f)(1)(B)(viii).

These definitions are:

Acceptable means the plan meets the requirements driven by a threat or hazard, meets cost and time limitations, and is consistent with the law.

Adequate means the plan identifies and addresses critical courses of action effectively; can accomplish the assigned function; and the assumptions are valid and reasonable.

Complete means the plan

- Incorporates all courses of action to be accomplished for all selected threats and hazards and identified functions;
- Integrates the needs of the whole school community;
- Provides a complete picture of what should happen, when, and at whose direction;
- Estimates time for achieving objectives, with safety remaining as the utmost priority;
- Identifies success criteria and a desired end state; and
- Conforms with the planning principles outlined in the Guide for Developing High-Quality School Emergency Operations Plans.

Compliant means the plan complies with applicable State and local requirements because these provide a baseline that facilitates both planning and execution.

Feasible means the school can accomplish the assigned function and critical tasks by using available resources within the time contemplated by the plan, and that the plan explains where or how the district and school will obtain the resources to support the execution of a course of action or to meet a requirement established in the plan.

High-Quality School Emergency Operations Plan (EOP) means a comprehensive emergency operations plan that encompasses the five mission areas—(1) prevention, (2) protection, (3) mitigation, (4) response, and (5) recovery—and that is (a) adequate, (b) feasible, (c) acceptable, (d) complete, and (e) compliant.[4]

Mitigation means the capabilities necessary to eliminate or reduce the loss of life and property damage by lessening the impact of an event or emergency. It also means reducing the likelihood that threats and hazards will happen.

LEA means a local educational agency as defined by section 9101(26) of the ESEA.

Outlying areas means the United States Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands.

Prevention means the capabilities necessary to avoid, deter, or stop an imminent crime or threatened or actual mass casualty incident. Prevention is also the action schools take to prevent a threatened or actual incident from occurring; and includes those capabilities necessary to avoid, prevent, or stop a threatened or actual act of terrorism, and it includes preventing imminent threats.

Protection means the capabilities to secure schools against acts of violence and manmade or natural disasters. Protection focuses on ongoing actions that protect students, teachers, staff, visitors, networks, and property from a threat or hazard.

Recovery means the capabilities necessary to assist schools affected by an event or emergency in restoring the learning environment.

Response means the capabilities necessary to stabilize an emergency once it has already happened or is certain to happen in an unpreventable way; establish a safe and secure environment; save lives and property; and facilitate the transition to recovery.

Rural LEA means an LEA with one of the following district locale codes as assigned by the National Center for Education Statistics' Common Core of Data: Code 33 (Remote Town); Code 41 (Fringe Rural); Code 42 (Distant Rural); and Code 43 (Remote Rural). LEA locale codes may be obtained by searching the Common Core of Data database at: *http://nces.ed.gov/ccd/districtsearch/*.

SEA means a State educational agency as defined by section 9101 (41) of the Elementary and Secondary Education Act of 1965, as amended (ESEA).

State means any of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico, and each of the Outlying areas as defined in this notice.

Technical assistance means consultations, information, referrals, and other assistance on specific issues, topics, or problems as requested by the LEAs and other stakeholders. The grantee disseminates materials collected, developed, adapted, and adopted for this assistance. Technical assistance may proceed, follow, or be combined with training activities.

Training means instruction directed toward imparting knowledge, skills, and attitudes supportive of change by engaging, informing, equipping, and motivating trainees toward the development and implementation of plans responsive to the specific need or circumstances of the trainees. Training may consist of various formats (e.g., workshops, seminars, or computer-assisted tutorials).

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities, requirements, and definitions. Section 437(d)(1) of GEPA (20 U.S.C 1232(d)(1)), however, allows the Secretary to exempt from rulemaking requirements, regulations governing the first grant competition under a new or substantially revised program authority.

This is the first grant competition for this program under the appropriation for Safe Schools and Citizenship Education in the Department of Education Appropriations Act, 2014, Title III of Division H of Public Law 113–76, and section 4121 of the ESEA (20 U.S.C. 7131) and therefore qualifies for this exemption.

[4] Derived from: (1) Presidential Policy Directive 8, available at *https://www.dhs.gov/;presidential-policy-directive-8-national-preparedness* ; and (2) the Guide for Developing High-Quality Emergency Operations Plans, available at *http://rems.ed.gov/EOPGuides.*

In order to ensure timely grant awards, the Secretary has decided to forgo public comment on the priority, requirements, and definitions in this notice under section 437(d)(1) of GEPA. This priority, these requirements, and these definitions will apply to the FY 2014 grant competition and any subsequent year in which we make awards from the list of unfunded applicants from this competition.

Program Authority: 20 U.S.C. 7131; the Department of Education Appropriations Act, 2014, Title III of Division H of Public Law 113–76.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 76, 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 in 34 CFR part 299.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $29,700,000.

Estimated Range of Awards: $ 85,714 to $3,273,301.

Estimated Average Size of Awards: $503,389.

Estimated Number of Awards: 59.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 18 months. Budgets should be developed for a single project period of up to 18 months. No continuation awards will be provided.

Maximum Awards: We will not fund any budget exceeding the following maximum award amount for each eligible applicant. The Department developed these amounts as follows: First, the Department reserved 1 percent ($300,000) for the Bureau of Indian Education (BIE) schools operated by the Department of the Interior. (Those funds are not included within this notice inviting applications for new awards; rather, the Department will transfer them to the BIE under an interagency agreement.) Second, the Department reserved 2 percent ($600,000), and allocated it in equal amounts of $85,714 among each of the 7 Outlying Areas. The Department allocated the remaining $29,100,000 among the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico on the basis of school-aged (5- to 17-year-old) population data from the U.S. Census Bureau, with a minimum per State award of $250,000.

Alabama 400,269
Alaska 250,000
Arizona 577,218
Arkansas 252,562
California 3,273,301
Colorado 436,746
Connecticut 293,237
Delaware 250,000
District of Columbia 250,000
Florida 1,432,228
Georgia 886,937
Hawaii 250,000
Idaho 250,000
Illinois 1,098,371
Indiana 569,748
Iowa 257,314
Kansas 254,602
Kentucky 360,964
Louisiana 392,400
Maine 250,000
Maryland 478,177
Massachusetts 506,167
Michigan 826,376
Minnesota 453,370
Mississippi 264,604
Missouri 500,485
Montana 250,000
Nebraska 250,000
Nevada 250,000
New Hampshire 250,000
New Jersey 732,350
New Mexico 250,000
New York 1,512,831
North Carolina 814,371
North Dakota 250,000
Ohio 962,047
Oklahoma 330,034
Oregon 306,922
Pennsylvania 986,909
Puerto Rico 312,619
Rhode Island 250,000
South Carolina 382,946
South Dakota 250,000
Tennessee 532,643
Texas 2,464,627
Utah 307,907
Vermont 250,000
Virginia 658,271
Washington 557,940
West Virginia 250,000
Wisconsin 472,509
Wyoming 250,000
Guam 85,714
Virgin Islands 85,714
American Samoa 85,714
Commonwealth of the Northern Mariana Islands 85,714
Republic of Palau 85,714
Federated States of Micronesia 85,714
Republic of the Marshall Islands 85,714

III. Eligibility Information

1. *Eligible Applicants:* SEAs.

Note: Consistent with the definitions in this notice, eligible applicants include SEAs in the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands. Eligible applicants may collaborate informally or contract with other agencies to provide services to LEAs, including agencies such as:

- A State school safety center;
- The State Emergency Management Agency; and
- The State Homeland Security Department.

2. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

3. *Other:*

a. *Participation by Nonpublic School Students and Teachers.* Applicants are required to provide for the equitable participation of nonpublic school students, their teachers, and other educational personnel in nonpublic schools located in the State served by the grant. In order to ensure that grant program activities address the needs of nonpublic schools, the applicant must engage in timely and meaningful consultation with nonpublic school officials during the design and development of the program. This consultation must take place before any decision is made that affects the opportunities of eligible nonpublic school students, teachers, and other educational personnel to participate.

In order to ensure equitable participation of nonpublic school students, teachers, and other educational personnel, an applicant must consult with private school officials on school emergency management issues such as: threats and hazards unique to nonpublic schools in the State, training needs, and existing EOPs and school emergency management resources already available to the nonpublic schools.

b. *Administrative Direction and Control.* Administrative direction and control over grant funds must remain with the grantee.

c. *Limitation on Applications.* The Department will accept only one application per SEA.

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs).

To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a

telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.184Q.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or computer disc) by contacting the person listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative is where you, the applicant, provide the project narrative and management plan to address the selection criteria that reviewers use to evaluate your application. The required budget and budget narrative will be provided in a separate section. You must limit the application narrative to the equivalent of no more than 50 pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, 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 page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative section.

Our reviewers will not read any pages of your application that exceed the page limit.

3. *Submission Dates and Times:*

Applications Available: May 23, 2014.

Deadline for Transmittal of Applications: July 7, 2014.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice. Deadline for Intergovernmental Review: September 5, 2014.

4. *Intergovernmental Review:* This competition 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 reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management (SAM):* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM) (formerly the Central Contractor Registry (CCR)), the Government's primary registrant database;

c. Provide your DUNS number and TIN on the application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one-to-two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data entered into SAM database by an entity. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, you will need to allow 24 to 48 hours for the information to be available in Grants.gov before you can submit an application through Grants.gov.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also, note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *http://www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: *http://www.grants.gov/web/grants/register.html.*

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 Grants to States for School Emergency Management Program, CFDA number 84.184Q, must be submitted electronically using the Governmentwide Grants.gov Apply site. 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 Grants to States for School Emergency Management competition at *www.Grants.gov.* You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.184, not 84.184Q).

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. Except as otherwise noted in this section, will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

• The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

• You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You also can find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *http://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 section and all other attachments to your application as files in a PDF (Portable Document) read-only, non-modifiable format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF or submit a password-protected file, we will not review that material. Additional, detailed information on how to attach files is in the application instructions.

• Your electronic application must comply with any page-limit requirements described in this notice.

• After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by email. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to the Grants.gov system;

and

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining

which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and email or fax your statement to: Amy Banks, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E117, Washington, DC 20202–6450. FAX: (202) 453–6716.

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 84.184Q),
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 84.184Q),
550 12th Street SW., Room 7039,
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 applications 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 75.210 of EDGAR 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. The may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measure:* The Department has established the following Government Performance and Results Act of 1993 (GPRA) performance measure for the Grants to States for School Emergency Management program:

1. The number of LEAs with high-quality EOPs at the start of the grant compared to the number of LEAs with

high-quality EOPs at the end of the grant.

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Amy Banks, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E117, Washington, DC 20202–6450. Telephone: (202) 453–6704 or by email: *Amy.Banks@ed.gov.*

If you use a TDD or a TTY, call the Federal Relay Service, 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 computer diskette) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of 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 this site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *http://www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: May 20, 2014.

Deborah S. Delisle,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2014–12045 Filed 5–22–14; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Proposed Subsequent Arrangement

AGENCY: Office of Nonproliferation and International Security, Department of Energy.

ACTION: Proposed subsequent arrangement.

SUMMARY: This document is being issued under the authority of the Atomic Energy Act of 1954, as amended. The Department is providing notice of a proposed subsequent arrangement to be carried out in the Republic of Korea under the Agreement for Cooperation between the Government of the United States of America and the Government of the Republic of Korea Concerning Civil Uses of Atomic Energy, signed November 24, 1972, as amended (the ''Agreement'').

DATES: This subsequent arrangement will take effect no sooner than June 9, 2014

FOR FURTHER INFORMATION CONTACT: Ms. Katie Strangis, Office of Nonproliferation and International Security, National Nuclear Security Administration, Department of Energy. Telephone: 202–586–8623 or email: *Katie.Strangis@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION: This subsequent arrangement concerns a proposed Joint Determination by the Government of the United States of America and the Government of the Republic of Korea pursuant to Article VIII(C) of the Agreement, that the provisions of Article XI of the Agreement may be effectively applied for the alteration in form or content of U.S.-origin nuclear material irradiated in pressurized water reactors, CANDU reactors, and a research reactor, at the Post Irradiation Examination Facility (PIEF), the Irradiated Material Examination Facility (IMEF), the Radio Isotope Production Area (RIPA), and the DUPIC Fuel Development Facility (DFDF), along with identified analytical laboratories, at the Headquarters of the Korea Atomic Energy Research Institute (KAERI), in accordance with the plans contained in the documents KAERI/AR–1003/2013, ''Post-Irradiation Examination and R&D Programs Using Irradiated Fuels at KAERI,'' dated August 2013, and KAERI/AR–1004/2013, ''DUPIC Fuel Fabrication Using Spent PWR Fuel at KAERI,'' dated August 2013. These facilities are found acceptable to both parties pursuant to Article VIII(C) of the Agreement for the sole purpose of alteration in form or content of irradiated U.S.-origin nuclear material for post-irradiation examination and for research, development and manufacture of DUPIC fuel powders, pellets and elements for the period beginning on the date of entry into force of an agreement extending the terms of the Agreement beyond March 19, 2014, and ending on the earlier of March 19, 2016, or the date of entry into force of a successor agreement to the Agreement, unless terminated earlier by written agreement of the Parties to the Agreement. Any activities additional to the plans or changes in the equipment in these facilities will be reviewed by both parties to ensure the general consistency with the scope and objectives of the Joint Determination.

In accordance with section 131a. of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security of the United States of America.

Dated: May 7, 2014.

For the Department of Energy.

Anne M. Harrington,

Deputy Administrator, Defense Nuclear Nonproliferation.

[FR Doc. 2014–12000 Filed 5–22–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Proposed Subsequent Arrangement

AGENCY: Office of Nonproliferation and International Security, Department of Energy.

ACTION: Proposed subsequent arrangement.

SUMMARY: This document is being issued under the authority of the Atomic Energy Act of 1954, as amended. The Department is providing notice of a proposed subsequent arrangement under the Agreement for Cooperation Concerning Civil Uses of Nuclear Energy Between the Government of the United States of America and the Government of Canada and the Agreement for Cooperation in the Peaceful Uses of Nuclear Energy Between the United States of America and the European Atomic Energy Community.

DATES: This subsequent arrangement will take effect no sooner than June 9, 2014.

FOR FURTHER INFORMATION CONTACT: Ms. Katie Strangis, Office of Nonproliferation and International Security, National Nuclear Security Administration, Department of Energy. Telephone: 202–586–8623 or email: *Katie.Strangis@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION: This subsequent arrangement concerns the retransfer of 423,063 kg of U.S.-origin natural uranium trioxide (UO3) (82.73% U), 350,000 kg of which is uranium, from Cameco Corporation (Cameco) in Saskatoon, Saskatchewan, to Springfields Fuels Ltd. in Lancashire, United Kingdom. The material, which is currently located at Cameco in Blind River, Ontario, will be converted to uranium hexafluoride (UF6) by Springfields Fuels, Ltd. in Lancashire,

United Kingdom. The material was originally obtained by Cameco from Cameco Resources-Crowe Butte Operation pursuant to export license XSOU8798.

In accordance with section 131a. of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement concerning the retransfer of nuclear material of United States origin will not be inimical to the common defense and security of the United States of America.

Dated: May 7, 2014.

For the Department of Energy.

Anne M. Harrington,

Deputy Administrator, Defense Nuclear Nonproliferation.

[FR Doc. 2014–11996 Filed 5–22–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Extension

AGENCY: U.S. Energy Information Administration (EIA), Department of Energy.

ACTION: Agency Information Collection Activities: Information Collection Extension; Notice and Request for Comments.

SUMMARY: The EIA, pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years with the Office of Management and Budget (OMB), Form EIA–846, ''Manufacturing Energy Consumption Survey.'' 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 July 22, 2014. 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 Tom Lorenz, Office of Energy Consumption and Efficiency Statistics, EI–22, Forrestal Building, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585 or by fax at (202) 586–9753, or by email at *Thomas.Lorenz@eia.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Tom Lorenz at the address listed above. To view the form online please go to: *http://www.eia.gov/survey/notice/consumption_mecs2014.cfm.*

SUPPLEMENTARY INFORMATION: This information collection request contains:

(1) *OMB No.:* 1905–0169;

(2) *Information Collection Request Title:* Manufacturing Energy Consumption Survey (MECS);

(3) *Type of Request:* Reinstatement, with change, of a previously approved collection for which approval has expired;

(4) *Purpose:*

The Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) and (42 U.S.C. 7135(i)) require the EIA to carry out a centralized, comprehensive, and unified energy information program. This program collects, evaluates, assembles, analyzes, and disseminates information on energy resource reserves, production, demand, technology, and related economic and statistical information. This information is used to assess the adequacy of energy resources to meet near and longer term domestic demands and to promote sound policymaking, efficient markets, and public understanding of energy and its interaction with the economy and the environment.

The Manufacturing Energy Consumption Survey (MECS) is a self-administered sample survey designed to collect energy consumption and expenditures data from establishments in the manufacturing sector; i.e., North American Industry Classification System (NAICS) codes 31–33. Previous MECS required multiple collection forms depending on an establishment's primary business activity classification under NAICS. The increased use of technology by means of an Internet data collection system however, has allowed the MECS to eliminate the need to have multiple forms.

The 2014 MECS will collect information during 2015 for business activities in calendar year 2014, and the 2016 MECS, if implemented, will collect information during 2017 for business activities in calendar year 2016. For the 2014 and 2016 MECS, as in the past, EIA proposes to collect the following data from each MECS establishment: (1) For each energy source consumed—consumption (total, fuel and nonfuel uses) and the expenditures for each energy source, energy storage (as applicable), energy produced onsite, and shipments (as applicable); (2) energy end uses; (3) fuel-switching capabilities (4) general energy-saving technologies; (5) energy management activities; and (6) square footage, and number of buildings in the establishment.

The MECS has been conducted eight times previously, covering the years 1985, 1988, 1991, 1994, 1998, 2002, 2006, and 2010. In all eight survey years, the MECS has collected baseline data on manufacturers' energy consumption and expenditures. The MECS collected data on fuel-switching capabilities in all years except 1998. In the 1991, 1994, 1998, 2002, 2006, and 2010 surveys, the MECS also collected data on end-uses, energy management activities, building square footage, and energy-saving technologies.

The MECS information is the basis for data and analytic products that can be found at *http://www.eia.gov/consumption/manufacturing.* Also on this Web site are past publications, articles, and a special analytic series, ''Industry Analysis Briefs.'' The 2014 and 2016 MECS will also be used to benchmark EIA's industry forecasting model and update changes in the energy intensity and greenhouse gases data series.

The proposed 2014 and 2016 MECS uses experience gained from the administration and processing of the seven previous surveys and past consultations with respondents, trade association representatives, and data users to improve the survey.

Please refer to the forms and instructions for more information about the purpose, who must report, when to report, where to submit, the elements to be reported, detailed instructions, provisions for confidentiality, and uses of the information. For instructions on obtaining materials, see the ''For Further Information Contact'' section;

(4a) *Proposed Changes to Information Collection:*

EIA proposes making several changes from the 2010 MECS for use in the 2014 and 2016 MECS. The first substantial change for the 2014 and 2016 MECS is shortening the collection time frame. The past MECS cycles, going back to 1988, have been quadrennial surveys; however with the increased importance of relevant energy data, EIA is proposing to shorten the collection time frame from a quadrennial to a biennial survey.

This change doubles the response burden because EIA would be collecting two rounds of data from respondents under this OMB clearance number.

In the past EIA has calculated the amount of petrochemical feedstocks and asphalt that are produced by a refinery and used elsewhere in manufacturing. To obtain more accurate estimates of these two energy sources EIA proposes collecting data about petrochemical feedstocks and asphalt. The data collected about petrochemical feedstocks and asphalt will be largely what the MECS collects about other energy sources; purchases, expenditures, transfers in, produced on-site, used as fuel and nonfuel, and shipments data. Petrochemical feedstocks and asphalt are used in a few industries, so the MECS will collect data about these energy sources from those NAICS codes that use this type of energy; namely, petrochemical manufacturing (NAICS 325110), asphalt paving mixture and block manufacturing (NAICS 324121), and asphalt shingle and coating materials manufacturing (NAICS 324122). The response burden will be kept to a minimum because the data collected about petrochemical feedstocks and asphalt will only be collected from the industries listed above.

EIA is working with the Advanced Manufacturing Office (AMO) at DOE to reform the questions in the Energy Management and General Technologies sections on the MECS. The data collected would help EIA and DOE to develop manufacturing energy efficiency improvements. These will be ''Yes''/''No'' questions that will not significantly affect response burden.

Further, EIA plans to ask iron and steel mills (NAICS 331111) about their use of blast furnaces and electric arc furnaces (EAF) at the establishment. This will help EIA identify whether an iron and steel mill is an integrated or a mini mill, and help determine if all the essential energy data has been collected from the establishment. These will be ''Yes''/''No'' questions that will not significantly affect response burden.

Besides the changes already discussed, the content of the 2014 and 2016 MECS will be largely unchanged from the 2010 survey. Most respondents will submit their data electronically in a question-answer format as opposed to the spreadsheet format used in the past. The MECS information products will continue to present industry-by-Census Region level data as well as national data;

(5) *Annual Estimated Number of Respondents:* 31,000;

(6) *Annual Estimated Number of Total Responses:* 10,333;

(7) *Annual Estimated Number of Burden Hours:* 95,160;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* EIA estimates that there are no additional costs to respondents associated with the survey other than the costs associated with the burden hours;

Statutory Authority: Section 13(b) of the Federal Energy Administration Act of 1974, Pub. L. 93–275, codified at 15 U.S.C. 772(b).

Issued in Washington, DC, on May 16, 2014.

Stephen Harvey,

Assistant Administrator of Energy Statistics, U.S. Energy Information Administration.

[FR Doc. 2014–12008 Filed 5–22–14; 8:45 am]

BILLING CODE 6450–01–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: EC14–87–000.
Applicants: Oklahoma Cogeneration, LLC.
Description: Application for Authorization for Disposition of Jurisdictional Facilities of Oklahoma Cogeneration, LLC.
Filed Date: 5/15/14.
Accession Number: 20140515–5121.
Comments Due: 5 p.m. ET 6/5/14.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER14–1576–000.
Applicants: Emera Maine.
Description: Supplement to March 21, 2014 Request for Waiver of 18 CFR Section 37.6(k) of Emera Maine.
Filed Date: 5/8/14.
Accession Number: 20140508–5180.
Comments Due: 5 p.m. ET 5/22/14.

Docket Numbers: ER14–1964–000.
Applicants: LSP Safe Harbor Holdings, LLC.
Description: Notice of Succession to be effective 5/14/2014.
Filed Date: 5/14/14.
Accession Number: 20140514–5148.
Comments Due: 5 p.m. ET 6/4/14.

Docket Numbers: ER14–1965–000.
Applicants: Southwest Power Pool, Inc.
Description: 1765R10 KCP&L–GMO NITSA and NOA to be effective 5/1/2014.
Filed Date: 5/15/14.
Accession Number: 20140515–5057.
Comments Due: 5 p.m. ET 6/5/14.

Docket Numbers: ER14–1966–000.
Applicants: Idaho Power Company.
Description: Notice of Cancellation of Goshen-Kinport Line Communications Agreement to be effective 7/17/2014.
Filed Date: 5/15/14.
Accession Number: 20140515–5064.
Comments Due: 5 p.m. ET 6/5/14.

Docket Numbers: ER14–1967–000.
Applicants: Southwest Power Pool, Inc.
Description: Notice of Cancellation of MEAN Meter Agent Services Agreement of Southwest Power Pool, Inc.
Filed Date: 5/15/14.
Accession Number: 20140515–5157.
Comments Due: 5 p.m. ET 6/5/14.

Docket Numbers: ER14–1968–000.
Applicants: Southwest Power Pool, Inc.
Description: Notice of Cancellation of LES Meter Agent Services Agreement of Southwest Power Pool, Inc.
Filed Date: 5/15/14.
Accession Number: 20140515–5158.
Comments Due: 5 p.m. ET 6/5/14.

Docket Numbers: ER14–1969–000.
Applicants: Public Service Company of Colorado.
Description: 2014–5–15 Wind Integration Filing to be effective 8/1/2014.
Filed Date: 5/15/14.
Accession Number: 20140515–5202.
Comments Due: 5 p.m. ET 6/5/14.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES14–41–000.
Applicants: NorthWestern Corporation.
Description: Application for Authorization under Section 204 of the Federal Power Act to Issue Securities of NorthWestern Corporation.
Filed Date: 5/15/14.
Accession Number: 20140515–5129.
Comments Due: 5 p.m. ET 6/5/14.

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: May 15, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–11936 Filed 5–22–14; 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:

Filings Instituting Proceedings

Docket Numbers: RP14–862–000.
Applicants: Southeast Supply Header, LLC.
Description: Negotiated Rate Cleanup to be effective 6/13/2014.
Filed Date: 5/12/14.
Accession Number: 20140512–5068.
Comments Due: 5 p.m. ET 5/27/14.

Docket Numbers: RP14–864–000.
Applicants: Columbia Gulf Transmission, LLC.
Description: Order to Show Cause Compliance Filing to be effective 5/20/2014.
Filed Date: 5/12/14.
Accession Number: 20140512–5085.
Comments Due: 5 p.m. ET 5/27/14.

Docket Numbers: RP14–865–000.
Applicants: Hardy Storage Company, LLC.
Description: Order to Show Cause Compliance Filing to be effective 5/20/2014.
Filed Date: 5/12/14.
Accession Number: 20140512–5087.
Comments Due: 5 p.m. ET 5/27/14.

Docket Numbers: RP14–866–000.
Applicants: Crossroads Pipeline Company.
Description: Order to Show Cause Compliance Filing to be effective 5/20/2014.
Filed Date: 5/12/14.
Accession Number: 20140512–5088.
Comments Due: 5 p.m. ET 5/27/14.

Docket Numbers: RP14–867–000.
Applicants: Central Kentucky Transmission Company.
Description: Order to Show Cause Compliance Filing to be effective 5/20/2014.
Filed Date: 5/12/14.
Accession Number: 20140512–5089.
Comments Due: 5 p.m. ET 5/27/14.

Docket Numbers: RP14–868–000.
Applicants: Southern Star Central Gas Pipeline, Inc.
Description: Show Cause Order Compliance Filing—Posting of Offers to Purchase Capacity to be effective N/A.
Filed Date: 5/12/14.
Accession Number: 20140512–5228.
Comments Due: 5 p.m. ET 5/27/14.

Docket Numbers: RP14–872–000.
Applicants: Granite State Gas Transmission, Inc.
Description: Change to General Terms and Conditions—Capacity Release to be effective 7/1/2014.
Filed Date: 5/14/14.
Accession Number: 20140514–5019.
Comments Due: 5 p.m. ET 5/27/14.

Docket Numbers: RP14–873–000.
Applicants: Panhandle Eastern Pipe Line Company, LP.
Description: Order to Show Clause Compliance Filing to be effective 7/1/2014.
Filed Date: 5/14/14.
Accession Number: 20140514–5034.
Comments Due: 5 p.m. ET 5/27/14.

Docket Numbers: RP14–874–000.
Applicants: Trunkline Gas Company, LLC.
Description: Order to Show Cause Compliance Filing to be effective 7/1/2014.
Filed Date: 5/14/14.
Accession Number: 20140514–5035.
Comments Due: 5 p.m. ET 5/27/14.

Docket Numbers: RP14–875–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: Order to Show Clause Compliance Filing to be effective 7/1/2014.
Filed Date: 5/14/14.
Accession Number: 20140514–5036.
Comments Due: 5 p.m. ET 5/27/14.

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: RP14–772–001.
Applicants: Millennium Pipeline Company, LLC.
Description: Negotiated Rate Svc Agmts—SW Amendment to be effective 5/1/2014.
Filed Date: 5/13/14.
Accession Number: 20140513–5145.
Comments Due: 5 p.m. ET 5/27/14.

Any person desiring to protest in any of 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, 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: Wednesday, May 14, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–11937 Filed 5–22–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER14–1955–000]

RTO Energy Trading, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of RTO Energy Trading, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is June 5, 2014.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an

eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive 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.

Dated: May 16, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–11938 Filed 5–22–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

[DOE/EIS–0438]

Notice of Cancellation of Environmental Impact Statement for the Proposed Hermosa West Wind Energy Project, Albany County, Wyoming

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of Cancellation of Environmental Impact Statement.

SUMMARY: The U.S. Department of Energy (DOE), Western Area Power Administration (Western) is issuing this notice to advise the public that it is cancelling the preparation of an environmental impact statement (EIS) under the National Environmental Policy Act (NEPA) on an interconnection request by Shell WindEnergy, Inc. (SWE).

DATES: This cancellation is effective on May 23, 2014.

FOR FURTHER INFORMATION CONTACT: For additional information on the cancellation of this EIS process, contact Mark Wieringa, NEPA Document Manager, Western Area Power Administration, P.O. Box 281213, Lakewood, CO 80228–8213, email *wieringa@wapa.gov,* telephone (720) 962–7448. For general information on DOE's NEPA review process, contact Carol M. Borgstrom, Director of NEPA Policy and Compliance, GC–54, Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–0119, telephone (202) 586–4600 or (800) 472–2756, facsimile (202) 586–7031.

SUPPLEMENTARY INFORMATION: SWE proposed to design, construct, operate, and maintain an up to 300-megawatt Hermosa West Wind Energy Project (Project) in Albany County, Wyoming, and interconnect that Project with Western's transmission system. SWE's interconnection request caused Western to initiate a NEPA review of its Federal action to allow the interconnection. Western published a Notice of Intent for the EIS in the **Federal Register** on January 14, 2010 (75 FR 2138), and started the EIS process. Public scoping meetings were held subsequent to the Notice of Intent, and a Draft EIS was approved by Western's acting Administrator for public review and comment on September 24, 2012. The Environmental Protection Agency's Notice of Availability for the Draft EIS was published on October 5, 2012 (77 FR 60986). Public hearings on the Draft EIS were held on October 29 and 30, 2012, in Laramie and Cheyenne, Wyoming, respectively. SWE has since decided to suspend further action on its proposed Project. SWE notified Western of their decision to withdraw their interconnection request and Western is now terminating the NEPA review process on its interconnection decision and SWE's proposed Project. No Final EIS or Record of Decision will be issued for the Hermosa West Wind Energy Project. SWE could decide to reinitiate the proposed Project at some future date. In that event Western would issue a new Notice of Intent, and would initiate an entirely new NEPA process.

On November 16, 2011, the DOE General Counsel re-delegated all EIS authorities to Western's Administrator. Under the authority granted by that memorandum, I have terminated the NEPA process for SWE's proposed Hermosa West Wind Energy Project with the publication of this notice.

Dated: May 5, 2014.

Mark A. Gabriel,

Administrator.

[FR Doc. 2014–12003 Filed 5–22–14; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9015–1]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 05/12/2014 Through 05/16/2014

Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20140150, Final EIS, NMFS, AK, Steller Sea Lion Protection Measures for Groundfish Fisheries in the Bering Sea and Aleutian Islands Management Area, Review Period Ends: 06/23/2014, Contact: Gretchen Harrington, 907–586–7228.

EIS No. 20140151, Draft EIS, USFWS, VA, Chincoteague and Wallops Island National Wildlife Refuges Draft Comprehensive Conservation Plan, Comment Period Ends: 07/15/2014, Contact: Thomas Bonetti 413–253–8307.

EIS No. 20140152, Final EIS, FERC, ME, Downeast Liquefied Natural Gas (LNG) Project, Review Period Ends: 06/23/2014, Contact: Shannon Crosley 202–502–8853.

EIS No. 20140153, Draft EIS, NPS, NC, Cape Lookout National Seashore Off-Road Vehicle Management Plan, Comment Period Ends: 07/21/2014, Contact: Michael B. Edwards 303–969–2694.

AMENDED NOTICES

EIS No. 20140147, Draft EIS, USFS, CA, Rim Fire Recovery, Comment Period Ends: 06/16/2014, Contact: Maria Benech 209–532–3671, Revision to FR Notice Published 05/16/2014; Correction to reduce comment period from 06/30/2014 to 06/16/2014 reflecting the President's Council on Environmental Quality (CEQ) alternative arrangement granted in accordance with 40 CFR 1506.11 on December 9, 2013. Among these alternative arrangements, CEQ specifically approved shortening the public comment for this DEIS from 45 to 30 days.

Dated: May 20, 2014.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2014–12020 Filed 5–22–14; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9911–31–OA]

Notification of a Public Teleconference of the Science Advisory Board Panel for the Review of the EPA Water Body Connectivity Report

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public teleconference of the SAB Panel to discuss its draft advisory report concerning the EPA document titled *Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence (September, 2013 External Review Draft, EPA/600/R–11/098B).*

DATES: The public teleconference will be held on Thursday, June 19, 2014 from 1 p.m. to 5 p.m. (Eastern Time).

Location: The public teleconferences will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain information concerning the public teleconference may contact Dr. Thomas Armitage, Designated Federal Officer (DFO), EPA Science Advisory Board Staff Office (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; via telephone at (202) 564–2155 or via email at *armitage.thomas@epa.gov.* General information concerning the SAB as well as any updates concerning the teleconference announced in this notice may be found on the EPA Web site at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to FACA and EPA policy, notice is hereby given that the SAB Panel for the Review of the EPA Water Body Connectivity Report will hold a public teleconference to discuss its draft advisory report concerning the EPA document titled *Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence (September, 2013 External Review Draft, EPA/600/R–11/098B).* This SAB panel will provide advice to the Administrator through the chartered SAB.

Background: The SAB Panel for the Review of the EPA Water Body Connectivity Report previously held a face-to-face meeting on December 16–18, 2013 to conduct a peer review of the EPA document titled *Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence (September, 2013 External Review Draft, EPA/600/R–11/098B)* [**Federal Register** Notice dated September 24, 2013 (78 FR 58536–58537)]. The Panel also held public teleconferences on April 28, 2014 and May 2, 2014 to discuss its draft advisory report [**Federal Register** Notice dated April 1, 2014 (79 FR 18293–18294)]. Specifically, the Panel has been asked to evaluate: The clarity and technical accuracy of the EPA document, whether it includes the most relevant peer reviewed literature, whether the literature has been correctly summarized, and whether the findings and conclusions in the Report are supported by the available science. The purpose of the upcoming teleconference is for the SAB Panel to continue discussing its draft advisory report.

Availability of Meeting Materials: Teleconference agenda, the SAB Panel's draft advisory report, and any other meeting materials will be placed on the SAB Web at *http://www.epa.gov/sab* in advance of the teleconference. For technical questions and information concerning the EPA document, *Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence (September, 2013 External Review Draft, EPA/600/R–11/098B),* please contact Dr. Laurie Alexander, National Center for Environmental Assessment, Office of Research and Development, U.S. EPA, 1200 Pennsylvania Avenue NW., Mail Code 8623P, Washington, DC 20460, telephone (703) 347–8630 or via email at *alexander.laurie@epa.gov.*

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit comments for a federal advisory committee to consider as it develops advice for EPA. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for SAB panels to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide oral statements to the SAB Panel should contact the DFO directly. *Oral Statements:* In general, individuals or groups requesting an oral presentation at a public teleconference will be limited to three minutes. Interested parties should contact Dr. Thomas Armitage, DFO, in writing (preferably via email) at the contact information noted above by

June 16, 2014 to be placed on the list of public speakers. *Written Statements:* Members of the public wishing to provide written comments may submit them to the EPA Docket electronically via www.regulations.gov by email, by mail, or by hand delivery/courier. Please follow the detailed instructions provided in the written statements section of this notice. Written statements should be received in the EPA Docket by June 16, 2014 so that the information may be made available to the SAB Panel for its consideration. Written statements should be identified by Docket ID No. EPA–HQ–OA–2013–0582 and submitted to the Docket at *www.regulations.gov* by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: Docket_OEI@epa.gov:* Include the docket number in the subject line of the message.
- *Mail:* Office of Environmental Information (OEI) Docket (Mail Code: 28221T), Docket ID No. EPA–HQ–OA–2013–0582, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460. The phone number is (202) 566–1752.
- *Hand Delivery:* The OEI Docket is located in the EPA headquarters Docket Center, Room 3334, EPA West Building, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744. Deliveries are only accepted during the

docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Direct your comments to Docket ID No. EPA–HQ–OA–2013–0582. Please ensure that your comments are submitted by June 16, 2014. Comments received after that date will be marked late and may not be provided to the SAB Panel for consideration before the June 19, 2014 teleconference. It is EPA's policy to include all comments received in the public docket without change and to make the comments available on-line at *www.regulations.gov,* including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information 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 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 comments due to technical difficulties and cannot contact you for clarification, the SAB Panel may not be able to consider your comments. Electronic files should avoid the use of special characters and 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 *www.epa.gov/epahome/dockets.htm.*

Documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material will be publicly available only in hard copy. Publicly available docket materials are available either electronically at www.regulations.gov or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Accessibility: For information on access or services for individuals with disabilities, please contact Dr. Thomas Armitage at (202) 564–2155 or *armitage.thomas@epa.gov.* To request accommodation of a disability, please contact Dr. Armitage preferably at least ten days prior to the teleconference to give EPA as much time as possible to process your request.

Dated: May 14, 2014.

Thomas H. Brennan,

Deputy Director, EPA Science Advisory Staff Office.

[FR Doc. 2014–12026 Filed 5–22–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9911–38–OAR; EPA–HQ–OEI–2013–0807]

Privacy Act; Notification of a New System of Records Notice for the Engine and Vehicle Exemptions System (EV–ES)

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency's (EPA) Office of Air and Radiation, Office of Transportation and Air Quality, is giving notice that it proposes to create a new system of records pursuant to the provisions of the Privacy Act of 1974 (5 USC 552a). This system of records contains personally identifiable information (PII) collected from owners of motor vehicles who wish to temporarily import their vehicle into the United States for personal use and who are not residents of the United States.

DATES: Persons wishing to comment on this new system of records notice must do so by July 2, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OEI–2013–0807, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: oei.docket@epa.gov*
- *Fax:* (202) 566–1752
- *Mail:* OEI Docket, Environmental Protection Agency, Mail code: 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
- *Hand Delivery:* OEI Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OEI–2013-0807. 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 for which disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov*. 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: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available (e.g., CBI or other information for which disclosure is restricted by statute). Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the OEI Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1745.

FOR FURTHER INFORMATION CONTACT: Holly Pugliese, Compliance Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 2000 Traverwood, Ann Arbor,

Michigan 48105; telephone number: 734–214–4288; fax number: 734–214–4869; email address: *pugliese.holly@epa.gov*.

SUPPLEMENTARY INFORMATION:

General Information

The U.S. Environmental Protection Agency (EPA) plans to create a Privacy Act system of records for the Engine and Vehicle Exemptions System (EV–ES). The information collected in this system supports the Imports Exemptions program under the Clean Air Act (CAA) and implementing regulations codified in 40 CFR Parts 85 and 1068. The CAA requires manufacturers of motor vehicles and engines to design and build vehicles that will comply with emissions standards throughout the vehicle's life span. EPA and Customs and Border Protection (CBP) regulations allow for individuals who are not residents of the United States and who reside outside of the United States to import nonconforming on-highway vehicles (e.g., cars, motorcycles or motor homes) for a period of up to one year for personal use. Applicants are required to provide their name, address, phone number or email and the vehicle identification number (VIN) as part of the application process in order for EPA to provide approval or denial letters to the requestors. The information that will be maintained regarding program participants includes the vehicle owner's name, address, phone number, email address and vehicle identification number (VIN).

The information is contained in computer and paper files at EPA's National Vehicle and Fuel Emissions Laboratory in Ann Arbor, Michigan. Only contractor employees (governed by Privacy Act compliance terms in their contract) and EPA employees administering the program have access to the information contained in the database. Files containing personal information are kept in locked filing cabinets. Physical access to the filing cabinets is limited to authorized personnel employees with building key cards.

Dated: May 7, 2014.

Renee P. Wynn,

Acting Assistant Administrator and Acting Chief Information Officer.

EPA–65

SYSTEM NAME:

Engine and Vehicle Exemptions System (EV–ES)

SYSTEM LOCATION:

US EPA, 109 T.W. Alexander Drive, Research Triangle Park, NC 27711

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who apply to the EPA for a nonresident exemption to import a nonconforming on-highway vehicle (e.g., cars, motorcycles or motor homes) for a period of up to one year for personal use.

CATEGORIES OF RECORDS IN THE SYSTEM:

The vehicle owner's name, address, phone number, email address and vehicle identification number (VIN).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM (INCLUDES ANY REVISIONS OR AMENDMENTS):

Title II of the Clean Air Act, (42 U.S.C. 7521 et seq.) provides that the EPA may issue exemptions and exclusions for nonconforming vehicles to enter into the United States.

PURPOSE(S):

The primary purpose of the system is to collect and maintain the information necessary for EPA to determine if the request for a nonresident exemption meets the criteria established in the regulations implementing this program codified in 40 CFR Parts 85 and 1068. In addition, the information collected is used to contact the requestor if there are questions regarding the request and to subsequently issue an approval or denial letter regarding the request. The information may also be used by CBP and EPA's Office of Enforcement and Compliance Assurance (OECA) to validate that the shipment at the port is valid.

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

General routine uses A, F, H, K and L apply to this system. (A detailed description of these routine uses can be found in the Agency's Systems of Records Web site at *http://www.epa.gov/privacy/notice/general.htm*.)

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on computer disks and tapes at the National Computer Center, Research Triangle Park, North Carolina and at EPA's Office of Transportation and Air Quality (OTAQ), Ann Arbor, MI.

RETRIEVABILITY:

Records are retrievable by all or part of the person's name, phone number, physical address, or email address.

SAFEGUARDS:

—Computer-stored information is protected in accordance with the Agency's security requirements.

—Access to the information in the system is limited to authorized Agency and contractor personnel who administer the program. No external access to the system is provided.

—Any contractor is subject to the Federal Acquisition Regulations (FAR) Privacy Act clauses in its contract with EPA.

RETENTION AND DISPOSAL:

Records stored in this system are subject to Schedule 483.

SYSTEM MANAGER(S) AND ADDRESS:

Holly Pugliese, Compliance Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 2000 Traverwood, Ann Arbor, Michigan 48105; telephone number: 734–214–4288; fax number: 734–214–4869; email address: *pugliese.holly@epa.gov.*

NOTIFICATION PROCEDURE:

Any individual who wants to know whether this system of records contains a record about him or her, who wants access to his or her record, or who wants to contest the contents of a record, should make a written request to the EPA FOIA Office, Attn: Privacy Act Officer, MC 2822T, 1200 Pennsylvania Avenue NW., Washington, DC 20460.

RECORD ACCESS PROCEDURE:

Request for access must be made in accordance with the procedures described in EPA's Privacy Act regulations at 40 CFR part 16. Requesters will be required to provide adequate identification, such as a driver's license, employee identification card, or other identifying document. Additional identification procedures may be required in some instances.

CONTESTING RECORDS PROCEDURES:

Requests for correction or amendment must identify the record to be changed and the corrective action sought. Complete EPA Privacy Act procedures are described in EPA's Privacy Act regulations at 40 CFR part 16.

RECORD SOURCE CATEGORIES:

There are two sources of information for records stored in the system:

(1) Vehicle Identification Numbers (VINs) provided to EPA by the requestor of the exemption.

(2) Information on the vehicles provided by their owners from potential and actual participants in the program.

SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE PRIVACY ACT:

None.

[FR Doc. 2014–12019 Filed 5–22–14; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collections Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communication Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before June 23, 2014. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov;* and to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain*, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0849.

Title: Commercial Availability of Navigation Devices.

Form Number: Not applicable.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 962 respondents; 585,800 responses.

Estimated Time per Response: 0.00278 hours—120 hours.

Frequency of Response: Recordkeeping requirement; Third party disclosure requirement; On occasion reporting requirement; Annual reporting requirement; Semi-annual reporting requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority is contained in Sections 4(i), 303(r) and 629 of the Communications Act of 1934, as amended.

Total Annual Burden: 48,152 hours.

Total Annual Cost: $2,620.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: In January 2013, the D.C. Circuit released its opinion in *EchoStar Satellite L.L.C.* v. *FCC,* 704 F.3d 992 (D.C. Cir. 2013). In that decision, the D.C. Circuit vacated the *15336 Second Report and Order, FCC 03–225 (released October 9, 2003). Therefore, the information collection requirements that were contained in 47 CFR 76.1905(c)(2) and (c)(3), 47 CFR 76.1906(a)(1) and (b) and the complaint requirement are no longer a part of this information collection. The Commission is revising this collection to remove those requirements and the burden hours and cost burden associated with them.

These information collection requirements are also a part of this collection and have not changed since last approved by the Office of Management and Budget (OMB): 47 CFR 76.1205(b)(1) states a multichannel video programming provider that is subject to the requirements of Section 76.1204(a)(1) must provide the means to allow subscribers to self-install the CableCARD in a CableCARD-reliant device purchased at retail and inform a subscriber of this option when the subscriber requests a CableCARD. This requirement shall be effective August 1, 2011, if the MVPD allows its subscribers to self-install any cable modems or operator-leased set-top boxes and November 1, 2011 if the MVPD does not allow its subscribers to self-install any cable modems or operator-leased set-top boxes.

47 CFR 76.1205(b)(1)(A) states that this requirement shall not apply to cases in which neither the manufacturer nor the vendor of the CableCARD-reliant device furnishes to purchasers appropriate instructions for self-installation of a CableCARD, and a manned toll-free telephone number to answer consumer questions regarding CableCARD installation but only for so long as such instructions are not furnished and the call center is not offered.

The requirements contained in Section 76.1205 are intended to ensure that consumers are able to install CableCARDs in the devices that they purchase at retail, which the Commission determined is essential to a functioning retail market.

47 CFR 76.1205(b)(2) states effective August 1, 2011, provide multi-stream CableCARDs to subscribers, unless the subscriber requests a single-stream CableCARD.This requirement will ensure that consumers have access to CableCARDs that are compatible with their retail devices, and can request such devices from their cable operators.

47 CFR 76.1205(b)(5) requires to separately disclose to consumers in a conspicuous manner with written information provided to customers in accordance with Section 76.1602, with written or oral information at consumer request, and on Web sites or billing inserts. This requirement is intended to ensure that consumers understand that retail options are available and that cable operators are not subsidizing their own devices with service fees in violation of Section 629 of the Act.

47 CFR 15.123(c)(3) states subsequent to the testing of its initial unidirectional digital cable product model, a

manufacturer or importer is not required to have other models of unidirectional digital cable products tested at a qualified test facility for compliance with the procedures of Uni-Dir-PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma'' (incorporated by reference, see § 15.38) unless the first model tested was not a television, in which event the first television shall be tested as provided in § 15.123(c)(1). The manufacturer or importer shall ensure that all subsequent models of unidirectional digital cable products comply with the procedures in the Uni-Dir-PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma'' (incorporated by reference, see § 15.38) and all other applicable rules and standards. The manufacturer or importer shall maintain records indicating such compliance in accordance with the verification procedure requirements in part 2, subpart J of this chapter. The manufacturer or importer shall further submit documentation verifying compliance with the procedures in the Uni-Dir-PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma'' (incorporated by reference, see § 15.38) to the testing laboratory representing cable television system operators serving a majority of the cable television subscribers in the United States.

47 CFR15.123(c)(5)(iii) states subsequent to the successful testing of its initial M–UDCP, a manufacturer or importer is not required to have other M–UDCP models tested at a qualified test facility for compliance with M-Host UNI–DIR–PICS–IOI–061101 (incorporated by reference, see § 15.38) unless the first model tested was not a television, in which event the first television shall be tested as provided in § 15.123(c)(5)(i). The manufacturer or importer shall ensure that all subsequent models of M–UDCPs comply with M-Host UNI–DIR–PICS–IOI–061101 (incorporated by reference, see § 15.38) and all other applicable rules and standards. The manufacturer or importer shall maintain records indicating such compliance in accordance with the verification procedure requirements in part 2, subpart J of this chapter. For each M–UDCP model, the manufacturer or importer shall further submit documentation verifying compliance with M-Host UNI–DIR–PICS–IOI–061101 to the testing laboratory representing cable television system operators serving a majority of the cable television subscribers in the United States.

47 CFR 76.1203 provides that a multichannel video programming distributor may restrict the attachment or use of navigation devices with its system in those circumstances where electronic or physical harm would be caused by the attachment or operation of such devices or such devices that assist or are intended or designed to assist in the unauthorized receipt of service. Such restrictions may be accomplished by publishing and providing to subscribers standards and descriptions of devices that may not be used with or attached to its system. Such standards shall foreclose the attachment or use only of such devices as raise reasonable and legitimate concerns of electronic or physical harm or theft of service.

47 CFR 76.1205 states that technical information concerning interface parameters which are needed to permit navigation devices to operate with multichannel video programming systems shall be provided by the system operator upon request.

47 CFR 76.1207 states that the Commission may waive a regulation adopted under this Part for a limited time, upon an appropriate showing by a provider of multichannel video programming and other services offered over multichannel video programming systems, or an equipment provider that such a waiver is necessary to assist the development or introduction of a new or improved multichannel video programming or other service offered over multichannel video programming systems, technology, or products. Such waiver requests are to be made pursuant to 47 CFR 76.7. 47 CFR 76.1208 states that any interested party may file a petition to the Commission for a determination to provide for a sunset of the navigation devices regulations on the basis that (1) the market for multichannel video distributors is fully competitive; (2) the market for converter boxes, and interactive communications equipment, used in conjunction with that service is fully competitive; and (3) elimination of the regulations would promote competition and the public interest.

47 CFR 15.118(a) and 47 CFR 15.19(d) (label and information disclosure)—The U.S. Bureau of the Census reports that, at the end of 2002, there were 571 U.S. establishments that manufacture audio and visual equipment. These manufacturers already have in place mechanisms for labeling equipment and including consumer disclosures in the form of owners' manuals and brochures in equipment packaging. We estimate that manufacturers who voluntarily decide to label their equipment will need no more than 5 hours to develop a label or to develop wording for a consumer disclosure for owners' manuals/brochures to be included with the device. Once developed, we do not anticipate any ongoing burden associated with the revision/modification of the label, if used, or the disclosure.

Status Reports—Periodic reports are required from large cable multiple system operators detailing CableCARD deployment/support for navigation devices. (This requirement is specified in FCC 05–76, CS Docket No. 97–80).

OMB Control Number: 3060–0980.

Title: Implementation of the Satellite Home Viewer Improvement Act of 1999: Local Broadcast Signal Carriage Issues and Retransmission Consent Issues, 47 CFR Section 76.66.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 10,280 respondents; 11,938 responses.

Estimated Time per Response: 1 hour to 5 hours.

Frequency of Response: Third party disclosure requirement; On occasion reporting requirement, One every three years reporting requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in 47 U.S.C. 325, 338, 339 and 340.

Total Annual Burden: 12,146 hours.

Total Annual Cost: 24,000.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The Commission is requesting a three-year extension of this currently approved collection. The following information collection requirements are covered by this submission:

47 CFR 76.66(b)(1) states each satellite carrier providing, under section 122 of title 17, United States Code, secondary transmissions to subscribers located within the local market of a television broadcast station of a primary transmission made by that station, shall carry upon request the signals of all television broadcast stations located within that local market, subject to section 325(b) of title 47, United States Code, and other paragraphs in this section. Satellite carriers are required to carry digital-only stations upon request

in markets in which the satellite carrier is providing any local-into-local service pursuant to the statutory copyright license.

47 CFR 76.66(b)(2) requires a satellite carrier that offers multichannel video programming distribution service in the United States to more than 5,000,000 subscribers shall, no later than December 8, 2005, carry upon request the signal originating as an analog signal of each television broadcast station that is located in a local market in Alaska or Hawaii; and shall, no later than June 8, 2007, carry upon request the signals originating as digital signals of each television broadcast station that is located in a local market in Alaska or Hawaii. Such satellite carrier is not required to carry the signal originating as analog after commencing carriage of digital signals on June 8, 2007. Carriage of signals originating as digital signals of each television broadcast station that is located in a local market in Alaska or Hawaii shall include the entire free over-the-air signal, including multicast and high definition digital signals.

47 CFR 76.66(c)(3) requires that a commercial television station notify a satellite carrier in writing whether it elects to be carried pursuant to retransmission consent or mandatory consent in accordance with the established election cycle.

47 CFR 76.66(c)(5) requires that a noncommercial television station must request carriage by notifying a satellite carrier in writing in accordance with the established election cycle.

47 CFR 76.66(c)(6) requires a commercial television broadcast station located in a local market in a noncontiguous state to make its retransmission consent-mandatory carriage election by October 1, 2005, for carriage of its signals that originate as analog signals for carriage commencing on December 8, 2005 and ending on December 31, 2008, and by April 1, 2007 for its signals that originate as digital signals for carriage commencing on June 8, 2007 and ending on December 31, 2008. For analog and digital signal carriage cycles commencing after December 31, 2008, such stations shall follow the election cycle in 47 CFR 76.66(c)(2) and 47 CFR 76.66(c)(4). A noncommercial television broadcast station located in a local market in Alaska or Hawaii must request carriage by October 1, 2005, for carriage of its signals that originate as an analog signal for carriage commencing on December 8, 2005 and ending on December 31, 2008, and by April 1, 2007 for its signals that originate as digital signals for carriage commencing on June 8, 2007 and ending on December 31, 2008. Moreover, Section 76.66(c) requires a commercial television station located in a local market in a noncontiguous state to provide notification to a satellite carrier whether it elects to be carried pursuant to retransmission consent or mandatory consent.

47 CFR 76.66(d)(1)(ii) states an election request made by a television station must be in writing and sent to the satellite carrier's principal place of business, by certified mail, return receipt requested.

47 CFR 76.66(d)(1)(iii) states a television station's written notification shall include the:

(A) Station's call sign;

(B) Name of the appropriate station contact person;

(C) Station's address for purposes of receiving official correspondence;

(D) Station's community of license;

(E) Station's DMA assignment; and

(F) For commercial television stations, its election of mandatory carriage or retransmission consent.

47 CFR 76.66(d)(1)(iv)—Within 30 days of receiving a television station's carriage request, a satellite carrier shall notify in writing: (A) Those local television stations it will not carry, along with the reasons for such a decision; and (B) those local television stations it intends to carry.

47 CFR 76.66(d)(2)(i) states a new satellite carrier or a satellite carrier providing local service in a market for the first time after July 1, 2001, shall inform each television broadcast station licensee within any local market in which a satellite carrier proposes to commence carriage of signals of stations from that market, not later than 60 days prior to the commencement of such carriage:

(A) Of the carrier's intention to launch local-into-local service under this section in a local market, the identity of that local market, and the location of the carrier's proposed local receive facility for that local market;

(B) Of the right of such licensee to elect carriage under this section or grant retransmission consent under section 325(b);

(C) That such licensee has 30 days from the date of the receipt of such notice to make such election; and

(D) That failure to make such election will result in the loss of the right to demand carriage under this section for the remainder of the 3-year cycle of carriage under section 325.

47 CFR 76.66(d)(2)(ii) states satellite carriers shall transmit the notices required by paragraph (d)(2)(i) of this section via certified mail to the address for such television station licensee listed in the consolidated database system maintained by the Commission.

47 CFR 76.66(d)(2)(iii) requires a satellite carrier with more than five million subscribers to provide a notice as required by 47 CFR 76.66(d)(2)(i) and 47 CFR 76.66(d)(2)(ii) to each television broadcast station located in a local market in a noncontiguous state, not later than September 1, 2005 with respect to analog signals and a notice not later than April 1, 2007 with respect to digital signals; provided, however, that the notice shall also describe the carriage requirements pursuant to Section 338(a)(4) of Title 47, United States Code, and 47 CFR 76.66(b)(2).

47 CFR 76.66(d)(2)(iv) requires that a satellite carrier shall commence carriage of a local station by the later of 90 days from receipt of an election of mandatory carriage or upon commencing local-into-local service in the new television market.

47 CFR 76.66(d)(2)(v) states within 30 days of receiving a local television station's election of mandatory carriage in a new television market, a satellite carrier shall notify in writing: Those local television stations it will not carry, along with the reasons for such decision, and those local television stations it intends to carry.

47 CFR 76.66(d)(2)(vi) requires satellite carriers to notify all local stations in a market of their intent to launch HD carry-one, carry-all in that market at least 60 days before commencing such carriage.

47 CFR 76.66(d)(3)(ii) states a new television station shall make its election request, in writing, sent to the satellite carrier's principal place of business by certified mail, return receipt requested, between 60 days prior to commencing broadcasting and 30 days after commencing broadcasting. This written notification shall include the information required by paragraph (d)(1)(iii) of this section.

47 CFR 76.66(d)(3)(iv) states within 30 days of receiving a new television station's election of mandatory carriage, a satellite carrier shall notify the station in writing that it will not carry the station, along with the *14511 reasons for such decision, or that it intends to carry the station.

47 CFR 76.66(d)(5)(i) states beginning with the election cycle described in § 76.66(c)(2), the retransmission of significantly viewed signals pursuant to § 76.54 by a satellite carrier that provides local-into-local service is subject to providing the notifications to stations in the market pursuant to paragraphs (d)(5)(i)(A) and (B) of this section, unless the satellite carrier was

retransmitting such signals as of the date these notifications were due.

(A) In any local market in which a satellite carrier provided local-into-local service on December 8, 2004, at least 60 days prior to any date on which a station must make an election under paragraph (c) of this section, identify each affiliate of the same television network that the carrier reserves the right to retransmit into that station's local market during the next election cycle and the communities into which the satellite carrier reserves the right to make such retransmissions;

(B) In any local market in which a satellite carrier commences local-into-local service after December 8, 2004, at least 60 days prior to the commencement of service in that market, and thereafter at least 60 days prior to any date on which the station must thereafter make an election under § 76.66(c) or (d)(2), identify each affiliate of the same television network that the carrier reserves the right to retransmit into that station's local market during the next election cycle.

47 CFR 76.66(f)(3) states except as provided in 76.66(d)(2), a satellite carrier providing local-into-local service must notify local television stations of the location of the receive facility by June 1, 2001 for the first election cycle and at least 120 days prior to the commencement of all election cycles thereafter.

47 CFR 76.66(f)(4) states a satellite carrier may relocate its local receive facility at the commencement of each election cycle. A satellite carrier is also permitted to relocate its local receive facility during the course of an election cycle, if it bears the signal delivery costs of the television stations affected by such a move. A satellite carrier relocating its local receive facility must provide 60 days notice to all local television stations carried in the affected television market.

47 CFR 76.66(h)(5) states a satellite carrier shall provide notice to its subscribers, and to the affected television station, whenever it adds or deletes a station's signal in a particular local market pursuant to this paragraph.

47 CFR 76.66(m)(1) states whenever a local television broadcast station believes that a satellite carrier has failed to meet its obligations under this section, such station shall notify the carrier, in writing, of the alleged failure and identify its reasons for believing that the satellite carrier failed to comply with such obligations.

47 CFR 76.66(m)(2) states the satellite carrier shall, within 30 days after such written notification, respond in writing to such notification and comply with such obligations or state its reasons for believing that it is in compliance with such obligations.

47 CFR 76.66(m)(3) states a local television broadcast station that disputes a response by a satellite carrier that it is in compliance with such obligations may obtain review of such denial or response by filing a complaint with the Commission, in accordance with § 76.7 of title 47, Code of Federal Regulations. Such complaint shall allege the manner in which such satellite carrier has failed to meet its obligations and the basis for such allegations.

47 CFR 76.66(m)(4) states the satellite carrier against which a complaint is filed is permitted to present data and arguments to establish that there has been no failure to meet its obligations under this section.

Non-rule requirement: Satellite carriers must immediately commence carriage of the digital signal of a television station that ceases analog broadcasting prior to the February 17, 2009 transition deadline provided that the broadcaster notifies the satellite carrier on or before October 1, 2008 of the date on which they anticipate termination of their analog signal.

OMB Control Number: 3060–0750.

Title: 47 CFR 73.671, Educational and Informational Programming for Children; 47 CFR Section 73.673, Public Information Initiatives Regarding Educational and Informational Programming for Children.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 2,303 respondents; 4,215 responses.

Estimated Time per Response: 1 to 5 minutes.

Frequency of Response: Third party disclosure requirement.

Obligation To Respond: Required to obtain benefits. The statutory authority for this collection is contained in Sections 154(i) and 303 of the Communications Act of 1934, as amended.

Total Annual Burden: 30,865 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: 47 CFR 73.671(c)(5) states that a core educational television program must be identified as specifically designed to educate and inform children by the display on the television screen throughout the program of the symbol E/I.

47 CFR 73.673 states each commercial television broadcast station licensee must provide information identifying programming specifically designed to educate and inform children to publishers of program guides. Such information must include an indication of the age group for which the program is intended.

These requirements are intended to provide greater clarity about broadcasters' obligations under the Children's Television Act (CTA) of 1990 to air programming ''specifically designed'' to serve the educational and informational needs of children and to improve public access to information about the availability of these programs. These requirements provide better information to the public about the shows broadcasters' air to satisfy their obligation to provide educational and informational programming under the CTA.

OMB Control Number: 3060–0787.

Title: Implementation of the Subscriber Carrier Selection Changes Provisions of the Telecommunications Act of 1996, Policies and Rules Concerning Unauthorized Changes of Consumers' Long Distance Carriers, CC Docket No. 94–129, FCC 07–223. Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or household; Business or other for-profit; State, Local or Tribal Government.

Number of Respondents and Responses: 4,160 respondents; 22,330 responses.

Estimated Time per Response: 30 minutes (.50 hours) to 10 hours.

Frequency of Response: Recordkeeping requirement; Biennial, on occasion and one-time reporting requirements; Third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for the information collection requirements is found at Sec. 258 [47 U.S.C. 258] Illegal Changes In Subscriber Carrier Selections, Public Law 104–104, 110 Stat. 56.

Total Annual Burden: 91,547 hours.

Total Annual Cost: $51,285,000.

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's system of records notice (SORN), FCC/CGB–1, ''Informal Complaints and Inquiries.'' As required by the Privacy Act, 5 U.S.C. 552a, the Commission also

published a SORN, FCC/CGB–1 ''Informal Complaints and Inquiries'', in the **Federal Register** on December 15, 2009 (74 FR 66356) which became effective on January 25, 2010.

Privacy Impact Assessment: No impacts(s).

Needs and Uses: Section 258 of the Telecommunications Act of 1996 directed the Commission to prescribe rules to prevent the unauthorized change by telecommunications carriers of consumers' selections of telecommunications service providers (slamming). On March 17, 2003, the FCC released the Third Order on Reconsideration and Second Further Notice of Proposed Rulemaking, CC Docket No. 94–129, FCC 03–42 (Third Order on Reconsideration), in which the Commission revised and clarified certain rules to implement section 258 of the 1996 Act. On May 23, 2003, the Commission released an Order (CC Docket No. 94–129, FCC 03–116) clarifying certain aspects of the Third Order on Reconsideration. On January 9, 2008, the Commission released the Fourth Report and Order, CC Docket No. 94–129, FCC 07–223, revising its requirements concerning verification of a consumer's intent to switch carriers.

The Fourth Report and Order modified the information collection requirements contained in 64.1120(c)(3)(iii) to provide for verifications to elicit ''confirmation that the person on the call understands that a carrier change, not an upgrade to existing service, bill consolidation, or any other misleading description of the transaction, is being authorized.''

OMB Control No.: 3060–0106.

Title: Part 43 Reporting Requirements for U.S. Providers of International Telecommunications Services and Affiliates; 47 CFR 43.61.

Form No.: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Responses and Respondents: 1,255 respondents and 1,255 responses.

Estimated Time per Response: 2 hours–220 hours.

Frequency of Response: Annual reporting requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Sections 1, 4(i), 4(j) 11, 201–205, 211, 214, 219, 220, 303(r), 309, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 161, 201, 211, 214, 219, 220, 303(r), 309 and 403.

Total Annual Burden: 19,530 hours.

Total Annual Cost: $339,000.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: In general there is no need for confidentiality with this collection of information.

Needs and Uses: The Federal Communications Commission (''Commission'') is requesting a three-year extension of OMB Control No. 3060–0106 titled, ''Part 43 Reporting Requirements for U.S. Providers of International Telecommunications Services and Affiliates; 47 CFR 43.61.''

The reporting requirements for which the Commission is seeking a three year approval from the Office of Management and Budget (OMB) are as follows:

47 CFR 43.61: Reports of international telecommunications traffic.

(a) Each common carrier engaged in providing international telecommunications service between the United States (as defined in the Communications Act, as amended, 47 U.S.C. 153) and any country or point outside that area shall file a report with the Commission not later than July 31 of each year for service actually provided in the preceding calendar year.

(1) The information contained in the reports shall include actual traffic and revenue data for each and every service provided by a common carrier, divided among service billed in the United States, service billed outside the United States, and service transiting the United States.

(2) Each common carrier shall submit a revised report by October 31 identifying any inaccuracies included in the annual report exceeding five percent of the reported figure.

(3) The information required under this section shall be furnished in conformance with the instructions and reporting requirements prepared under the direction of the Chief, Wireline Competition Bureau, prepared and published as a manual, in consultation and coordination with the Chief, International Bureau.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2014–11850 Filed 5–22–14; 8:45 am]

BILLING CODE 6712–01–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.*

A2B Cargo LLC (OFF), 3509 Vicky Circle NW., Kennesaw, GA 30144. Officer: David R. Ashford, Member (QI). Application Type: New OFF License.

ABF Freight System, Inc. dba ABF International Services dba ABF, Global Supply Chain Services (NVO), 3801 Old Greenwood Road, Fort Smith, AR 72903. Officers: Stephen J. Vicary, Assistant Vice President (QI); Roy M. Slagle, President. Application Type: Delete Trade Names & QI Change.

ASC Global Logistics, Inc. (NVO), 14710 S. Maple Avenue, Gardena, CA 90248. Officer: Suwon Song, CEO (QI). Application Type: New NVO License.

Automax Transport Inc. (NVO & OFF), 232 E. Floral Avenue, Arcadia, CA 91006. Officer: Alex C. Huang, CEO (QI). Application Type: New NVO & OFF License.

Blade Express, Inc. dba BE Logistics dba Core Logistics dba B.E. Logistics, Inc., dba Belogistics (NVO), 12911 Simms Avenue, Hawthorne, CA 90250. Officers: Kathleen Martin, Secretary (QI); Daniel Dvorsky, President. Application Type: Add Trade Name Axis Ocean Logistics.

Caribbean Connection Import/Export Inc. (NVO & OFF), 9999 NW 89th Avenue, Bay 15, Medley, FL 33178. Officers: Marcia Thorpe, President (QI); Michael Thorpe, Vice President. Application Type: Add OFF Service.

Cargoworld Express, LLC dba Cargoworld Express (NVO), 16740 Hedgecroft Drive, Suite 406, Houston, TX 77060. Officers: Ho-Leung Tse, Managing Member (QI); Ivan P. Hong, Managing Member. Application Type: New NVO License.

D & P Wholesale & Distributors, Inc. dba Blue Sea Cargo & Logistics (NVO), 2331 S. Otis Street, Santa Ana, CA 92704. Officer: Thanh V. Phung, Director (QI). Application Type: New NVO License.

EP America Inc. dba Rubik (EP America) Inc. (NVO & OFF), 3340–B Greens

Road, Suite 300, Houston, TX 77032. Officers: Nicolas B. Pena, Vice President (QI); Jose M. Garza, President. Application Type: Delete of Trade Name & QI Change.

Expert Log LLC (NVO & OFF), 10540 NW 29TH Terrace, Doral, FL 33172. Officers: Annia Ortiz, Manager (QI); Maria Elizabet, Member. Application Type: QI Change.

Forest City Ocean Freight, LLC (OFF), 8615 E. Lindgren Road, Spokane, WA 99217. Officer: David A. Duer, Managing Director (QI). Application Type: New OFF License.

GP Logistics, Inc. (NVO & OFF), 2315 Landmeier Road, Elk Grove Village, IL 60007. Officers: Lars Kloch, President (QI); Regina March, Vice President. Application Type: QI Change.

GP Logistics, LLC (NVO & OFF), 4980 Beverly Road, Phoeniz, AZ 85044. Officers: Lars Kloch, President (QI); Regina March, Vice President. Application Type: New NVO & OFF License.

Hayek Services, Inc. (OFF), 8530 NW 72nd Street, Miami, FL 33166. Officer: Fransua A. Hayek, President (QI). Application Type: New OFF License.

HT Cargo USA, Inc. (NVO & OFF), 12103 Brookhurst Street, Suite C, Garden Grove, CA 92840. Officers: Tham T. Ho, President (QI); Tuu T. Ho, CFO. Application Type: New NVO & OFF License.

King Cargo Corporation (NVO & OFF), 8399 NW 66th Street, Suite 8 & 9, Miami, FL 33166. Officers: Luis Guilherme Gabiatti, Secretary (QI); Raphael Alves, CEO. Application Type: New NVO & OFF License.

Laft, Inc. (NVO & OFF), 12618 Yukon Avenue, Hawthorne, CA 90250. Officers: John J. Park, Vice President (QI); Tae Won Park, CEO. Application Type: New NVO & OFF License.

NIK Transport, Inc. (NVO & OFF), 17360 Colima Blvd., Suite 161, Rowland Heights, CA 91748. Officers: Freddy I. Kuo, Director (QI); Ling (Stephanie) Fang, Director. Application Type: QI Change.

Rota International, Inc. (NVO), 300 East 93rd Street, Suite #3D, New York, NY 10128. Officers: Hasan S. Akipek, President (QI); Billur O. Akipek, Secretary. Application Type: New NVO License.

Seabridge International, Inc. (NVO & OFF), 800 S. Conkling Street, Baltimore, MD 21224. Officer: Vernon R. Martin, President (QI). Application Type: QI Change.

Sovana Global Logistics, LLC (OFF), 45969 Nokes Boulevard, Suite 175, Dulles, VA 20166. Officers: Anita Knapp, Chief Officer for Maritime Transportation (QI); Varetta Wright, President. Application Type: New OFF License.

Total Freight LLC (OFF), 4454 NW 74 Avenue, Miami, FL 33166. Officers: Brian Contipelli, Managing Member (QI); Roseli G. Contipelli, Managing Member. Application Type: New OFF License.

Transoceanic Projects Development Co., Inc. dba AKL Shipping (NVO & OFF), 18421 Viscount Road, Bldg. 9, Suite 200, Houston, TX 77032. Officers: Leonard P. Headrick, Secretary (QI); Arval D. Headrick, Sr., President. Application Type: QI Change.

Universal Containers, LLC (NVO & OFF), 15821 Ventura Blvd., Suite 540, Encino, CA 91436. Officers: Ajay R. Rathod, Manager (QI); Amir G. Maghami, Member. Application Type: Add Trade Name Unicon Logistics.

Weida Freight System, Inc. dba WFS Global Logistics, Inc. (NVO), 819 West Arbor Vitae Street, Inglewood, CA 90301. Officers: Yongliang (Victor) Wei, President (QI); Maria L. Trujillo, Vice President (QI). Application Type: Additional QI.

Dated: May 16, 2014.

By the Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2014–11980 Filed 5–22–14; 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 June 9, 2014.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *John Van Dyke III, Menlo Park, California, as co-trustee with Mary Van Dyke, San Mateo, California, of the John & Mary Van Dyke Family Trust dated December 22, 1998, San Mateo, California (Van Dyke Trust), and as co-trustee with Alison Van Dyke, Menlo Park, California, of the John & Alison Van Dyke Family Trust, executed under declaration of trust dated May 10, 2001,* Menlo Park, California, to individually retain voting shares of Heritage Bancshares Group, Inc., Willmar, Minnesota, and thereby indirectly retain voting shares of Heritage Bank, N.A., Spicer, Minnesota.

In addition, *the Van Dyke Trust; Virginia Geiger, Bloomington, Minnesota (also known as Mary Virginia Geiger); Owen Geiger, Willmar, Minnesota; and Pearl Geiger,* Minneapolis, Minnesota; have applied to retain voting shares of Heritage Bancshares Group, Inc., Willmar, Minnesota, as part of the Geiger family shareholder group acting in concert.

Board of Governors of the Federal Reserve System, May 20, 2014.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2014–11961 Filed 5–22–14; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 19, 2014.

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Progressive National Financial Corporation,* Mansfield, Louisiana; to become a bank holding company by acquiring 100 percent of the voting shares of Progressive National Bank of DeSoto Parish, Mansfield, Louisiana.

Board of Governors of the Federal Reserve System, May 20, 2014.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2014–11962 Filed 5–22–14; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 19, 2014.

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. Diamond A Financial, L.P., Maedgen & White, L.P., Hilltop Holdings Inc., and PlainsCapital Corporation, all in Dallas, Texas; to acquire SWS Group, Inc., by merger with an intermediate tier, and indirectly acquire Southwest Securities, Federal Savings Bank, both in Dallas, Texas, and thereby engage in operating a savings association, pursuant to section 225.28(b)(4)(ii).

Board of Governors of the Federal Reserve System, May 20, 2014.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2014–11963 Filed 5–22–14; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting Standards Subcommittee

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards.

Time and Date: June 10, 2014, 9:00 a.m.–5:00 p.m. EST.

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW., Room 705–A, Washington, DC 20024, (202) 690–7100.

Status: Open.

Purpose: The purpose of this hearing is to review and discuss the current status of selected administrative simplification activities that are a priority for NCVHS in 2014.

The objectives of this hearing will be to receive a regulatory update, review and discuss the annual Designated Standards Maintenance Organization (DSMO) Report; discuss the status of development of Operating Rules; review the status of the Coordination of Benefits transaction; discuss new developments in the use of credit cards (including virtual cards) for claim payment; review the status of standards development of Health Care Attachments; discuss the planning and preparation of Health Plan ID; review and discuss the incorporation and use of a Unique Device Identifier (UDI) in administrative transactions; and discuss the status of ICD–10 delay.

Contact Person for More Information: Debbie M. Jackson, Acting Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2339, Hyattsville, Maryland 20782, telephone (301) 458–4614 or Terri Deutsch, Centers for Medicare and Medicaid Services, Office of E-Health Standards and Services, 7500 Security Boulevard, Baltimore, Maryland 21244, telephone (410) 786–9462. Program information as well as summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: May 13, 2014.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2014–11934 Filed 5–22–14; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a meeting June 10–11, 2014. The meeting is open to the public. However, pre-registration is required for both public attendance and public comment. Individuals who wish to attend the meeting and/or participate in the public comment session should register at *http://www.hhs.gov/nvpo/nvac.* Participants may also register by emailing *nvpo@hhs.gov* or by calling 202–690–5566 to provide your name, organization, and email address.

DATES: The meeting will be held on June 10–11, 2014. The meeting times and agenda will be posted on the NVAC Web site at *http://www.hhs.gov/nvpo/nvac* as soon they become available.

ADDRESSES: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Room 800, 200 Independence Avenue SW., Washington, DC 20201.

The meeting can also be accessed through a live webcast the day of the meeting. For more information, visit *http://www.hhs.gov/nvpo/nvac/meetings/upcomingmeetings/index.html.*

FOR FURTHER INFORMATION CONTACT: National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715–H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

Phone: (202) 690–5566; email: *nvpo@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

The topics to be discussed at the NVAC meeting will include presentations addressing immunization infrastructure needs at the state and federal levels; an update on successes and remaining challenges for increasing influenza vaccination among healthcare personnel; a discussion of how HHS has supported vaccine innovation and research and development using universal influenza vaccines as an example; updates from the National Vaccine Program Office; and a discussion of on-going community actions to increase human papilloma virus (HPV) vaccination coverage among adolescents. In addition, NVAC working groups on HPV Vaccination and Maternal Immunization will present their recommendations and findings for NVAC consideration and vote. The NVAC Vaccine Confidence Working Group will also provide an update on its progress. The meeting agenda will be posted on the NVAC Web site: *http://www.hhs.gov/nvpo/nvac* prior to the meeting.

Public attendance at the meeting is limited to the available space. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the National Vaccine Program Office at the address/phone listed above at least one week prior to the meeting. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the Web cast can be found at *http://www.hhs.gov/nvpo/nvac/meetings/upcomingmeetings/index.html.*

Members of the public will have the opportunity to provide comments at the NVAC meeting during the public comment periods designated on the agenda. Individuals who would like to submit written statements should email their comments to the National Vaccine Program Office (*nvpo@hhs.gov*) at least five business days prior to the meeting.

Dated: May 19, 2014.

Bruce Gellin,

Director, National Vaccine Program Office, Executive Secretary, National Vaccine Advisory Committee.

[FR Doc. 2014–12014 Filed 5–22–14; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Time and Date:

June 11, 2014, 9:00 a.m.–5:30 p.m. EDT
June 12, 2014, 8:00 a.m.–12:00 p.m. EDT

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW., Room 705–A, Washington, DC 20024, (20) 690–7100.

Status: Open.

Purpose

The purpose of this meeting is to review NCVHS Status of Activities, continue to plan for 2014 objectives and deliverables, and review and approve at least one action item: The Eleventh HIPAA Report to Congress. The Committee will also review the deliberative process for the letters submitted for action at the May 15th Conference call—Electronic Standards for Public Health Information Exchange; Findings from the February 2014 hearing; and the ICD 10 delay, and take any follow-up action needed. The Committee will receive a briefing on Data Segmentation initiatives and also an update from the recently conducted June 2014 DataPalooza. Finally, the Working Group on HHS Data Access and Use will continue strategic discussions on usability, use, and usefulness of HHS open data.

The times shown above are for the full Committee meeting. Subcommittee issues will be included as part of the Full Committee schedule and identified as ''blocks'' on the afternoon of the first day and morning the second day. Agendas for these block sessions will be developed later and posted on the NCVHS Web site (URL below) when available.

Contact Person for More Information: Substantive program information may be obtained from Debbie M. Jackson, Acting Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2339, Hyattsville, Maryland 20782, telephone (301) 458–4614. Summaries of meetings and a roster of committee members are available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: May 13, 2014.

James Scanlon,

Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2014–11935 Filed 5–22–14; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENT OF AGRICULTURE

Announcement of the Fourth 2015 Dietary Guidelines Advisory Committee Meeting

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health; and U.S. Department of Agriculture, Food, Nutrition and Consumer Services and Research, Education, and Economics.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act (FACA), the U.S. Department of Health and Human Services (HHS), in collaboration with the U.S. Department of Agriculture (USDA), is hereby giving notice that a meeting of the 2015 Dietary Guidelines Advisory Committee (DGAC) will be held and will be open to the public.

DATES: This meeting will be held on July 17, 2014, from 1:15–5:15 p.m. E.D.T. and July 18, 2014 from 8:00 a.m.–3:45 p.m. E.D.T.

ADDRESSES: This will not be an in-person meeting. Virtual technology will be utilized to conduct this meeting. The meeting will be accessible by webcast on the Internet.

FOR FURTHER INFORMATION CONTACT: Designated Federal Officer (DFO), 2015 DGAC, Richard D. Olson, M.D., M.P.H.; Office of Disease Prevention and Health Promotion, OASH/HHS; 1101 Wootton Parkway, Suite LL100 Tower Building; Rockville, MD 20852: Telephone: (240) 453–8280; Fax: (240) 453–8281; Alternate DFO, 2015 DGAC, Kellie (O'Connell) Casavale, Ph.D., R.D., Nutrition Advisor; Office of Disease Prevention and Health Promotion, OASH/HHS; 1101 Wootton Parkway, Suite LL100 Tower Building; Rockville, MD 20852: Telephone: (240) 453–8280; Fax: (240) 453–8281; Lead USDA Co-

Executive Secretary, Colette I. Rihane, M.S., R.D., Director, Office of Nutrition Guidance and Analysis, Center for Nutrition Policy and Promotion, USDA; 3101 Park Center Drive, Room 1034; Alexandria, VA 22302; Telephone: (703) 305–7600; Fax: (703) 305–3300; and/or USDA Co-Executive Secretary, Shanthy A. Bowman, Ph.D., Nutritionist, Food Surveys Research Group, Beltsville Human Nutrition Research Center, Agricultural Research Service, USDA; 10300 Baltimore Avenue, BARC-West Bldg 005, Room 125; Beltsville, MD 20705–2350; Telephone: (301) 504–0619. Additional information about the 2015 DGAC and this meeting is available on the Internet at *www.DietaryGuidelines.gov*.

SUPPLEMENTARY INFORMATION: Under Section 301 of Public Law 101–445 (7 U.S.C. 5341, the National Nutrition Monitoring and Related Research Act of 1990, Title III) the Secretaries of Health and Human Services (HHS) and Agriculture (USDA) are directed to issue at least every five years a report titled *Dietary Guidelines for Americans*. The law instructs that this publication shall contain nutritional and dietary information and guidelines for the general public, shall be based on the preponderance of scientific and medical knowledge current at the time of publication, and shall be promoted by each federal agency in carrying out any federal food, nutrition, or health program. The *Dietary Guidelines for Americans* was issued voluntarily by HHS and USDA in 1980, 1985, and 1990; the 1995 edition was the first statutorily mandated report, followed by subsequent editions at appropriate intervals. To assist with satisfying the mandate, a discretionary federal advisory committee is established every five years to provide independent, science-based advice and recommendations. The 2015 DGAC consists of a panel of experts who were selected from the public/private sector. Individuals who were selected to serve on the Committee have current scientific knowledge in the field of human nutrition and chronic disease.

Appointed Committee Members: Fourteen members currently serve on the 2015 DGAC. They were appointed by the Secretaries of HHS and USDA in May 2013. Information on the 2015 DGAC membership is available at *www.DietaryGuidelines.gov*.

Authority: The 2015 DGAC is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended.

Committee's Task: The work of the 2015 DGAC is solely advisory in nature and time-limited. The Committee is tasked with developing recommendations based on the preponderance of current scientific and medical knowledge using a systematic review approach. The 2015 DGAC will examine the current *Dietary Guidelines for Americans,* take into consideration new scientific evidence and current resource documents, and develop a report that is to be given to the Secretaries of HHS and USDA. The report will outline science-based recommendations and rationales which will serve as the basis for developing the eighth edition of the *Dietary Guidelines for Americans*. When the 2015 DGAC was established, it was planned for the Committee to hold approximately six public meetings to review and discuss recommendations. This will be the fourth meeting of the 2015 DGAC. Additional meeting dates, times, locations, and other relevant information will be announced at least 15 days in advance of each meeting via **Federal Register** notice. As stipulated in the charter, the Committee will be terminated after delivery of its final report to the Secretaries of HHS and USDA or two years from the date the charter was filed, whichever comes first.

Purpose of the Meeting: In accordance with FACA and to promote transparency of the process, deliberations of the Committee will occur in a public forum. At this meeting, the Committee will continue its deliberations.

Meeting Agenda: The meeting agenda will include (a) review of Committee work since the last public meeting and (b) plans for future Committee work.

Meeting Registration: The meeting will be publicly accessible by webcast on the Internet; registration is required and is expected to open on June 4, 2014. To register, please go to *www.DietaryGuidelines.gov* and click on the link for ''Meeting Registration.'' To register by phone, please call National Capitol Contracting, Andrea Popp at (703) 243–9696 by 5:00 p.m. e.d.t., July 11, 2014. To register, the person's name, affiliation, and phone number or email address must be provided. After registering, individuals will receive webcast access information via email.

Written Public Comments: Written comments from the public will continue to be accepted throughout the Committee's deliberative process. Written public comments can be submitted and/or viewed at *www.DietaryGuidelines.gov* using the ''Submit Comments'' and ''Read Comments'' links, respectively. Those commenting are asked to provide comments as early as possible in the Committee's process to increase the opportunity for meaningful impact. A deadline for comment submission prior to each public meeting will no longer be used. The Committee requests that commenters provide a brief summary (consisting of no more than 250 words) of the points or issues in the comment text box. If commenters are providing literature or other resources, complete citations or abstracts and electronic links to full articles or reports are preferred instead of attaching these documents to the comment. As the Committee continues its work, it may request additional public comments on specific topics; these requests and any instructions for submitting them are posted on the Web site.

Meeting Documents: Documents pertaining to Committee deliberations, including meeting agendas, summaries, and webcasts will be available on *www.DietaryGuidelines.gov* under ''Meetings.'' Meeting information will continue to be accessible online, at the NIH Library, and upon request at the Office of Disease Prevention and Health Promotion, OASH/HHS; 1101 Wootton Parkway, Suite LL100 Tower Building; Rockville, MD 20852: Telephone (240) 453–8280; Fax: (240) 453–8281.

Dated: May 1, 2014.

Don Wright,

Deputy Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services.

Dated: May 1, 2014.

Jackie Haven,

Acting Executive Director, Center for Nutrition Policy and Promotion, U.S. Department of Agriculture.

Dated: May 6, 2014.

Chavonda Jacobs-Young,

Administrator, Agricultural Research Service, U.S. Department of Agriculture.

[FR Doc. 2014–12010 Filed 5–22–14; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control

Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns NIOSH Member Conflict Review, PA 07–318, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease

Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 1:00 p.m.–4:00 p.m., Jun 19, 2014 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''NIOSH Member Conflict Review, PA 07–318, initial review.''

Contact Person for More Information: Nina Turner, Ph.D., Scientific Review Officer, 1095 Willowdale Road, Morgantown, West Virginia 26506, Telephone: (304) 285–5976.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–11968 Filed 5–22–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Office for State, Tribal, Local and Territorial Support (OSTLTS) Meeting

In accordance with Presidential Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of November 5, 2009, and September 23, 2004, Consultation and Coordination with Indian Tribal Governments, CDC/Agency for Toxic Substances and Disease Registry (ATSDR), announces the following meeting and Tribal Consultation Session:

Name: Tribal Advisory Committee (TAC) Meeting and 11th Biannual Tribal Consultation Session

Times and Dates:

8:00 a.m.–5:00 p.m., C.D.T., August 12, 2014 (TAC Meeting)

8:00 a.m.–5:00 p.m., C.D.T., August 13, 2014 (11th Biannual Tribal Consultation Session)

8:00 a.m.–5:00 p.m., C.D.T., August 14, 2014 (TAC Meeting, continued)

Place: The TAC Meeting and Tribal Consultation Session will be held at the Grand Traverse Resort, 100 Grand Traverse Village Boulevard, Michigan AB Meeting Room, Acme, Michigan 49610.

Status: The meetings are being hosted by CDC/ATSDR and are open to the public. Attendees must pre-register before July 11, 2014, at the following Web link: *http://www.cdc.gov/tribal/meetings.html.*

Purpose: During 2011–2013, CDC revised its existing Tribal Consultation Policy (issued in 2005) with the primary purpose of providing guidance across the agency to work effectively with American Indian/Alaska Native (AI/AN) tribes, communities, and organizations to enhance AI/AN access to CDC resources and programs. Within the CDC Consultation Policy, it is stated that CDC will conduct government-to-government consultation with elected tribal officials or their authorized representatives before taking actions and/or making decisions that affect them. Consultation is an enhanced form of communication that emphasizes trust, respect, and shared responsibility. It is an open and free exchange of information and opinion among parties that leads to mutual understanding and comprehension. CDC believes that consultation is integral to a deliberative process that results in effective collaboration and informed decision making with the ultimate goal of reaching consensus on issues. Although formal responsibility for the agency's overall government-to-government consultation activities rests within the CDC Office of the Director, leaders in other CDC Centers, Institute, and Offices shall actively participate in TAC meetings and HHS-sponsored regional and national tribal consultation sessions as frequently as possible.

Matters for Discussion: The TAC and CDC leaders will discuss the following public health issue topics identified by tribal leaders: Traditional foods, environmental health, and other disease-specific topics; however, discussion is not limited to these topics. The TAC Meeting will also include site visits to area tribes.

During the 11th Biannual Tribal Consultation Session, tribes and CDC leaders will engage in consultation on Native specimens and the National Tribal Environmental Health Think Tank, and tribes will have an opportunity to present formal testimony on tribal health issues.

Tribal leaders are encouraged to submit written testimony by 11:59 p.m., EDT, on July 16, 2014, to April R. Taylor, Public Health Analyst, Tribal Support Unit, or CAPT Craig Wilkins, Acting Director for the Tribal Support Unit, CDC/OSTLTS, by mail to 4770 Buford Highway NE., MS E–70, Atlanta, Georgia 30341, or by email to *tribalsupport@cdc.gov.*

Depending on the time available, it may be necessary to limit the presentation time of each presenter.

The agenda is subject to change as priorities dictate.

Information about the TAC, CDC's Tribal Consultation Policy, and previous meetings may be referenced on the following Web link: *http://www.cdc.gov/tribal.*

Contact Person for More Information: April R. Taylor, Public Health Analyst, CDC/OSTLTS, by mail to 4770 Buford Highway NE., MS E–70, Atlanta, Georgia 30341, or by email to *ARTaylor@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Gary J. Johnson,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–12025 Filed 5–22–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following committee meeting:

Time and Date: 11:00 a.m.–2:00 p.m., EST, Wednesday, June 18, 2014.

Place: Audio Conference Call via FTS Conferencing. The USA toll-free, dial-in number is 1–866–659–0537 and the pass code is 9933701.

Status: Open to the public. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-free, dial-in number, 1–866–659–0537 and the passcode is 9933701.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines, which have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the

CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2015.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters For Discussion: The agenda for the conference call includes: Final Vote Tally for Joslyn Manufacturing Plant and Nuclear Metals Inc. SEC Petition Actions; Work Group Site Profile Review Assignments; SEC Petitions Update for the July 2014 Advisory Board Meeting; Plans for the July 2014 Advisory Board Meeting; and Advisory Board Correspondence.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Theodore M. Katz, M.P.A., Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road, NE., Mailstop: E–20, Atlanta, Georgia 30333, Telephone (513) 533–6800, Toll Free 1–800–CDC–INFO, Email *ocas@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–11966 Filed 5–22–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Reducing Youth Exposure to Alcohol Marketing, Special Interest Projects (SIP)14–009, Panel A, initial review.

SUMMARY: This document corrects a notice that was published in the **Federal Register** on April 25, 2014 (79 FR 22975). The time and date should read as follows:

Time and Date: 10 a.m.–5 p.m., June 17, 2014 (Closed).

FOR FURTHER INFORMATION CONTACT: M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway, NE., Mailstop F46, Atlanta, Georgia 30341, Telephone: (770) 488–3585, *EEO6@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–11977 Filed 5–22–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH)

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Time and Date: 8:30 a.m.—3:00 p.m., June 20, 2014.

Place: Patriots Plaza I, 395 E Street, SW., Room 9200, Washington, DC 20201.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 33 people. If you wish to attend in person or by webcast, please see the NIOSH Web site to register (*http://www.cdc.gov/niosh/bsc/*) or call (404) 498–2539 at least 48 hours in advance for building access information. Teleconference is available toll-free; please dial (888) 397–9578, Participant Pass Code 63257516.

Purpose: The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors shall provide guidance to the Director, National Institute for Occupational Safety and Health on research and prevention programs. Specifically, the Board shall provide guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings and disseminating results. The Board shall evaluate the degree to which the activities of the National Institute for Occupational Safety and Health: (1) Conform to appropriate scientific standards, (2) address current, relevant needs, and (3) produce intended results.

Matters for Discussion: NIOSH Director Update; Implementation of the National Academies Program Recommendations, NIOSH Disaster Science Research Initiative to Enhance Responder Safety and Health, and the NIOSH Center for Motor Vehicle Safety.

Agenda items are subject to change as priorities dictate. An agenda is also posted on the NIOSH Web site (*http://www/cdc/gov/niosh/bsc*).

Contact Person for More Information: John Decker, Designated Federal Officer, BSC, NIOSH, CDC, 1600 Clifton Road, NE., MS–E20, Atlanta, Georgia 30329–4018, telephone (404) 498–2500, fax (404) 498–2526.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–11967 Filed 5–22–14; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Nutrition and Obesity Policy Research and Evaluation Network (NOPREN) Coordinating Center, Special Interest Projects (SIP)14–026, and Nutrition and Obesity Policy Research and Evaluation Network (NOPREN) Collaborating Center, SIP14–027, Panel M, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Times and Dates:

9:30 a.m.–6 p.m., June 19, 2014 (Closed)
9:30 a.m.–6 p.m., June 20, 2014 (Closed)

Place: Teleconference

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the

Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Nutrition and Obesity Policy Research and Evaluation Network (NOPREN) Coordinating Center, (SIP)14–026, and Nutrition and Obesity Policy Research and Evaluation Network (NOPREN) Collaborating Center, SIP14–027, Panel M, initial review.''

Contact Person for More Information: M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F–80, Atlanta, Georgia 30341, Telephone: (770) 488–3585, *EEO6@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–11978 Filed 5–22–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Miner Safety and Health Training Program—Western United States (U60) RFA–OH–14–004, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 1:00 p.m.–4:00 p.m., June 16, 2014 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Miner Safety and Health Training Program—Western United States (U60) RFA–OH–14–004,'' initial review.

Contact Person for More Information: George Bockosh, M.S., Scientific Review Officer, CDC/NIOSH, 1600 Clifton Road, Mailstop E–74, Atlanta, Georgia 30333, Telephone: (412) 386–6465.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–11969 Filed 5–22–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3291–N]

Announcement of the Re-Approval of AABB (Foremerly Known as the American Association of Blood Banks) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

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

ACTION: Notice.

SUMMARY: This notice announces the application of AABB for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that AABB meets or exceeds the applicable CLIA requirements. In this notice, we announce the approval and grant AABB deeming authority for a period of 6 years. This deeming authority is granted to AABB for the Blood Bank and Transfusion Service (BB/TS) program, the Immunohematology Reference Laboratory (IRL) program, the Molecular Testing (MT) program, and the Cellular Therapy (CT) program.

DATES: *Effective Date:* This notice is effective from May 23, 2014 to May 25, 2020.

FOR FURTHER INFORMATION CONTACT: Daralyn Hassan, 410–786–9360.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of AABB as an Accreditation Organization

In this notice, we approve AABB as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for the following specialty and subspecialty areas under CLIA:

- Microbiology, including Bacteriology, Mycology, and Virology.
- Diagnostic Immunology, including Syphilis Serology, General Immunology.
- Chemistry, including Routine Chemistry, Urinalysis, Toxicology.
- Hematology.
- Immunohematology, including ABO Group & Rh Group, Antibody Detection, Antibody Identification, Compatibility Testing.

We have examined the initial AABB application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that AABB meets or exceeds the applicable CLIA requirements. We have also determined that AABB will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant AABB approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for the submitted specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by AABB

during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the listed subspecialties and specialties, and therefore, will generally not be subject to routine inspections by a state survey agency to determine its compliance with CLIA requirements. However, the accredited laboratory is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of the AABB Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the AABB accreditation program meets the necessary requirements to be approved by CMS as an accreditation program with deeming authority under the CLIA program. AABB formally applied to CMS for approval as an accreditation organization under CLIA for the following specialties and subspecialties:

- Microbiology, including Bacteriology, Mycology, Virology.
- Diagnostic Immunology, including Syphilis Serology, General Immunology.
- Chemistry, including Routine Chemistry, Urinalysis, Toxicology.
- Hematology.
- Immunohematology, including ABO Group & Rh Group, Antibody Detection, Antibody Identification, Compatibility Testing.

In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

A. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

AABB submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. We have determined that AABB policies and procedures for oversight of laboratories performing laboratory testing for the submitted CLIA specialties and subspecialties are equivalent to those required by our CLIA regulations in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. AABB submitted documentation regarding its requirements for monitoring and inspecting laboratories, and describing its own standards regarding accreditation organization data management, inspection processes, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. We have determined that the requirements of the accreditation programs submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

B. Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

We have determined that the AABB's requirements are equal to the CLIA requirements at § 493.801 through § 493.865. Like CLIA, all of AABB's accredited laboratories are required to participate in an HHS-approved PT program for tests listed in subpart I. Additionally, AABB administers a non-regulated PT program to challenge the ability of the laboratories in the IRL program to resolve complex serological problems. Laboratories in the MT program are required to participate in a graded PT program or a sample exchange program.

C. Subpart J—Facility Administration for Nonwaived Testing

We have determined that the AABB's requirements are equal to the CLIA requirements at § 493.1100 through § 493.1105.

D. Subpart K—Quality System for Nonwaived Testing

We have determined that the AABB requirements are equal to or more stringent than the CLIA requirements at § 493.1200 through § 493.1299.

E. Subpart M—Personnel for Nonwaived Testing

We have determined that the AABB requirements are equal to the CLIA requirements at § 493.1403 through § 493.1495 for laboratories that perform moderate and high complexity testing.

F. Subpart Q—Inspections

We have determined that the AABB requirements are equal to the CLIA requirements at § 493.1771 through § 493.1780. AABB will continue to conduct biennial onsite inspections.

G. Subpart R—Enforcement Procedures

We have determined that the AABB meets the requirements of subpart R to the extent that such requirements are utilized by accreditation organizations. AABB policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, AABB will deny, suspend, or revoke accreditation in a laboratory accredited by AABB and report that action to us within 30 days. AABB also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that AABB's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The federal validation inspections of laboratories accredited by AABB may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the state survey agencies, will be our principal means for verifying that the laboratories accredited by AABB remain in compliance with CLIA requirements. This federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of AABB, for cause, before the end of the effective date of approval. If we determine that AABB has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which AABB would be allowed to address any identified issues. Should AABB be unable to address the identified issues within that timeframe, CMS may, in accordance with the applicable regulations, revoke AABB's deeming authority under CLIA.

Should circumstances result in our withdrawal of AABB's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated

with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938–0686.

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Dated: May 12, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–11918 Filed 5–22–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10525]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *July 22, 2014*:

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10525 Health Plan Monitoring System Level I and Level II Data Entry for the Program of All-Inclusive Care for the Elderly

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Existing collection in use without an OMB control number); *Title of Information Collection:* Health Plan Monitoring System Level I and Level II Data Entry for the Program of All-Inclusive Care for the Elderly; *Use:* This information collection would require Program of All-Inclusive Care for the Elderly (PACE) organizations to enter Level I and Level II data into the CMS's Health Plan Monitoring System. The collected information will be used to develop a quality improvement strategy for PACE. *Form Number:* CMS–10525 (OMB control number: 0938-New); *Frequency:* Quarterly and occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 100; *Total Annual Responses:* 7,000; *Total Annual Hours:* 1,575. (For policy questions regarding this collection contact Tamika Gladney at 410–786–0648).

Dated: May 20, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–11947 Filed 5–22–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10520]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing

collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by June 23, 2014:

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *or* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New Collection (Request for a new control number); *Title of Information Collection:* Marketplace Quality Standards; *Use:* Section 1311(c)(3) of the Affordable Care Act directs the Secretary to develop a rating system for qualified health plans (QHPs) on the relative basis of quality and price and requires Marketplaces to display this quality rating information on their Web sites. Section 1311(c)(4) of the Affordable Care Act requires the Secretary to develop an enrollee satisfaction survey system (ESS) that assesses consumer experience with QHPs (with more than 500 enrollees in the previous year) offered through a Marketplace and requires Marketplaces to display enrollee satisfaction information to allow individuals to easily compare enrollee satisfaction levels between comparable plans. Section 1311(h) requires QHPs to contract with certain hospitals that meet specific patient safety and health care quality standards beginning January 1, 2015. The collection of information from QHP issuers is necessary to implement these quality standards and to provide adequate and timely health care quality information to consumers, regulators and Marketplaces. Specifically, for implementation and reporting for the Federal Quality Rating System (QRS) and for the ESS, the collection, validation and submission of validated data is required as outlined in § 156.1120 and § 156.1125. In addition, QHP issuers must demonstrate compliance with the patient safety standards outlined in § 156.1110 which involves associated information collection, recordkeeping and disclosure requirements. It is also necessary to collect information per § 156.1105 to appropriately monitor and provide a process for survey vendors to appeal HHS' decision to not approve ESS vendor applications.

Form Number: CMS–10520 (OMB control number: 0938-New); *Frequency:* Annual; *Affected Public:* Individuals; Private Sector—Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 620; *Total Annual Responses:* 620; *Total Annual Hours:* 980,995. (For policy questions regarding this collection contact Nidhi Singh Shah at 301–492–5110.)

Dated: May 20, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–11948 Filed 5–22–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0192]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing and Maintaining a List of United States Dairy Product Manufacturers/Processors With Interest in Exporting

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 June 23, 2014.

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 0910–0509. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Establishing and Maintaining Lists of U.S. Milk Product Manufacturers/Processors With Interest in Exporting (OMB Control Number 0910–0509)—Extension

The United States exports a large volume and variety of foods in international trade. For certain food products, foreign governments may require assurances from the responsible authority of the country of origin of an imported food that the processor of the food is in compliance with applicable country of origin regulatory requirements. With regard to U.S. milk products, FDA is the competent U.S. food safety authority to provide this information to foreign governments. We provide the requested information about processors in the form of lists. The lists are provided to the foreign governments and also posted online at *http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/default.htm.* The term ''milk product'', for purposes of this information collection, includes products defined in 21 CFR 1240.3(j) and any product requested by foreign governments to be included in this list process.

We currently provide Chile a list of U.S. milk product manufacturers/processors that have expressed interest in exporting their products to Chile, are subject to our jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., an injunction or seizure) or a pending warning letter. In the **Federal Register** of June 22, 2005 (70 FR 36190), we announced the availability of a revised guidance document entitled ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile.'' The guidance can be found at *http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm078936.htm.*

FDA was asked to provide a list to China in response to China's State General Administration of the People's Republic of China for Quality Supervision and Inspection and Quarantine (AQSIQ) issuance of Administrative Measures for Registration of Overseas Manufacturers, known as AQSIQ Decree 145. Accordingly, we established and maintain for China a list that identifies U.S. milk product manufacturers/processors that have expressed interest to us in exporting milk products to China, are subject to our jurisdiction, and are not the subject of a pending judicial enforcement action (i.e., an injunction or seizure) or a pending warning letter. On January 9, 2014, we issued a guidance document entitled ''Establishing and Maintaining a List of U.S. Milk Product Manufacturers/Processors with Interest in Exporting to China.'' The guidance can be found at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ImportsExports/ucm378777.htm.*

As noted, we provided the new list to China in response to AQSIQ Decree 145. In accordance with 5 CFR 1320.13, FDA requested emergency OMB review and approval of the collections of information found in the guidance document. The routine course of OMB approval would not have been in the best interest of the public health because it would have delayed our ability to collect the information from firms and, thus, would have been disruptive in our efforts to facilitate services that have been requested by China in AQSIQ Decree 145. OMB granted the approval under the emergency clearance procedures on November 7, 2013.

The guidance documents are published under the authority of section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)), which authorizes the Secretary to develop guidance documents with public participation presenting the views of the Secretary on matters under the jurisdiction of FDA.

The guidance documents explain what information firms should submit to us in order to be considered for inclusion on the lists and what criteria we intend to use to determine eligibility for placement on the lists. The guidance documents also explain how we intend to update the list and how we intend to communicate any new information to the government that requested the list. Finally, the guidance documents note that the information is provided voluntarily by firms with the understanding that it will be posted on our Web site and communicated to, and possibly further disseminated by, the government that requested the list; thus, we consider the information on the lists to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4).

Application for inclusion on each list is voluntary. In the guidance documents, we recommend that U.S. firms that want to be placed on either list send the following information to us: Name and address of the firm and the manufacturing plant; name, telephone number, and email address (if available) of the contact person; a list of products presently shipped and expected to be shipped in the next 3 years; identities of agencies that inspect the plant and the date of last inspection; plant number and copy of last inspection notice; and, if other than an FDA inspection, copy of last inspection report. We request that this information be updated every 2 years.

We use the information submitted by firms to determine their eligibility for placement on the list, which is published on our Web site. The purpose of the list is to help the governments of Chile and China in their determination of which U.S. milk product manufacturers are eligible to export to their respective countries.

Description of Respondents: Respondents to this information collection include U.S. food product manufacturers/processors subject to our jurisdiction that wish to export products requested by foreign governments to be included in this list process.

In the **Federal Register** of February 18, 2014 (79 FR 9221) FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received; however, they were not responsive to the information collection topics solicited in the notice.

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
New written requests to be placed on the list	125	1	125	1.5	188
Biennial update	125	1	125	1	125
Occasional updates	50	1	50	[2]0.5	25

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					338

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 30 minutes.

The estimate of the number of firms that will submit new written requests to be placed on the list, biennial updates, and occasional updates is based on the FDA's experience maintaining the list over the past 8 years. The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list or update its information is based on FDA's experience with firms submitting similar requests. FDA believes that the information to be submitted will be readily available to the firms.

Based on submissions received for the Chile list over the past 3 years and the China list over the past 3 months, we estimate that, annually, an average of 100 new firms will submit written requests to be placed on the China list and 25 new firms will seek to be placed on the Chile list, reported as 125 total respondents on line 1 of table 1. We estimate that a firm will require 1.5 hours to read the guidance, to gather the information needed, and to prepare a communication to FDA that contains the information and requests that the firm be placed on the list, for a total of 187.5 burden hours, rounded to 188, as reported on line 1 of table 1. Under the guidance, every 2 years each firm on the list must provide updated information in order to remain on the list.

There are approximately 250 firms on the 2 lists combined. We estimate that, each year, approximately half of the firms on the list, 125 firms, will resubmit the information to remain on the list. We estimate that a firm already on the list will require 1 hour to biennially update and resubmit the information to us, including time reviewing the information and corresponding with us, for a total of 125 hours. In addition, we expect that, each year, approximately 50 firms will need to submit an occasional update and each firm will require 0.5 hour to prepare a communication to us reporting the change, for a total of 125 hours.

Dated: May 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11927 Filed 5–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0485]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health

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 June 23, 2014.

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 title ''Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health—(OMB Control Number 0910–NEW)

This information collection request collects information voluntarily submitted to the Center for Devices and Radiological Health (CDRH) on actual or potential health risk concerns about a medical device or radiological product or its use. Because there has been no established guidelines or instructions on how to submit an allegation to CDRH, allegations often contain minimal information and are received via phone calls, emails, or conversationally from any CDRH staff. CDRH seeks to establish a consistent format and process for the submission of device allegations that will enhance our timeliness in receiving, assessing and evaluating voluntary allegations. The information provided in the allegations received by CDRH may be used to clarify the recurrence or emergence of significant device-related risks to the general public and the need to initiate educational outreach or regulatory action to minimize or mitigate identified risks.

In the **Federal Register** of May 6, 2013 (78 FR 26373), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Allegation reporting respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
	700	1	700	[2].25	175

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 15 minutes.

Dated: May 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11922 Filed 5–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0610]

Increasing the Quality and Efficiency of Clinical Trials

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the efforts of the Center for Drug Evaluation and Research/Office of Medical Policy to increase the quality and efficiency of clinical trials. The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Medical Policy is announcing its intent to accept and consider a single-source application for the award of a grant to the Duke University's Duke Translational Medicine Institute (DTMI).

DATES: The application due date is June 30, 2014, by 11:59 p.m. Eastern Time. The expiration date is July 1, 2014.

ADDRESSES: Submit electronic applications to: *http://www.grants.gov.* For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Mark Lauda, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10990 New Hampshire Ave., Bldg. 51, Rm. 2212, Silver Spring, MD 20993, 301–796–0381, email: *Mark.Lauda@fda.hhs.gov;* or Lisa Ko, Office of Acquisition & Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD, 240–402–7592, email: *Lisa.Ko@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.grants.gov.* Search by Funding Opportunity Number: RFA–FD–14–017.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–14–017
93.103

A. Background

It has long been recognized that the clinical trial enterprise will need to evolve in order to meet the demand to provide data to support evidence-based decisionmaking. A memorandum of understanding (MOU) between FDA and Duke University published in the **Federal Register** on November 23, 2007, served as the basis for the establishment of the Clinical Trials Transformation Initiative (CTTI). CTTI is a public-private partnership whose mission is to identify and promote practices that will increase the quality and efficiency of clinical trials. This award will be made to DTMI within Duke University to identify and implement projects and disseminate resulting findings that will increase the quality and efficiency of clinical trials, CTTI's mission.

CTTI membership is broad and includes stakeholders from government, industry, patient advocacy and consumer groups, professional societies, clinical research organizations, and academia. CTTI helps to effect change through the conduct of projects that identify existing inefficiencies, elucidate superior practices, and/or provide innovative approaches to evidence generation and medical product development. CTTI conducts projects that are either: (1) Proposed by its member organizations, including FDA, developed during review by its Steering Committee, and endorsed by its Executive Committee or (2) responsive to urgent needs of FDA.

The opportunity for meaningful interaction with a broad set of stakeholders committed to improving the clinical trial enterprise and also the ability to rapidly gather data to address emerging issues offer significant value to the clinical trial enterprise. Since its inception, CTTI has undertaken many projects that have direct relevance to FDA's mission, including investigational new drug (IND) safety reporting, clinical trial monitoring, use of central investigational review boards, and antibacterial drug development.

B. Research Objectives

The goals of this program are to develop and maintain an administrative and scientific infrastructure to support the creation and execution of a series of projects under the auspices of CTTI that will increase the quality and efficiency of clinical trials. The following are examples of activities that could be supported by this grant:

- Maintaining an adequate administrative and scientific infrastructure to implement all related projects under this collaborative effort.
- Identifying and/or hiring a sufficient number of qualified personnel to conduct activities, including project management, such as review of project milestones for degree of completion, preparation/reporting of project findings, periodic and final reports, and for subsequent distribution in the public domain.
- Developing plans for the conduct of identified projects.
- Identifying, securing, and/or building, and effectively leveraging other resources for the conduct of identified projects.
- Upon completion of a given project, generating project results and recommendations and proposing related studies/projects, if needed, to build on the findings of the project and continuing to leverage established resources and personnel.

C. Eligibility Information

The following organization is eligible to apply: DTMI located within Duke University.

II. Award Information/Funds Available

A. Award Amount

This is a multiyear grant. FDA/CDER intends to fund up to $7,500,000 in total costs (direct and indirect) in Fiscal Year 2014. Awards are contingent upon the availability of funds.

Subject to the availability of Federal funds and successful performance of the FOA's stated goals and objectives, four additional years of support may be

available. Funding beyond the first year will be noncompetitive and will depend on: (1) Satisfactory performance during the preceding year and (2) the availability of Federal fiscal year funds.

Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect):

Year 01: $7,500,000
Year 02: $7,500,000
Year 03: $7,500,000
Year 04: $7,500,000
Year 05: $7,500,000

B. Length of Support

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at *http://www.grants.gov.* Search by Funding Opportunity Number: RFA–FD–14–017. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 6, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit electronic applications to: *http://www.grants.gov.*

Dated: May 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11924 Filed 5–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0835]

Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another Institutional Review Board; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for IRBs, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another IRB.'' The guidance announced in this document discusses regulatory responsibilities of institutional review boards (IRBs), clinical investigators, and sponsors when oversight of a previously approved clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. The guidance also addresses questions that have been previously raised concerning procedures and processes that are required and/or recommended by FDA when such oversight is transferred.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002 (1–888–463–6332 or 301–796–3400); or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448 (1–800–835–4709 or 301–827–1800); or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4622, Silver Spring, MD 20993 (1–800–638–2041 or 301–796–7100). Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Managements (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Bridget Foltz, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5174, Silver Spring, MD 20993, 301–796–8340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled, ''Guidance for IRBs, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another IRB.'' The guidance discusses the regulatory responsibilities of IRBs, clinical investigators, and sponsors when oversight of a previously approved clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. In particular, the guidance discusses eight steps to be considered when transferring oversight of a previously approved clinical investigation from one IRB to another IRB. These include identifying those studies for which IRB oversight is being transferred; ensuring availability and retention of pertinent records; establishing an effective date for the transfer of oversight; conducting a review of the study(ies) by the receiving IRB, where appropriate; confirming or establishing the date for the next continuing review; determining whether the consent form needs to be revised; notifying the key parties; and updating IRB registration information. The IRB transfer process is expected to vary depending on the reasons for the transfer, the parties involved, and the number and risk of the studies being transferred.

To enhance human subject protections and reduce regulatory burden, FDA and the Office for Human Research Protections (OHRP) have been actively working to harmonize the agencies' regulatory requirements and guidance for human subjects research. This guidance document was developed as a part of these efforts and in consultation with OHRP.

In the **Federal Register** of June 12, 2012 (77 FR 34958), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and considered them in preparing the final guidance. In response to the comments, FDA added a recommendation that the receiving IRB notify the sponsor if it decides to suspend or terminate study

approval. FDA also clarified both drug and device sponsor's reporting requirements related to such suspensions and terminations. Section III(6) was modified to recommend the use of a letter to provide currently enrolled subjects with any changes in contact information regarding subject rights or research-related injuries from a resulting IRB transfer. In addition, numerous editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated June 2012.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in 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 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 56 have been approved under OMB control number 0910–0130.

III. Comments

Interested persons may submit either electronic comments regarding this document *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.regulations.gov* or *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm.*

Dated: May 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11923 Filed 5–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–0469]

Determination of Regulatory Review Period for Purposes of Patent Extension; LINZESS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LINZESS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product LINZESS (linaclotide). LINZESS is indicated for treatment of irritable bowel syndrome with constipation and chronic idiopathic constipation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LINZESS (U.S. Patent No. 7,304,036) from Ironwood Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 10, 2013, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LINZESS represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for LINZESS is 2,863 days. Of this time, 2,475 days occurred during the testing phase of the regulatory review period, while 388 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* October 30, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 30, 2004.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* August 9, 2011. FDA has verified the applicant's claim

that the new drug application (NDA) for LINZESS (NDA 202811) was submitted on August 9, 2011.

3. *The date the application was approved:* August 30, 2012. FDA has verified the applicant's claim that NDA 202811 was approved on August 30, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 945 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 22, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 19, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. 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. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11926 Filed 5–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–0034]

Determination of Regulatory Review Period for Purposes of Patent Extension; INLYTA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for INLYTA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product INLYTA (axitinib). INLYTA is indicated for treatment of advanced renal cell carcinoma after failure of one prior systemic therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for INLYTA (U.S. Patent No. 6,534,524) from Agouron Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 19, 2013, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of INLYTA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for INLYTA is 3,699 days. Of this time, 3,410 days occurred during the testing phase of the regulatory review period, while 289 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* December 13, 2001. The applicant claims December 14, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 13, 2001, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 14, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for INLYTA (NDA 202324) was submitted on April 14, 2011.

3. *The date the application was approved:* January 27, 2012. FDA has verified the applicant's claim that NDA 202324 was approved on January 27, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,763 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 22, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 19, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. 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. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov*, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11925 Filed 5–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than June 23, 2014.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Delta States Rural Development Network Grant Program Performance Improvement Measurement System Measures OMB No. 0915-xxxx—New

Abstract: The Delta States Rural Development Network Grant Program supports projects that demonstrate evidence based and/or promising approaches around cardiovascular disease, diabetes, or obesity in order to improve health status in rural communities throughout the Delta Region. Key features of programs are collaboration, adoption of an evidence-based approach, demonstration of health outcomes, program replicability, and sustainability.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Public Law 103–62). These measures cover the principal topic areas of interest to the Office of Rural Health Policy, including: (a) access to care; (b) the underinsured and uninsured; (c) workforce recruitment and retention; (d) sustainability; (e) health information technology; (f) network development; and (g) health related clinical measures. Several measures will be used for this program. These measures will speak to the Office's progress toward meeting set goals. Summary of Prior Comments and Agency Response: A 60-day Federal Register Notice was published in the *Federal Register* on February 11, 2014 (79 FR 8196). There were no comments.

Likely Respondents: Delta States Rural Development Network Grant Program award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Delta States Rural Development Network Program Performance Measures	12	1	12	6	72
Total	12	1	12	6	72

Dated: May 19, 2014.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2014–12042 Filed 5–22–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than June 23, 2014.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Small Health Care Provider Quality Improvement Program. OMB No. 0915-xxxx—NEW.

Abstract: This program is authorized by Title III, Public Health Service Act, Section 330A(g) (42 U.S.C. 254c(g)), as amended by Section 201, Public Law 107–251, and Section 4, Public Law 110–355. This authority directs the Office of Rural Health Policy (ORHP) to support grants that expand access to, coordinate, contain the cost of, and improve the quality of essential health care services, including preventive and emergency services, through the development of health care networks in rural and frontier areas and regions. Across these various programs, the authority allows HRSA to provide funds to rural and frontier communities to support the direct delivery of health care and related services, to expand existing services, or to enhance health service delivery through education, promotion, and prevention programs.

The purpose of the Small Health Care Provider Quality Improvement Grant (Rural Quality) Program is to provide support to rural primary care providers for implementation of quality improvement activities. The goal of the program is to promote the development of an evidence-based culture and delivery of coordinated care in the primary care setting. Additional objectives of the program include: Improved health outcomes for patients; enhanced chronic disease management; and better engagement of patients and their caregivers. Organizations participating in the program are required to utilize an evidence-based quality improvement model, perform tests of change focused on improvement, and use health information technology (HIT) to collect and report data. HIT may include an electronic patient registry (EPR) or an electronic health record (EHR), and is a critical component for improving quality and patient outcomes. With HIT it is possible to generate timely and meaningful data, which helps providers track and plan care.

Need and Proposed Use of the Information: ORHP collects this information to quantify the impact of grant funding on access to health care, quality of services, and improvement of health outcomes. ORHP uses the data for program improvement and grantees use the data for performance tracking and improvement.

Summary of Prior Comments and Agency Response: A 60-day Federal Register Notice was published in the **Federal Register** on February 11, 2014. See, 79 FR 8201. There were no comments.

Likely Respondents: The respondents will be grantees of the Small Health Care Provider Quality Improvement Program.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondents	Total responses	Average burden per response (in hours)	Total burden hours
Performance Improvement and Measurement System (PIMS) Database	30	2	60	8	480
Total	30	2	60	8	480

Dated: May 19, 2014.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2014–12044 Filed 5–22–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel Radiation Modulators.

Date: June 6, 2014.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 3W030, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Thomas M. Vollberg, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activites, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Rockville, MD 20850, 240–276–6341, *vollbert@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/sep/sep.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS).

Dated: May 19, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–11916 Filed 5–22–14; 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 PAR Panel: Pregnancy in Women with Disabilities.

Date: June 16, 2014.

Time: 11:00 a.m. to 1:00 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: 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: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group, Cellular, Molecular and Integrative Reproduction Study Section.

Date: June 18, 2014.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Gary Hunnicutt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301–435–0229, *hunnicuttgr@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group Neurodifferentiation, Plasticity, Regeneration and Rhythmicity Study Section.

Date: June 19–20, 2014.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Villa Florence Hotel, 225 Powell Street, San Francisco, CA 94102.

Contact Person: Joanne T Fujii, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435–1178, *fujiij@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group, Integrative and Clinical Endocrinology and Reproduction Study Section.

Date: June 19, 2014.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Kinzie Hotel, 20 West Kinzie Street, Chicago, IL 60654.

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, *dianne.hardy@nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group, Integrative Nutrition and Metabolic Processes Study Section.

Date: June 19, 2014.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Gary Hunnicutt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301–435–0229, *hunnicuttgr@csr.nih.gov.*

Name of Committee: Oncology 1—Basic Translational Integrated Review Group, Cancer Molecular Pathobiology Study Section.

Date: June 23–24, 2014.

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: Manzoor Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, *zargerma@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Cardiovascular and Surgical Devices.

Date: June 23, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Crystal City, 2399 Jefferson Davis Hwy, Arlington, VA 22202.

Contact Person: Donald Scott Wright, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108,

MSC 7854, Bethesda, MD 20892, (301) 435–8363, *wrightds@csr.nih.gov.*

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group, Molecular Neurogenetics Study Section.
Date: June 23, 2014.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Pier Five Hotel, 711 Eastern Avenue, Baltimore, MD 21202.
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: Biobehavioral and Behavioral Processes Integrated Review Group, Child Psychopathology and Developmental Disabilities Study Section.
Date: June 23–24, 2014.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Torrance Marriott South Bay, 3635 Fashion Way, Torrance, CA 90503.
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: Healthcare Delivery and Methodologies Integrated Review Group, Health Services Organization and Delivery Study Section.
Date: June 23–24, 2014.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.
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.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Orthopedic and Skeletal Biology.
Date: June 23–24, 2014.
Time: 8:00 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, (Virtual Meeting).
Contact Person: Baljit S Moonga, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7806, Bethesda, MD 20892, 301–435–1777, *moongabs@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Risk, Prevention and Intervention for Addictions Overflow.
Date: June 23–24, 2014.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.
Contact Person: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, 301–496–0726, *prenticekj@mail.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group, Nursing and Related Clinical Sciences Study Section.
Date: June 23–24, 2014.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.
Contact Person: Priscah Mujuru, RN, 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, Small Business: Drug Discovery for Aging, Neuropsychiatric and Neurologic Disorders.
Date: June 23–24, 2014.
Time: 8:00 a.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hotel Palomar, 2121 P Street, NW, Washington, DC 20037.
Contact Person: Yuan Luo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301–915–6303, *luoy2@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Psycho/Neuropathology, Lifespan Development, and Science Education.
Date: June 23–24, 2014.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road NW., Washington, DC 20008.
Contact Person: John H Newman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, (301) 267–9270, *newmanjh@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group Development—1 Study Section.
Date: June 23, 2014.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Jonathan Arias, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301–435–2406, *ariasj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Biological Chemistry, Biophysics and Drug Discovery.
Date: June 23–24, 2014.
Time: 8:30 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Handlery Union Square Hotel, 351 Geary Street, San Francisco, CA 94102.
Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301–435–1180, *ruvinser@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Molecular Genetics A Study Section.
Date: June 23–24, 2014.
Time: 8:30 a.m. to 1:00 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: Center for Scientific Review Special Emphasis Panel, Member Conflict: Child Psychopathology and Developmental Disabilities.
Date: June 23, 2014.
Time: 1:00 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: Mark Lindner, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7770, Bethesda, MD 20892, 301–435–0913, *mark.lindner@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 19, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–11917 Filed 5–22–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2014–0405]

Navigation Safety Advisory Council

AGENCY: Coast Guard, DHS.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The Navigation Safety Advisory Council (NAVSAC) will meet on June 11–12, 2014 in Arlington,

Virginia to discuss matters relating to maritime collisions, rammings, and groundings, Inland Rules of the Road, International Rules of the Road, navigation regulations and equipment, routing measures, marine information, diving safety, and aids to navigation systems. These meetings will be open to the public.

DATES: NAVSAC will meet Wednesday, June 11, 2014, from 8 a.m. to 5 p.m., and Thursday, June 12, 2014, from 8 a.m. to 1 p.m. Please note that these meetings may close early if the Council has completed its business. Pre-registration, all submitted written materials, comments and request to make oral presentations at the meetings should reach Mr. Burt Lahn, NAVSAC meeting Coordinator no later than

May 28, 2014. For contact information, please see the **FOR FURTHER INFORMATION CONTACT** section below. Any written material submitted by the public will be distributed to the Council and become part of the public record.

ADDRESSES: The meeting will be held at the Coast Guard Personnel Service Center, 9th floor conference room, 4200 Wilson Boulevard, Suite 900, Arlington, Virginia 20598.

https://maps.google.com/maps?hl=en&gbv=2&safe=active&q=4200+Wilson+Boulevard,+Suite+900&ie=UTF-8&hq=&hnear=0x89b7b42469129bbb:0xe556c5a677a3032b,4200+Wilson+Blvd.+%23900,+Arlington,+VA+22203&gl=us&ei=-utCU6e2Gq_NsQTF-4CIBA&ved=0CBwQ8gEoATAA. All visitors to the Coast Guard Personnel Service Center must pre-register to be admitted to the building. You may pre-register by contacting Mr. Burt Lahn listed in the **FOR FURTHER INFORMATION CONTACT** section below.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Mr. Burt Lahn listed in the **FOR FURTHER INFORMATION CONTACT** section 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. You may submit written comments no later than May 28, 2014 and must be identified by USCG–2014–0405 using one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments (preferred method to avoid delays in processing).
- *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.

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* insert USCG–2014–0405 in the Search box, press Enter, and then click on the item you wish to view.

A public comment period will be held during the meeting on June 11, 2014, from 3:00 p.m. to 4:00 p.m. and June 12, 2014 prior to the close of the meeting. Public presentations may also be given. Speakers are requested to limit their presentation and comments to 10 minutes. Please note that the public comment period may end before the time indicated, following the last call for comments. To register as a speaker, contact Mr. Burt Lahn listed in the **FOR FURTHER INFORMATION CONTACT** section below.

FOR FURTHER INFORMATION CONTACT: If you have questions about these meetings, please contact Mr. Mike Sollosi, the NAVSAC Alternate Designated Federal Officer (ADFO), Commandant (CG–NAV–3), U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Stop 7418, Washington, DC 20593, telephone 202–372–1545 or email *mike.m.sollosi@uscg.mil*, or Mr. Burt Lahn, NAVSAC meeting coordinator, at telephone 202–372–1526 or email *burt.a.lahn@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826 or 1–800–647–5527.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix, Public Law 92–463, 86 Stat, 770, as amended.

The NAVSAC is an advisory committee authorized in 33 U.S.C. 2073 and chartered under the provisions of the FACA. NAVSAC provides advice and recommendations to the Secretary, through the Commandant of the U.S. Coast Guard, on matters relating to prevention of maritime collisions, rammings, and groundings, Inland and International Rules of the Road, navigation regulations and equipment, routing measures, marine information, diving safety, and aids to navigation systems.

A copy of all meeting documentation is available at *https://homeport.uscg.mil/NAVSAC.* Alternatively, you may contact Mr. Burt Lahn as noted in the **FOR FURTHER INFORMATION CONTACT** section above.

The meeting will be held at the Coast Guard Personnel Service Center, 9th floor conference room, 4200 Wilson Boulevard, Suite 900, Arlington, Virginia 20598.

Agenda: The NAVSAC will meet to review, discuss and formulate recommendations on the following topics:

Wednesday, June 11, 2014:

(1) Update on all past resolutions to the Council.

(2) The Coast Guard's *Future of Navigation* initiative. This program leverages technology in order to optimize navigation services provided by the Coast Guard in cooperation with the U.S. Corps of Engineers and the National Oceanic and Atmospheric Administration. The Coast Guard will provide information on this project including updates on international developments in E-Navigation and the Coast Guard's efforts to put e-Navigation principles into practice, which includes deployment of AIS aids to Navigation and enhanced delivery of marine safety information to better serve commercial and recreational waterway users.

(3) Atlantic Coast Ports Access Route Study (ACPARS). The ACPARS was initiated to study the navigational users and industrial development off the Atlantic Coast. The Coast Guard will provide an update on the results of this ongoing effort.

Following the above presentations, the Council will form working groups to discuss and provide recommendations on the following tasks as appropriate:

(1) NAVSAC Task 14–01—Modernization of Marine Safety Information systems
(2) NAVSAC Task 14–02—Automatic Identification Systems (AIS) Aids to Navigation
(3) NAVSAC Task 14–03—Navigation Interests in Marine Planning

Public comments or questions will be taken during the meeting as the Council discusses each issue and prior to the Council formulating recommendations

on each issue. There will also be a public comment period at the end of the meeting.

Thursday, June 12, 2014:

(1) Working Group discussions continued from June 11, 2014.
(2) Working Group reports presented to the Council.
(3) New Business:
  a. Summary of NAVSAC action items.
  b. Schedule next meeting date—Fall 2014.
  c. Council discussions and acceptance of new tasks.

A public comment period will be held after the discussion of new tasks. Speakers' comments are limited to 10 minutes each. Public comments or questions will be taken at the discretion of the Designated Federal Official (DFO) during the discussion and recommendations, and new business portion of the meeting.

Minutes: Minutes from the meeting will be available for public view and copying within 90 days following the meeting at *https://homeport.mil/NAVSAC.*

Dated: May 19, 2014.

G.C. Rasicot,

Director, Marine Transportation Systems, U.S. Coast Guard.

[FR Doc. 2014–11958 Filed 5–22–14; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5786–C–02]

Correction to Federal Housing Administration (FHA): Homeowners Armed With Knowledge (HAWK) for New Homebuyers Contact Information

AGENCY: Office of General Counsel, HUD.

ACTION: Notice; Correction.

SUMMARY: HUD published a notice in the **Federal Register** on May 15, 2014, announcing a proposed four year, two-phase, housing counseling pilot, ''HAWK for New Homebuyers.'' The document contained the incorrect contact for individuals to seek further information. This notice provides the correct contact information.

FOR FURTHER INFORMATION CONTACT: Arlene Nunes, (202) 402–2532, about this notice.

Correction:

In the May 15, 2014 **Federal Register**, in FR Doc. 2014–11152, in the **FOR FURTHER INFORMATION CONTACT** section, correct the **FOR FURTHER INFORMATION CONTACT** section to read:

FOR FURTHER INFORMATION CONTACT: Email specific program questions to *housing.counseling@hud.gov* and include ''HAWK Notice Question'' in the subject line. You may also send inquiries to the attention of: Arlene Nunes, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 9224, Washington, DC 20410; or call (202) 402–2532 (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the toll-free Federal Relay Service at 800– 877–8339.

Dated: May 19, 2014.

Camille E. Acevedo,

Associate General Counsel for Legislation and Regulations.

[FR Doc. 2014–12027 Filed 5–22–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5750–N–21]

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 use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 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 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Ritta, Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 5B–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2265 (This is not a toll-free number). HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers

interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: AGRICULTURE: Ms. Debra Kerr, Department of Agriculture, Reporters Building, 300 7th Street SW., Room 300, Washington, DC 20024, (202) 720–887; COE: Mr. Scott Whiteford, Army Corps of Engineers, Real Estate, CEMP–CR, 441 G Street NW., Washington, DC 20314; (202) 761–5542; COAST GUARD: Commandant, United States Coast Guard, Attn: Jennifer Stomber, 2100 Second St. SW., Stop 7901, Washington, DC 20593–0001; (202) 475–5609; GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405, (202) 501–0084; NASA: Mr. Frank T. Bellinger, Facilities Engineering Division, National Aeronautics & Space Administration, Code JX, Washington, DC 20546, (202) 358–1124; NAVY: Mr. Steve Matteo, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426; (These are not toll-free numbers).

Dated: May 15, 2014.

Ann Marie Oliva,

Deputy Assistant Secretary (Acting) for Special Needs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM, FEDERAL REGISTER REPORT FOR 05/23/2014

Suitable/Available Properties

Building

Arizona

13 Buildings
Wellton Property
Wellton AZ 85356
Landholding Agency: GSA
Property Number: 54201420005
Status: Excess
GSA Number: 9–X–AZ–0865–AA
Directions: Landholding Agency: DHS; Disposal Agency: GSA; AZ0084; AZ0085; AZ0086; AZ0087; AZ0088; AZ0089; AZ0406; AZ0407; AZ0408; AZ3960; AZ0221; AZ0222; AZ0223
Comments: 95,521.44 total sq. ft. for all properties; built in 2004 & 2007; contact GSA for more information on a specific property

Arkansas

Concrete Masonry Vault Toilet
Pine Bluff Project Office
Pine Bluff AR 71602
Landholding Agency: COE
Property Number: 31201420006
Status: Excess
Comments: off-site removal only; 480 sq. ft.; 38+ yrs.-old; structurally sounds; contact COE for more information

California

1500-Del Rosa Garage
4121 Quail Canyton Rd.
San Bernardino CA 92404
Landholding Agency: Agriculture
Property Number: 15201420006
Status: Excess
Comments: off-site removal only; 600 sq. ft.; storage; 79+ yrs.-old; fair conditions; secured area; contact Agriculture for more information

1000- Del Rosa Office
4121 Quail Canyton Rd.
San Bernardino CA 92404
Landholding Agency: Agriculture
Property Number: 15201420008
Status: Excess
Comments: off-site removal only; 1,872 sq. ft.; office; 81+ yrs.-old; poor conditions; secured area; contact Agriculture for more information

1620- Del Rosa Shed
4121 Quail Canyton Rd
San Bernardino CA 92404
Landholding Agency: Agriculture
Property Number: 15201420009
Status: Excess
Comments: off-site removal; 198 sq. ft.; storage; poor conditions; 80+ yrs.-old; secured area; contact Agriculture for more information

Florida

CG Station Marathon Housing
57525 Goodley St.
Marathon FL 33050
Landholding Agency: Coast Guard
Property Number: 88201420002
Status: Unutilized
Comments: 1,520 sq. ft.; 33+ yrs.-old; poor conditions; contact Coast Guard for more information

USCG Station
151/153 Treasure Harbor Dr.
Islamorada FL 33036
Landholding Agency: Coast Guard
Property Number: 88201420005
Status: Unutilized
Comments: 5,052 sq. ft.; deterioration; moisture damage; surrounded by a fence boundary; contact Coast Guard for more information

USCG Station
141/143 Treasure Harbor Dr.
Islamorada FL 33036
Landholding Agency: Coast Guard
Property Number: 88201420006
Status: Unutilized
Comments: 5,052 sq. ft.; 38+ yrs.-old; deterioration; surrounded by a fence boundary; contact Coast Guard for more information

Illinois

Peoria Radio Repeater Site
Btw. Spring Creek & Caterpillar Ln.
Peoria IL
Landholding Agency: COE
Property Number: 31201420004
Status: Excess
Comments: pre-1978; 8 x 12 equipment storage shed; repairs needed; contact COE for more information

Mississippi

Building No. 591-
Registration House
Enid Lake
Enid Lake MS
Landholding Agency: COE
Property Number: 31201420007
Status: Unutilized
Comments: 400 sq. ft.; registration house for Chickasaw Hill Rec. area; 228+ months vacant; extensive deterioration; major repairs needed; contact COE for more information

Montana

West Fork Cookhouse, Bldg.
#D2408
Mile 14 on Montana Hwy 38
Philipsburg MT 59858
Landholding Agency: Agriculture
Property Number: 15201420010
Status: Excess
Comments: off-site removal only; relocation may not be feasible due to the dilapidated conditions; no foundation; rodent infestation; 864 sq. ft.; storage; contact Agriculture for more info.

Ohio

N. Appalachian Experimental
Watershed Research Ctr.
28850 State Rte. 621
Coshocton OH 43824
Landholding Agency: GSA
Property Number: 54201420006
Status: Excess
GSA Number: 1–A–OH–849
Directions: Landholding Agency: Agriculture; Disposal Agency: GSA
Comments: 70,539 total sq. ft. for two bldgs.; storage/office; fair to poor conditions; lead-based paint; asbestos; PCBs; mold; remediation required; contact GSA for more information

Oklahoma

SWT—Hulah Lake
396120 State Hwy
Copan OK 74022
Landholding Agency: COE
Property Number: 31201420008
Status: Unutilized
Comments: 289 sq. ft.; toilet; 52+ yrs.-old; repairs needed; contact COE for more information

Texas

Greenhouse Asset ID #
620240B033/RPUID 03.54364
#13101 Southern Plains Agric. Res. Ctr.
College Station TX 77845
Landholding Agency: Agriculture

Property Number: 15201420007
Status: Unutilized
Comments: 1,950 sq. ft.; 48+ yrs.-old; repairs required for mechanical equipment; contact Agriculture for more information

SWT—Pat Mayse Lake
12 miles North of Paris, TX
Powderly TX 75473
Landholding Agency: COE
Property Number: 31201420005
Status: Unutilized
Directions: XCAA02 (64 sq. ft.); XCAA03 (64 sq. ft.)
Comments: off-site removal only; no future agency need; gatehouses; built in 1987; repairs needed; secured area; contact COE for more information

California

Storehouse (HVAC)
Edwards AFB
Edwards AFB CA
Landholding Agency: NASA
Property Number: 71201420004
Status: Excess
Comments: public access denied and no alternative method to gain access w/out compromising national security
Reasons: Secured Area

B–261
Naval Base San Diego
San Diego CA
Landholding Agency: Navy
Property Number: 77201420007
Status: Excess
Directions: NFA 100000746758
Comments: public access denied and no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

Building 23199
Fuels Rd.
Camp Pendleton CA 92055
Landholding Agency: Navy
Property Number: 77201420009
Status: Excess
Comments: public access denied and no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

Colorado

VOR Site—Byers, CO
Lat. 39.746396, Long 103.972340
Byers CO 80103
Landholding Agency: GSA
Property Number: 54201420004
Status: Excess
GSA Number: 7–W–CO–0691–AA
Directions: Landholding Agency: FAA; Disposal Agency: GSA
Comments: can only be reached by crossing private property and there is no established right or means to entry.
Reasons: Other—landlocked Not accessible by road

Florida

CG Station Islamorada Housing
161/163 Treasure Harbor Dr.
Islamorada FL 33036
Landholding Agency: Coast Guard
Property Number: 88201420004
Status: Unutilized
Comments: public access denied and no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

CG Station Marathon Housing
1800 Overseas Hwy
Marathon FL 33050
Landholding Agency: Coast Guard
Property Number: 88201420007
Status: Unutilized
Comments: public access denied and no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

Illinois

Building 1–A, Admin. Offc.
201 Decatur Ave.
Great Lakes IL 60088
Landholding Agency: Navy
Property Number: 77201420008
Status: Unutilized
Comments: public access denied and no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

New York

3 Building
10 Search Ln.
Staten Island NY 10305
Landholding Agency: Coast Guard
Property Number: 88201420003
Status: Underutilized
Directions: 2; 5; 6
Comments: public access denied and no alternative method to gain access w/out compromising national security.
Reasons: Secured Area

[FR Doc. 2014–11695 Filed 5–22–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5800–N–04]

Notice of HUD's Funding Availability for Fiscal Year 2014 Lead-Based Paint Hazard Control Grant Program and Lead Hazard Reduction Demonstration Grant Program

AGENCY: Office of Lead Hazard and Healthy Homes, Department of Housing and Urban Development (HUD).

ACTION: Notice of Funding Availability (NOFA).

SUMMARY: This notice announces that HUD has posted on *http://www.Grants.gov* and *http://www.HUD.gov* its Lead-Based Paint Hazard Control (LBPHC) Grant Program and Lead Hazard Reduction Demonstration (LHRD) Grant Program. The Lead-Based Paint Hazard Control (LBPHC) Grant Program and Lead Hazard Reduction Demonstration (LHRD) Grant Program NOFA is comprised of both the General Section to the Department's FY 2014 NOFAs for Discretionary Programs (General Section) published February 19, 2014 and this NOFA. In addition to the application requirements set forth in the NOFA, applicants must also comply with the requirements established in the General Section, and all Lead-Based Paint Hazard Control (LBPHC) Grant Program and Lead Hazard Reduction Demonstration (LHRD) Grant Program requirements. This NOFA announces the availability of funding of approximately $104,000,000 million. The overarching purpose of the Lead-Based Paint Hazard Control Grant Program and the Lead Hazard Reduction Demonstration Grant Program is to assist states, cities, counties/parishes, Native American Tribes or other units of local government in undertaking comprehensive programs to identify and control lead-based paint hazards in eligible privately owned rental or owner-occupied housing; the Lead Hazard Reduction Demonstration Grant Program is targeted to urban jurisdictions with the greatest lead-based paint hazard control needs. The Healthy Homes Supplemental Funding is being offered to assist those units eligible for use of lead funds to utilize the Healthy Homes Rating System for assessing, prioritizing and remediating other health and safety issues within those eligible units.

FOR FURTHER INFORMATION CONTACT: For programmatic questions, you may contact: Michelle Miller, Director, Programs Division, Office of Healthy Homes and Lead Hazard Control: Department of Housing and Urban Development; 451 Seventh Street SW., Room 8236, Washington, DC 20410–3000; telephone 202–402–5769 (this is not a toll-free number); facsimile 202–755–1000; or email *Michelle.M.Miller@hud.gov.*

For administrative questions, you may contact Nadine L. Heath, Director, Grants Services Division, at the address above or by telephone at 202–402–7680 (this is not a toll-free number); facsimile 202–755–1000; or email *Nadine.L.Heath@hud.gov.*

SUPPLEMENTARY INFORMATION: Today's **Federal Register** notice announces that HUD has posted its FY Lead-Based Paint Hazard Control (LBPHC) Grant Program and Lead Hazard Reduction Demonstration (LHRD) Grant Program NOFA on *http://www.Grants.gov and http://portal.hud.gov/hudportal/HUD?src=/program_offices/administration/grants/fundsavail.*

The application deadline date is June 27, 2014. Applications must be received by *Grants.gov* no later than 11:59:59 p.m. Eastern Time on the application deadline date. See Section IV of the General Section, regarding application procedures, timely filing requirements, and grace period policy. HUD may issue

a technical correction to this NOFA if necessary. Any such technical correction will provide detailed instructions for Applicants regarding the resubmission of applications to address the revised NOFA requirements.

Dated: May 15, 2014.

Anne M. Morillon,

Director, Grants Management and Oversight Division, Office of Strategic Planning and Management.

[FR Doc. 2014–12029 Filed 5–22–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5789–N–01]

Notice of Regulatory Waiver Requests Granted for the First Quarter of Calendar Year 2014

AGENCY: Office of the General Counsel, HUD.

ACTION: Notice.

SUMMARY: Section 106 of the Department of Housing and Urban Development Reform Act of 1989 (the HUD Reform Act) requires HUD to publish quarterly **Federal Register** notices of all regulatory waivers that HUD has approved. Each notice covers the quarterly period since the previous **Federal Register** notice. The purpose of this notice is to comply with the requirements of section 106 of the HUD Reform Act. This notice contains a list of regulatory waivers granted by HUD during the period beginning on January 1, 2014, and ending on March 31, 2014.

FOR FURTHER INFORMATION CONTACT: For general information about this notice, contact Camille E. Acevedo, Associate General Counsel for Legislation and Regulations, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10282, Washington, DC 20410–0500, telephone 202–708–1793 (this is not a toll-free number). Persons with hearing- or speech-impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

For information concerning a particular waiver that was granted and for which public notice is provided in this document, contact the person whose name and address follow the description of the waiver granted in the accompanying list of waivers that have been granted in the first quarter of calendar year 2014.

SUPPLEMENTARY INFORMATION: Section 106 of the HUD Reform Act added a new section 7(q) to the Department of Housing and Urban Development Act (42 U.S.C. 3535(q)), which provides that:

1. Any waiver of a regulation must be in writing and must specify the grounds for approving the waiver;

2. Authority to approve a waiver of a regulation may be delegated by the Secretary only to an individual of Assistant Secretary or equivalent rank, and the person to whom authority to waive is delegated must also have authority to issue the particular regulation to be waived;

3. Not less than quarterly, the Secretary must notify the public of all waivers of regulations that HUD has approved, by publishing a notice in the **Federal Register**. These notices (each covering the period since the most recent previous notification) shall:

a. Identify the project, activity, or undertaking involved;

b. Describe the nature of the provision waived and the designation of the provision;

c. Indicate the name and title of the person who granted the waiver request;

d. Describe briefly the grounds for approval of the request; and

e. State how additional information about a particular waiver may be obtained.

Section 106 of the HUD Reform Act also contains requirements applicable to waivers of HUD handbook provisions that are not relevant to the purpose of this notice.

This notice follows procedures provided in HUD's Statement of Policy on Waiver of Regulations and Directives issued on April 22, 1991 (56 FR 16337). In accordance with those procedures and with the requirements of section 106 of the HUD Reform Act, waivers of regulations are granted by the Assistant Secretary with jurisdiction over the regulations for which a waiver was requested. In those cases in which a General Deputy Assistant Secretary granted the waiver, the General Deputy Assistant Secretary was serving in the absence of the Assistant Secretary in accordance with the office's Order of Succession.

This notice covers waivers of regulations granted by HUD from January 1, 2014 through March 31, 2014. For ease of reference, the waivers granted by HUD are listed by HUD program office (for example, the Office of Community Planning and Development, the Office of Fair Housing and Equal Opportunity, the Office of Housing, and the Office of Public and Indian Housing, etc.). Within each program office grouping, the waivers are listed sequentially by the regulatory section of title 24 of the Code of Federal Regulations (CFR) that is being waived. For example, a waiver of a provision in 24 CFR part 58 would be listed before a waiver of a provision in 24 CFR part 570.

Where more than one regulatory provision is involved in the grant of a particular waiver request, the action is listed under the section number of the first regulatory requirement that appears in 24 CFR and that is being waived. For example, a waiver of both § 58.73 and § 58.74 would appear sequentially in the listing under § 58.73.

Waiver of regulations that involve the same initial regulatory citation are in time sequence beginning with the earliest-dated regulatory waiver.

Should HUD receive additional information about waivers granted during the period covered by this report (the first quarter of calendar year 2014) before the next report is published (the second quarter of calendar year 2014), HUD will include any additional waivers granted for the first quarter in the next report.

Accordingly, information about approved waiver requests pertaining to HUD regulations is provided in the Appendix that follows this notice.

Dated: May 19, 2014.

Damon Y. Smith,

Acting General Counsel.

Appendix

Listing of Waivers of Regulatory Requirements Granted by Offices of the Department of Housing and Urban Development January 1, 2014 through March 31, 2014

Note to Reader: More information about the granting of these waivers, including a copy of the waiver request and approval, may be obtained by contacting the person whose name is listed as the contact person directly after each set of regulatory waivers granted.

The regulatory waivers granted appear in the following order:

I. Regulatory Waivers Granted by the Office of Community Planning and Development.

II. Regulatory Waivers Granted by the Office of Housing.

III. Regulatory Waivers Granted by the Office of Public and Indian Housing.

I. Regulatory Waivers Granted by the Office of Community Planning and Development

For further information about the following regulatory waivers, please see the name of the contact person that immediately follows the description of the waiver granted.

• Regulation: 24 CFR 576.106(d)(1).

Project/Activity: Du Page County, IL and the State of West Virginia each requested a waiver of 24 CFR 576.106(d) to allow the use Emergency Solutions Grants (ESG) rapid re-housing and homelessness prevention funding for housing units with rents exceeding HUD's Fair Market Rent (FMR) requirements.

Nature of Requirement: Under 24 CFR 576.106(d)(1), rental assistance cannot be provided unless the rent is equal to or less than the FMR established by HUD, as provided under 24 CFR part 888, and complies with HUD's standard of rent reasonableness, as established under 24 CFR 982.507. This restriction is intended to ensure that program participants can remain in their housing after their ESG assistance ends. This restriction also helps ensure that the amount of ESG assistance provided for rental assistance is reasonable, while serving the greatest number of program participants possible.

Granted By: Mark Johnston, Deputy Assistant Secretary for Special Needs, Office of Community Planning and Development.

Date Granted: March 27, 2014.

Reason Waived: Du Page County, Illinois, and the State of West Virginia sufficiently demonstrated their requested waivers were necessary to ensure their program participants could find habitable units in which ESG rental assistance could be used. In addition, the waivers were sufficiently limited to permit Du Page County, IL and the State of West Virginia to assist with rents that are only slightly higher than the FMR and meet HUD's standard of rent reasonableness. HUD determined that the slightly higher rents would not prevent program participants from being able to retain the housing after the assistance ends.

Contact: Ann M. Oliva, Director, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7262, Washington, DC 20410, telephone number (202) 708–4300.

- Regulation: 24 CFR 882.410(a)(2).

Project/Activity: The Housing Authority of New Orleans (HANO, LA) requested a waiver of 24 CFR 882.410(a)(2) to allow a special rent adjustment to cover the costs of substantial increases in property insurance premiums for a Moderate Rehabilitation Single Room Occupancy (Mod Rehab SRO) project in the City of New Orleans.

Nature of Requirement: This regulation permits a special rent adjustment to reflect increases in the actual and necessary expenses of owning and maintaining the unit which have resulted from substantial general increases in real property taxes, assessments, utility rates and utilities not covered by regulated rates. The list of costs covered by special adjustments at this regulation does not include property insurance.

Granted By: Mark Johnston, Deputy Assistant Secretary for Special Needs, Office of Community Planning and Development.

Date Granted: March 20, 2014

Reason Waived: The granting of the waiver was based on the statutory authority for special adjustments at section 8(c)(2)(B) of the U.S. Housing Act of 1937,which provides for ''similar costs.'' The granting of the waiver recognized property insurance premiums as a similar cost.

Contact: Ann M. Oliva, Director, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7262, Washington, DC 20410, telephone number (202) 708–4300.

- Regulation: Neighborhood Stabilization Program 3 Notice 75 FR 64333 (II.H.3.F) in accordance with Title XII of Division A under the heading Community Planning and Development: Community Development Fund of the American Recovery and Reinvestment Act of 2009.

Project/Activity: The city of Warren, MI requested a waiver of the 10 percent demolition cap under the Neighborhood Stabilization Program (NSP) which restricts grantees from spending more than 10 percent of total grant funds on demolition activities. The city requested a waiver to spend $277,701.28 or approximately 16 percent of its Neighborhood Stabilization Program 3 (NSP3) allocation on the demolition of blighted structures.

Nature of Requirement: Section II.H.3.F of the NSP3 Notice provides that a grantee may not use more than 10 percent of its grant for demolition activities.

Granted By: Mark Johnston, Deputy Assistant Secretary for Special Needs, Office of Community Planning and Development.

Date Granted: January 8, 2014.

Reason Waived: The city provided statistical data showing high vacancy and abandonment rates that resulted from significant population and job loss. The city explained that there are a high number of properties requiring immediate demolition to remove safety hazards and the destabilizing influence of the blighted properties. The city committed to link the targeted demolition units with the rehabilitation of several units in the same locality that would assist in restoring stability in the area. On the basis of this information, the waiver was granted.

Contact: Jessie Handforth Kome, Deputy Director, Office of Block Grant Assistance, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7286, Washington, DC 20410, telephone (202) 402–5539.

- Regulation: Neighborhood Stabilization Program 3 Notice 75 FR 64333 (II.H.3.F) in accordance with Title XII of Division A under the heading Community Planning and Development: Community Development Fund of the American Recovery and Reinvestment Act of 2009.

Project/Activity: Lorain County, OH requested a waiver of the 10 percent demolition cap under the Neighborhood Stabilization Program (NSP) which restricts grantees from spending more than 10 percent of total grant funds on demolition activities. The county requested a waiver to spend $900,000.00 or approximately 55 percent of its NSP3 allocation on demolition of blighted structures.

Nature of Requirement: Section II.H.3.F of the NSP3 Notice provides that a grantee may not use more than 10 percent of its grant for demolition activities.

Granted By: Mark Johnston, Deputy Assistant Secretary for Special Needs, Office of Community Planning and Development.

Date Granted: February 26, 2014.

Reason Waived: The county provided statistical data showing high vacancy and abandonment rates due to significant population and job loss in the region. The county explained that there are 44 units in the city of Elyria and several units in the city of Lorain that require immediate demolition. The removal of these safety hazards and destabilizing influence would promote meaningful development to occur within a faster timeframe. On the basis of this information, the waiver was granted.

Contact: Jessie Handforth Kome, Deputy Director, Office of Block Grant Assistance, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7286, Washington, DC 20410, telephone (202) 402–5539.

- Regulation: Neighborhood Stabilization Program 3 Notice 75 FR 64333 (II.H.3.F) in accordance with Title XII of Division A under the heading Community Planning and Development: Community Development Fund of the American Recovery and Reinvestment Act of 2009.

Project/Activity: Anderson, IN requested a waiver of the 10 percent demolition cap under the Neighborhood Stabilization Program (NSP) which restricts grantees from spending more than 10 percent of total grant funds on demolition activities. The city requested a waiver to spend $512,881 or approximately 42 percent of its NSP3 allocation on the demolition of blighted structures.

Nature of Requirement: Section II.H.3.F of the NSP3 Notice provides that a grantee may not use more than 10 percent of its grant for demolition activities.

Granted By: Mark Johnston, Deputy Assistant Secretary for Special Needs, Office of Community Planning and Development.

Date Granted: February 21, 2014.

Reason Waived: The city provided statistical data evidencing high vacancy and abandonment rates due to significant population and job loss. These demolition funds would remove and assist in stabilizing commercial sites that will in turn attract investments and jobs. On the basis of this information, the waiver was granted.

Contact: Jessie Handforth Kome, Deputy Director, Office of Block Grant Assistance, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7286, Washington, DC 20410, telephone (202) 402–5539.

II. Regulatory Waivers Granted by the Office of Housing—Federal Housing Administration (FHA)

For further information about the following regulatory waivers, please see the name of the contact person that immediately follows the description of the waiver granted.

- Regulation: 24 CFR 200.73(c).

Project/Activity: Broadway Townhomes, Camden, N.J., Project Number: 035–35103.

Nature of Requirement: HUD's regulation at 24 CFR 200.73(c) requires that one site contains at least five rental dwelling units. HUD's Handbook 4425.1, Chapter 3, Part 3–7, elaborates on this regulation by stating that the project must be one site and the site may consist of two or more non-contiguous

parcels, i.e. a ''scattered site,'' if they meet the requirements outlined in the handbook. In the case of a scattered site, however, a waiver of 24 CFR § 200.73(c) is needed if each noncontiguous parcel does not contain at least five rental dwelling units.

Granted By: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: February 25, 2014.

Reason Waived: Each noncontiguous parcel in the project did not contain at least five units. The project demonstrated marketability and the capability of being managed as a single real estate entity. All of the properties continue to be professionally managed and maintained as a group, have existing housing assistance payment (HAP) contracts and have been allocated low-income housing tax credits. The applicable Internal Revenue Service (IRS) provisions related to the tax credits ended in December 2004; however, the partnership managing the project executed an extended low-income housing covenant for a total period of 30 years, which ends December 31, 2019. No physical or other changes to the property were identified which would impact its ongoing recognition as a single project constituting 157 sites containing 175 multifamily rental units. The combined total land area for the (157) parcels in 3.91 acres or 170,295 square feet contained within 10 square blocks.

Contact: Theodore K. Toon, Director, Office of Multifamily Housing Development, HTD, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6134, Washington, DC 20410, telephone (202) 402–8386.

- Regulation: 24 CFR 203.32(a) and 24 CFR 203.41(a)(3).

Project/Activity: Downpayment Assistance/Quicken Loans' Employee Down Payment Assistance Program in Detroit, Michigan. Quicken Loans requested authority to provide downpayment assistance loans with restrictions for an amount not to exceed $20,000 per loan to its employees who purchase principal residences with FHA-insured mortgages in downtown Detroit, Michigan, so long as no part of the downpayment assistance loan was used to fund the borrower's minimum required investment for the first mortgage. For each year that an employee maintains employment with Quicken Loans, continues to occupy the property as its principal residence, and does not sell or transfer the home during a five year period, 20 percent of the unpaid principal balance on the down payment assistance loan will be forgiven. Under this waiver Quicken Loans may provide no more than eighty down payment assistance loans over a two year period.

Nature of Requirement: HUD's regulation at 24 CFR 203.32(a) prohibits a contractual liability resulting in unpaid obligations in connection with an FHA-insured mortgage insured, and HUD's regulation at 24 CFR203.41(a)(3) prohibits any legal restriction on the conveyance of a property insured by the FHA.

Granted By: Carol J. Galante, Assistant Secretary for Housing—Federal Housing Commissioner.

Date Granted: January 31, 2014.

Reason Waived: A wavier of the regulation was granted because the Quicken

Loans program is aligned with HUD's focus on assisting Detroit, Michigan with its recovery from bankruptcy. The Quicken Loans program would support Detroit's local economy by encouraging investment in the Detroit housing market, thereby stimulating economic development, increasing tax revenues and renovating the housing stock in downtown Detroit. Furthermore, FHA determined that risk to the Mutual Mortgage Insurance Fund would be minimal due to the limited scope of the program targeting one metropolitan area.

Contact: Arlene Nunes, Office of the Deputy Assistant Secretary of Single Family Housing, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 9266, Washington, DC 20410, telephone (202) 708–3000.

- Regulation: 24 CFR 219.220(b).

Project/Activity: Pine Grove Apartments, FHA Project Number 023–027NI, Taunton, MA. The owners have requested deferral of repayment of the Flexible Subsidy Operating Assistance Loan on this project due to their inability to repay the loan in full upon prepayment of the 236 Loan.

Nature of Requirement: Section 219.220(b) which governs the repayment of operating assistance provided under the Flexible Subsidy Program for Troubled Projects prior to May 1, 1996 states: ''Assistance that has been paid to a project owner under this subpart must be repaid at the earlier of the expiration of the term of the mortgage, termination of mortgage insurance, prepayment of the mortgage, or a sale of the project . . .'' Either of these actions would typically terminate FHA involvement with the property, and the Flexible Subsidy Loan would be repaid, in whole, at that time.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: January 13, 2014.

Reason Waived: The owner requested and was granted waiver of the requirement to defer repayment of the Flexible Subsidy Operating Assistance Loan to allow the much needed preservation and moderate rehabilitation of the project. The project will be preserved as an affordable housing resource of Taunton, MA.

Contact: Minnie Monroe-Baldwin, Director of Preservation, Office of Affordable Housing Preservation, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6222, Washington, DC 20410, telephone (202) 402–2636.

- Regulation: 24 CFR 219.220(b).

Project/Activity: Garfield Park Village Apartments, FHA Project Number 121–SH022 and 121–SH072, Santa Cruz, CA. The owners have requested deferral of repayment of the Flexible Subsidy Operating Assistance Loan on this project due to their inability to repay the loan in full upon prepayment of the 202 Loan.

Nature of Requirement: Section 219.220(b) which governs the repayment of operating assistance provided under the Flexible Subsidy Program for Troubled Projects prior to May 1, 1996 states: ''Assistance that has been paid to a project owner under this subpart must be repaid at the earlier of the expiration of the term of the mortgage, termination of mortgage insurance, prepayment of the mortgage, or a sale of the project . . .'' Either of these actions would typically terminate FHA involvement with the property, and the Flexible Subsidy Loan would be repaid, in whole, at that time.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: March 25, 2014.

Reason Waived: The owner requested and was granted waiver of the requirement to defer repayment of the Flexible Subsidy Operating Assistance Loan to allow the much needed preservation and moderate rehabilitation of the project. The project will be preserved as a senior affordable housing resource of Santa Cruz, CA.

Contact: Minnie Monroe-Baldwin, Director of Preservation, Office of Affordable Housing Preservation, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6222, Washington, DC 20410, telephone (202) 402–2636.

- Regulation: 24 CFR 219.220(b).

Project/Activity: Southwicke Square Cooperative 1–3, FHA Project Number 044–44057/44058/44059, Trenton, Michigan. The owners requested deferral of repayment of the Flexible Subsidy Operating Assistance Loan on this project due to their inability to repay the loan in full upon maturity.

Nature of Requirement: HUD's regulation at 24 CFR 219.220(b), which governs the repayment of operating assistance provided under the Flexible Subsidy Program for Troubled Projects prior to May 1, 1996, states: ''Assistance that has been paid to a project owner under this subpart must be repaid at the earlier of the expiration of the term of the mortgage, termination of mortgage insurance, prepayment of the mortgage, or a sale of the project . . .'' Either of these actions would typically terminate FHA involvement with the property, and the Flexible Subsidy Loan would be repaid, in whole, at that time.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: February 21, 2014.

Reason Waived: The owner requested and was granted waiver of the requirement to defer repayment of the Flexible Subsidy Operating Assistance Loan. Deferral of repayment of the Flexible Subsidy Loan would allow for refinancing of the loan and for significant repairs/improvements to be made to the project, assuring its preservation as an affordable housing resource for an additional 35 years.

Contact: Mark B. Van Kirk, Director, Office of Asset Management, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6160, Washington, DC 20410, telephone (202) 708–3730.

- Regulation: 24 CFR 219.220(b).

Project/Activity: Memorial Apartments, FHA Project Number 052–SH006, Baltimore, Maryland. The owner requested deferral of

repayment of the Flexible Subsidy Operating Assistance Loan due to their inability to pay the loan in full upon maturity.

Nature of Requirement: HUD's regulation at 24 CFR 219.220(b), which governs the repayment of operating assistance provided under the Flexible Subsidy Program for Troubled Projects prior to May 1, 1996, states: ''Assistance that has been paid to a project owner under this subpart must be repaid at the earlier of the expiration of the term of the mortgage, termination of mortgage insurance, prepayment of the mortgage, or a sale of the project . . .'' Either of these actions would typically terminate FHA involvement with the property, and the Flexible Subsidy Loan would be repaid, in whole, at that time.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: February 18, 2014.

Reason Waived: The owner requested and was granted waiver of this regulation because it has been demonstrated that it is in the public's best interest to defer repayment of the Flexible Subsidy Operating Assistance Loan. The loan will be refinanced, facilitating the substantial rehabilitation of the aging project. Waiving the requirement will provide the long-term preservation of this property as an affordable housing resource for an additional term of 40 years.

Contact: Mark B. Van Kirk, Director, Office of Asset Management, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6160, Washington, DC 20410, telephone (202) 708–3730.

• Regulation: 24 CFR 219.220(b).

Project/Activity: Holy Family Apartments, FHA Project Number 064–55043T, Lafayette, Louisiana. The owners requested deferral of repayment of the Flexible Subsidy Operating Assistance Loan on this project due to their inability to repay the loan in full upon maturity.

Nature of Requirement: HUD's regulation at 24 CFR 219.220(b), which governs the repayment of operating assistance provided under the Flexible Subsidy Program for Troubled Projects prior to May 1, 1996, states: ''Assistance that has been paid to a project owner under this subpart must be repaid at the earlier of the expiration of the term of the mortgage, termination of mortgage insurance, prepayment of the mortgage, or a sale of the project . . .'' Either of these actions would typically terminate FHA involvement with the property, and the Flexible Subsidy Loan would be repaid, in whole, at that time.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: January 16, 2014.

Reason Waived: The owner requested and was granted approval to defer repayment of the Flexible Subsidy Operating Assistance Loan for this project as good cause has been shown that it is in the public's best interest. The owner committed to refinance the loan and use the proceeds to complete urgently needed rehabilitation, building code changes and updates of the project. The funding sources will enable the owner to maintain the project as affordable housing for low-income families for 40 years.

• Regulation: 24 CFR 232.7.

Project/Activity: VIP Care Pavilion (VIP) serves memory care residents. The facility is licensed for 111 residents. The facility does not meet the requirements of 24 CFR § 232.7 ''Bathroom'' of FHA's regulations. The building is located in Margate, FL.

Nature of Requirement: HUD's regulation at 24 CFR 232.7 mandates in a board and care home or assisted living facility that not less than one full bathroom be provided for every four residents. Also, the bathroom cannot be accessed from a public corridor or area.

Granted By: Carol J. Galante, Assistant Secretary for Housing—Federal Housing Commissioner.

Date Granted: February 3, 2014.

Reason Waived: The memory care residents of VIP all need assistance with bathing and toileting. The bathrooms/shower rooms provide enough space for staff to safely assist the residents. VIP concluded that this arrangement is safer for the residents.

Contact: Vance T. Morris, Special Assistant, Office of Healthcare Programs, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 9172, Washington, DC 20410, telephone (202) 402–2419.

• Regulation: 24 CFR 232.7.

Project/Activity: Trinity Shores of Port Lavaca (Trinity) is a licensed assisted living facility in Port Lavaca, Texas. The facility has 62 units of which 13 are Memory Care in a secured wing. The 49 assisted living units are fully compliant with 24 CFR 232.7 ''Bathroom.''

Nature of Requirement: HUD's regulation at 24 CFR 232.7 mandates in a board and care home or assisted living facility that not less than one full bathroom be provided for every four residents. Also, the bathroom cannot be accessed from a public corridor or area.

Granted By: Carol J. Galante, Assistant Secretary for Housing—Federal Housing Commissioner.

Date Granted: March 18, 2014.

Reason Waived: The memory care residents of Trinity all need assistance with bathing and toileting. The bathrooms/shower rooms provide enough space for staff to safely assist the residents. Trinity concluded that this arrangement is safer for the residents.

Contact: Vance T. Morris, Special Assistant, Office of Healthcare Programs, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 9172, Washington, DC 20410, telephone (202) 402–2419.

• Regulation: 24 CFR 891.100(d).

Project/Activity: Independence Oaks Apartments, Cleveland, TX, Project Number: 114–HD048/TX24–Q101–002.

Nature of Requirement: Section 891.100(d) prohibits amendment of the amount of the approved capital advance funds prior to closing.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: January 28, 2014.

Reason Waived: The project is economically designed and comparable in cost to similar projects in the area, and the sponsor/owner exhausted all efforts to obtain additional funding from other sources.

Contact: Catherine M. Brennan, Director, Office of Housing Assistance and Grant Administration, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6134, Washington, DC 20410, telephone (202) 708–3000.

• Regulation: 24 CFR 891.100(d).

Project/Activity: Stephenson 202, Stephenson, MI, Project Number: 047–EE052/MI33–S101–002.

Nature of Requirement: Section 891.100(d) prohibits amendment of the amount of the approved capital advance funds prior to closing.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: January 28, 2014.

Reason Waived: The project is economically designed and comparable in cost to similar projects in the area, and the sponsor/owner exhausted all efforts to obtain additional funding from other sources.

Contact: Catherine M. Brennan, Director, Office of Housing Assistance and Grant Administration, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6134, Washington, DC 20410, telephone (202) 708–3000.

• Regulation: 24 CFR 891.100(d).

Project/Activity: InReach Apartments, Charlotte, NC, Project Number: 053–HD257/NC19–Q101–006.

Nature of Requirement: Section 891.100(d) prohibits amendment of the amount of the approved capital advance funds prior to closing.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: January 28, 2014.

Reason Waived: The project is economically designed and comparable in cost to similar projects in the area, and the sponsor/owner exhausted all efforts to obtain additional funding from other sources.

Contact: Catherine M. Brennan, Director, Office of Housing Assistance and Grant Administration, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6134, Washington, DC 20410, telephone (202) 708–3000.

• Regulation: 24 CFR 891.100(d).

Project/Activity: Options Supportive Housing Project XV, Lake Grove, NY,

Project Number: 012–HD144/NY36–Q101–001.

Nature of Requirement: Section 891.100(d) prohibits amendment of the amount of the approved capital advance funds prior to closing.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: January 28, 2014.

Reason Waived: The project is economically designed and comparable in cost to similar projects in the area, and the sponsor/owner exhausted all efforts to obtain additional funding from other sources.

Contact: Catherine M. Brennan, Director, Office of Housing Assistance and Grant Administration, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6134, Washington, DC 20410, telephone (202) 708–3000.

• Regulation: 24 CFR 891.100(d).

Project/Activity: Focus Manor, Louisville, MS, Project Number: 065–HD045/MS26–Q101–001.

Nature of Requirement: Section 891.100(d) prohibits amendment of the amount of the approved capital advance funds prior to closing.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: March 26, 2014.

Reason Waived: The project is economically designed and comparable in cost to similar projects in the area, and the sponsor/owner exhausted all efforts to obtain additional funding from other sources.

Contact: Catherine M. Brennan, Director, Office of Housing Assistance and Grant Administration, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6134, Washington, DC 20410, telephone (202) 708–3000.

• Regulation: 24 CFR 891.165.

Project/Activity: Hayward Senior Housing—Phase II, Hayward, CA, Project Number: 121–EE234/CA39–S101–011.

Nature of Requirement: Section 891.165 provides that the duration of the fund reservation of the capital advance is 18 months from the date of issuance with limited exceptions up to 36 months, as approved by HUD on a case-by-case basis.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: January 8, 2014.

Reason Waived: Additional time was needed in order to meet the construction lender's loan requirement for this capital advance upon completion mixed-finance project.

Contact: Catherine M. Brennan, Director, Office of Housing Assistance and Grant Administration, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6134, Washington, DC 20410, telephone (202) 708–3000.

• Regulation: 24 CFR 891.165.

Project/Activity: Westcliff Heights Senior Apartments, Las Vegas, NV, Project Number: 125–EE131/NV25–S081–001.

Nature of Requirement: Section 891.165 provides that the duration of the fund reservation of the capital advance is 18 months from the date of issuance with limited exceptions up to 36 months, as approved by HUD on a case-by-case basis.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: January 28, 2014.

Reason Waived: Additional time was needed due to the minimum length of time of the construction loan before this capital advance upon completion project can reach initial closing.

Contact: Catherine M. Brennan, Director, Office of Housing Assistance and Grant Administration, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6134, Washington, DC 20410, telephone (202) 708–3000.

• Fiscal Year 2012 (FY12) Section 811 Project Rental Assistance Demonstration Program NOFA (Docket No. FR–5600–N–28–C1)

Project/Activity: Waiver of NOFA provisions in the FY 2012 Section 811 Project Rental Assistance Demonstration Program NOFA dated May 15, 2012 to allow for revisions to the environmental requirements.

Nature of Requirement: The FY 2012 NOFA detailed environmental requirements and environmental assurance provisions (as corrected in a technical correction posted on July 2, 2012), which applicants selected for funding are obligated to implement. The waiver revised those provisions as follows:

○ Properties that are currently HUD-assisted or FHA-insured that will not engage in activities with physical impacts or changes beyond routine maintenance activities or minimal repairs will not have to comply with the environmental tenets.

○ Clarification that if, at the time that a project applies for PRAD assistance, the project is under construction or being rehabilitated, the project shall be subject to the environmental review requirements applicable to new construction or rehab if the work has not progressed beyond a stage of construction where modifications can be undertaken to avoid the adverse environmental impacts addressed by the requirement.

○ Projects will have the option to evaluate the site for contamination issues either through an assessment process that is detailed in the proposed revision and is similar to the Office of Community Planning and Development's Continuum of Care (a similar rental assistance program) contamination assessment requirements, or through an ASTM E 1527–05 (or most recent edition) Phase I ESA.

○ If the project involves an existing property for which a Phase I ESA was prepared previously for a real estate transaction, and that Phase I ESA met ASTM Phase I ESA requirements at the time it was prepared, a new Phase I ESA will not be required for that project.

○ Coastal Barrier Resources was removed as an environmental tenet and made a separate requirement because the statutory obligations of the Coastal Barrier Resources Act remain even without a HUD project level review.

Granted by: Carol J. Galante, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: March 14, 2014.

Reason Waived: The waiver responds to concerns raised by the grantees and further aligns the Section 811 Project Rental Assistance Demonstration NOFA with the environmental requirements and environmental policies of the Office of Housing and HUD generally. Properties that are currently HUD-assisted or FHA-insured and will undergo no more that routine maintenance activities or minimal repairs have already undergone applicable environmental reviews at time of the original assistance or insurance, and will not undergo significant new physical changes in connection with the PRA assistance. The optional process for evaluating a site for contamination issues, and the use of existing Phase I ESAs that were ASTM-compliant, will facilitate use of the PRA Demo by permitting less costly methods of assessment for contamination while continuing to protect the health and safety of residents. Revising the reference to the Coastal Barrier Resources Act will not alter the applicable requirement but will simply clarify that the requirement is required by statute.

Contact: Catherine M. Brennan, Director, Office of Housing Assistance and Grant Administration, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6134, Washington, DC 20410, telephone (202) 708–3000.

III. Regulatory Waivers Granted by the Office of Public and Indian Housing

For further information about the following regulatory waivers, please see the name of the contact person that immediately follows the description of the waiver granted.

• Regulation: 24 CFR 982.505(c)(5).

Project/Activity: City of Vallejo Housing and Community Development Division (CVHCDD), Vallejo, CA.

Nature of Requirement: HUD's regulation at 24 CFR 982.505(5) states that irrespective of any increase or decrease in the payment standard amount, if the family unit size increases or decreases during the housing assistance payments (HAP) term, the new family unit size must be used to determine the payment standard amount for the family beginning at the family's first regular reexamination following the change in family unit size.

Granted By: Sandra B. Henriquez, Assistant Secretary for Public and Indian Housing.

Date Granted: March 21, 2014.

Reason Waived: The regulation was waived to allow the CVHCDD to delay implementation of the reduced subsidy standards for affected families until the end of their lease term instead of the family's next annual reexamination, in cases where the lease term does not expire for at least 30 days after the date of the reexamination, and the landlord is unwilling to release the family from its lease. This waiver did not apply to families that are renting on a month-to-month basis.

Contact: Laure Rawson, Director, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• Regulation: 24 CFR 982.505(d).

Project/Activity: San Francisco Housing Authority (SFHA), San Francisco, CA.

Nature of Requirement: HUD's regulation at 24 CFR 982.505(d) states that a public housing agency may only approve a higher

payment standard for a family as a reasonable accommodation if the higher payment standard is within the basic range of 90 to 110 percent of the fair market rent (FMR) for the unit size.

Granted By: Sandra B. Henriquez, Assistant Secretary for Public and Indian Housing.

Date Granted: January 13, 2014.

Reason Waived: The four homeless veterans, who are disabled, required an exception payment standard to move to units in a building that provided services for veterans. To provide this reasonable accommodation so the clients could move to these units and pay no more than 40 percent of their adjusted income toward the family share, the SFHA was allowed to approve an exception payment standard that exceeded the basic range of 90 to 110 percent of the FMR.

Contact: Laure Rawson, Director, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• Regulation: 24 CFR 982.505(d).

Project/Activity: Howard County Housing Commission (HCHC), Howard County, MD.

Nature of Requirement: HUD's regulation at 24 CFR 982.505(d) states that a public housing agency may only approve a higher payment standard for a family as a reasonable accommodation if the higher payment standard is within the basic range of 90 to 110 percent of the fair market rent (FMR) for the unit size.

Granted By: Sandra B. Henriquez, Assistant Secretary for Public and Indian Housing.

Date Granted: March 14, 2014.

Reason Waived: The participant, who is disabled, required an exception payment standard to move to a new unit that met her health needs. To provide this reasonable accommodation so the client could be assisted in a new current unit and pay no more than 40 percent of her adjusted income toward the family share, the HCHC was allowed to approve an exception payment standard that exceeded the basic range of 90 to 110 percent of the FMR

Contact: Laure Rawson, Director, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• Regulation: 24 CFR 982.505(d).

Project/Activity: New Avenues to Independence, Inc. (NAII), Cleveland, OH.

Nature of Requirement: HUD's regulation at 24 CFR 982.505(d) states that a public housing agency may only approve a higher payment standard for a family as a reasonable accommodation if the higher payment standard is within the basic range of 90 to 110 percent of the fair market rent (FMR) for the unit size.

Granted By: Sandra B. Henriquez, Assistant Secretary for Public and Indian Housing.

Date Granted: March 31, 2014.

Reason Waived: The participant, who is disabled, required an exception payment standard to remain in his current unit that meets his needs without becoming rent burdened. To provide this reasonable accommodation so the client could be assisted in his current unit and pay no more than 40 percent of his adjusted income toward the family share, the NAII was allowed to approve an exception payment standard that exceeded the basic range of 90 to 110 percent of the FMR

Contact: Laure Rawson, Director, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4210, Washington, DC 20410, telephone (202) 708–0477.

• Regulation: 24 CFR 983.51(b)(1) and (c).

Project/Activity: New York City Department of Housing Preservation and Development (NYCDHPD), New York City, NY.

Nature of Requirement: HUD's regulation at 24 CFR 983.51 states the competitive selection and alternate selection requirements of project-based voucher (PBV) units.

Granted By: Sandra B. Henriquez, Assistant Secretary for Public and Indian Housing

Date Granted: January 6, 2014.

Reason Waived: The waiver was approved so that NYCDHPD could add an additional 15 percent of the 1,093 units in Ocean Village to the 103 units that were converted under the Rental Assistance Demonstration program due to the surge in housing need from the displacement of many homeowners due to Hurricane Sandy.

Contact: Laure Rawson, Director, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• Regulation: 24 CFR 983.59(b)(1).

Project/Activity: Scott County Community Development Agency (SCDDA), Shakopee, MN.

Nature of Requirement: HUD's regulation at 24 CFR 983.59(b)(1) states that the rent to owner for public housing agency (PHA) owned units is determined according to the same requirements as for other project-based voucher (PBV) units, except that the independent entity approved by HUD must establish the initial contract rents based on an appraisal by a licensed, state-certified appraiser.

Granted By: Sandra B. Henriquez, Assistant Secretary for Public and Indian Housing.

Date Granted: January 6, 2014.

Reason Waived: This waiver was approved to provide partial relief from these requirements.

Contact: Laure Rawson, Director, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• Regulation: 24 CFR 983.59(b)(1).

Project/Activity: Housing Authority of Snohomish County (HASC), Everett, WA.

Nature of Requirement: HUD's regulation at 24 CFR 983.59(b)(1) states that the rent to owner for public housing agency (PHA) owned units is determined according to the same requirements as for other project-based voucher (PBV) units, except that the independent entity approved by HUD must establish the initial contract rents based on an appraisal by a licensed, state-certified appraiser.

Granted By: Sandra B. Henriquez, Assistant Secretary for Public and Indian Housing.

Date Granted: March 18, 2014.

Reason Waived: This waiver was approved to provide partial relief from these requirements.

Contact: Laure Rawson, Director, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

• Regulation: 24 CFR 983.301(b)(1).

Project/Activity: Michigan State Housing Development Authority (MSHDA). Lansing, MI.

Nature of Requirement: HUD's regulation at 24 CFR 983.301(b)(1) allows the rent to owner to go below the initial rent in project-based voucher (PBV) units.

Granted By: Sandra B. Henriquez, Assistant Secretary for Public and Indian Housing.

Date Granted: January 2, 2014.

Reason Waived: The waiver was approved to allow MSHDA to apply provisions of the proposed rule to avoid a major operating deficit

Contact: Laure Rawson, Director, Housing Voucher Management and Operations Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4216, Washington, DC 20410, telephone (202) 708–0477.

[FR Doc. 2014–12011 Filed 5–22–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5748–N–02]

Notice of Single Family Loan Sales

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice of sales of mortgage loans.

SUMMARY: This notice announces HUD's intention to competitively sell certain unsubsidized single family mortgage loans, in a sealed bid sale offering called SFLS 2014–2, without Federal Housing Administration (FHA) mortgage insurance. This notice also generally

describes the bidding process for the sale and certain persons who are ineligible to bid. This is the second sale of Fiscal Year (FY) 2014 and the offerings will be held on June 11, 2014, and June 25, 2014.

DATES: For this sale action, the Bidder's Information Package (BIP) was made available to qualified bidders on or about May 12, 2014. Bids for the SFLS 2014–2 sale will be accepted on two Bid Dates and must be submitted on those dates, which are currently scheduled for June 11, 2014, and June 25, 2014 (Bid Dates). HUD anticipates that award(s) will be made on or about June 12, 2014, for the first offering and June 26, 2014 for the second (the Award Dates).

ADDRESSES: To become a qualified bidder and receive the BIP, prospective bidders must complete, execute, and submit a Confidentiality Agreement and a Qualification Statement acceptable to HUD. Both documents are available via the HUD Web site at: *http://www.hud.gov/sfloansales* or via: *http://www.DebtX.com.*

Please mail and fax executed documents to SEBA Professional Services:

SEBA Professional Services,
c/o The Debt Exchange,
133 Federal Street, 10th Floor,
Boston, MA 02111,
Attention: HUD SFLS Loan Sale Coordinator,
Fax: 1–617–531–3499.

FOR FURTHER INFORMATION CONTACT: John Lucey, Director, Asset Sales Office, Room 3136, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410–8000; telephone number 202–708–2625, extension 3927. Hearing- or speech-impaired individuals may call 202–708–4594 (TTY). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: HUD announces its intention to sell in SFLS 2014–2 certain unsubsidized non-performing mortgage loans (Mortgage Loans) secured by single-family properties located throughout the United States. A listing of the Mortgage Loans is included in the due diligence materials made available to qualified bidders. The Mortgage Loans will be sold without FHA insurance and with servicing released. HUD will offer qualified bidders an opportunity to bid competitively on the Mortgage Loans.

The Loans will be offered on two sale dates. On June 11, 2014, the Department will offer national loan pools for bid. On June 25, 2014, the Department will offer regionally-based pools, with additional purchaser requirements, that are called the Neighborhood Stabilization Outcome pools.

The Bidding Process

The BIP describes in detail the procedure for bidding in SFLS 2014–2. The BIP also includes a standardized non-negotiable Conveyance, Assignment and Assumption Agreement (CAA Agreement). Qualified bidders will be required to submit a deposit with their bid. Deposits are calculated based upon each qualified bidder's aggregate bid price.

HUD will evaluate the bids submitted and determine the successful bid, in terms of the best value to HUD, in its sole and absolute discretion. If a qualified bidder is successful, the qualified bidder's deposit will be non-refundable and will be applied toward the purchase price. Deposits will be returned to unsuccessful bidders. For SFLS2014–2, settlements are expected to take place on or about July 25, 2014, and August 25, 2014.

This notice provides some of the basic terms of sale. The CAA Agreement, which is included in the BIP, provides comprehensive contractual terms and conditions. To ensure a competitive bidding process, the terms of the bidding process and the CAA Agreement are not subject to negotiation.

Due Diligence Review

The BIP describes how qualified bidders may access the due diligence materials remotely via a high-speed Internet connection.

Mortgage Loan Sale Policy

HUD reserves the right to remove Mortgage Loans from SFLS 2014–2 at any time prior to the Award Date. HUD also reserves the right to reject any and all bids, in whole or in part, and include any Mortgage Loans in a later sale. Deliveries of Mortgage Loans will occur in at least two monthly settlements and the number of Mortgage Loans delivered will vary depending upon the number of Mortgage Loans the Participating Servicers have submitted for the payment of an FHA insurance claim. The Participating Servicers will not be able to submit claims on loans that are not included in the Mortgage Loan Portfolio set forth in the BIP.

There can be no assurance that any Participating Servicer will deliver a minimum number of Mortgage Loans to HUD or that a minimum number of Mortgage Loans will be delivered to the Purchaser.

The SFLS 2014–2 Mortgage Loans are assigned to HUD pursuant to section 204(a)(1)(A) of the National Housing Act as amended under Title VI of the Departments of Veterans Affairs and Housing and Urban Development and Independent Agencies Appropriations Act, 1999. The sale of the Mortgage Loans is pursuant to section 204(g) of the National Housing Act.

Mortgage Loan Sale Procedure

HUD selected an open competitive whole-loan sale as the method to sell the Mortgage Loans for this specific sale transaction. For SFLS 2014–2, HUD has determined that this method of sale optimizes HUD's return on the sale of these Mortgage Loans, affords the greatest opportunity for all qualified bidders to bid on the Mortgage Loans, and provides the quickest and most efficient vehicle for HUD to dispose of the Mortgage Loans.

Bidder Ineligibility

In order to bid in SFLS 2014–2 as a qualified bidder, a prospective bidder must complete, execute and submit both a Confidentiality Agreement and a Qualification Statement acceptable to HUD and applicable to the loan pool being purchased. If any of the following apply to (i) a prospective bidder, (ii) a prospective bidder's direct parent,, (iii) a prospective bidder's subsidiaries, and (iv) any entity with which the prospective bidder shares a common officer, director, subcontractor or sub-contractor who has access to Confidential information as defined in the Confidentiality Agreement or is involved in the formation of a bid transaction (''Related Entities'') or (v) a prospective bidder's repurchase lenders then the prospective bidder is ineligible to bid on any of the Mortgage Loans included in SFLS unless other exceptions apply as provided for in the Qualification Statement:

1. The prospective bidder is an employee of HUD, a member of such employee's household, or an entity owned or controlled by any such employee or member of such an employee's household with household to be inclusive of the employee's father, mother, stepfather, stepmother, brother, sister, stepbrother, stepsister, son, daughter, stepson, stepdaughter, grandparent, grandson, granddaughter, father-in-law, mother-in-law, brother-in-law, sister-in-law, son-in-law, daughter-in-law, first cousin, the spouse of any of the foregoing, and the employee's spouse.;

2. The prospective bidder is an individual or entity that is currently debarred, suspended, or excluded from doing business with HUD pursuant to the Governmentwide Suspension and Debarment regulations at title 2 of the

Code of Federal Regulations, parts 180 and 2424.

3. The prospective bidder is an individual or entity that has been suspended, debarred or otherwise restricted by any Department or Agency of the Federal Government or of a State Government from doing business with such Department or Agency.

4. The prospective bidder is an individual or entity that has been debarred, suspended, or excluded from doing mortgage related business, including having a business license suspended, surrendered or revoked, by any federal, state or local government agency, division or department;

5. The prospective bidder is an individual or entity that knowingly acquired or will acquire prior to the Sale Date material non-public information, other than the information which is made available to the prospective bidder by HUD pursuant to the terms of the Qualification Statement, about Mortgage Loans offered in the sale;

6. The prospective bidder is a contractor, subcontractor and/or consultant or advisor (including any agent, employee, partner, director, principal or affiliate of any of the foregoing) who performed services for or on behalf of HUD in connection with single family asset sales;

7. The prospective bidder is an individual or entity that uses the services, directly or indirectly, of any person or entity ineligible under subparagraphs 2 through 4 above to assist in preparing any of its bids on the Mortgage Loans;

8. The prospective bidder is an individual or entity which employs or uses the services of an employee of HUD (other than in such employee's official capacity) who is involved in single family asset sales;

9. The prospective bidder is an entity or individual that serviced or held any Mortgage Loan at any time during the 2-year period prior to the Award Date;

10. The prospective bidder is an entity or individual that is: (a) Any affiliate or principal of any entity or individual described in the preceding sentence (sub-paragraph 9); (b) any employee or subcontractor of such entity or individual during that 2-year period prior to Award Date; or (c) any entity or individual that employs or uses the services of any other entity or individual described in this paragraph in preparing its bid on such Mortgage Loan; or

12. The prospective bidder is an entity that has had its right to act as a Government National Mortgage Association (Ginnie Mae) issuer and its interest in mortgages backing Ginnie Mae mortgage-backed securities extinguished and terminated by Ginnie Mae.

Freedom of Information Act Requests

HUD reserves the right, in its sole and absolute discretion, to disclose information regarding SFLS 2014–2, including, but not limited to, the identity of any successful qualified bidder and its bid price or bid percentage for any pool of loans or individual loan, upon the closing of the sale of all the Mortgage Loans. Even if HUD elects not to publicly disclose any information relating to SFLS 2014–2, HUD will disclose any information that HUD is obligated to disclose pursuant to the Freedom of Information Act and all regulations promulgated thereunder.

Scope of Notice

This notice applies to SFLS 2014–2 and does not establish HUD's policy for the sale of other mortgage loans.

Dated: May 15, 2014.

Laura Marin,

Associate General Deputy Assistant Secretary for Housing-Associate Deputy Federal Housing Commissioner.

[FR Doc. 2014–12034 Filed 5–22–14; 8:45 am]

BILLING CODE 4210–47–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[DS10100000/133D5670LC/ DLCAP0000.000000/DX.10120]

Land Buy-Back Program for Tribal Nations under *Cobell* Settlement.

AGENCY: Office of the Deputy Secretary, Interior.

ACTION: Notice of tribal listening session; correction.

SUMMARY: The Office of the Secretary previously announced that it will conduct a listening session on the status of implementation of the Land Buy-Back Program for Tribal Nations. The purpose of the session is to meet with Indian tribes to discuss progress to date and receive feedback. Indian landowners may also attend to provide input. This notice corrects the previously published notice to provide RSVP and testimony information and an agenda.

DATES: The listening session will take place on May 29, 2014, from 1 p.m.–4 p.m. Pacific Time. Please RSVP by May 27, 2014.

ADDRESSES: The listening session will take place at the Federal Building, Auditorium, 911 NE 11th Avenue, Portland, OR 97232–4128. Please RSVP via email or telephone to Genevieve Giaccardo, *buybackprogram@ios.doi.gov* or (202) 208–1541.

FOR FURTHER INFORMATION CONTACT: Genevieve Giaccardo, Senior Advisor on Tribal Relations, (202) 208–1541.

SUPPLEMENTARY INFORMATION:

I. Background

The *Cobell* Settlement was approved with finality on November 24, 2012, following the exhaustion of appeals through the U.S. Supreme Court. Within a month following final approval, the Department of the Interior (the Department) established the Land Buy-Back Program for Tribal Nations (Buy-Back Program) and published an Initial Implementation Plan. The Department engaged in government-to-government consultation on this plan and released an Updated Implementation Plan in November 2013.

The Department is currently implementing the Buy-Back Program at multiple locations across Indian Country. Since November 24, 2012, the Department has sent offers to over 19,000 landowners. Thus far, Interior has paid nearly $60 million to Indian landowners across the United States for voluntarily restoring the equivalent of more than 170,000 acres of land to tribal governments. Tribal governments are helping plan for and implement the Buy-Back Program at specific locations through cooperative agreements or other arrangements.

The purpose of this session is to gather input from tribes in order for the Department to continue to refine its land consolidation processes. Landowners may also attend the session to provide input.

II. Additional Resources

The Updated Implementation Plan and additional information about the Buy-Back Program is available at: *http://www.doi.gov/buybackprogram.* In addition, landowners can contact their local Fiduciary Trust Officer or call Interior's Trust Beneficiary Call Center at (888) 678–6836.

III. Listening Session Details

Time and date: May 29, 2014, 1 p.m.–4 p.m. PT.

Place: Federal Building, Auditorium, 911 NE. 11th Avenue, Portland, OR 97232–4128.

Please RSVP by May 27, 2014 to Genevieve Giaccardo.

Written comments will be accepted prior to, during, or directly after the meeting. Due to time constraints during the meeting, written comments cannot be read but will be incorporated into the record.

The agenda for the listening session will be:

1:00 p.m.—Invocation
1:15 p.m.—Introductions
1:30 p.m.—Opening Remarks by Deputy Secretary Michael Connor
1:45 p.m.—Buy-Back Program Status Update
2:00 p.m.—Tribal Leader Oral Comments
3:00 p.m.—Break
3:15 p.m.—Individual Landowner Comments

Dated: May 16, 2014.

Michael Connor,

Deputy Secretary.

[FR Doc. 2014–11981 Filed 5–22–14; 8:45 am]

BILLING CODE 4310–10–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–CACO–15698; PPNECACOS0, PPMPSD1Z.YM0000]

Notice of June 9, 2014, Meeting for Cape Cod National Seashore Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: This notice sets forth the date of the 294th Meeting of the Cape Cod National Seashore Advisory Commission.

DATES: The public meeting of the Cape Cod National Seashore Advisory Commission will be held on Monday, June 9, 2014, at 1 p.m. (EASTERN).

ADDRESSES: The Commission members will meet in the conference room at park headquarters, 99 Marconi Site Road, Wellfleet, Massachusetts 02667.

The 294th meeting of the Cape Cod National Seashore Advisory Commission will take place on Monday, June 9, 2014, at 1:00 p.m., in the meeting room at Headquarters, 99 Marconi Station, in Wellfleet, Massachusetts to discuss the following:

1. Adoption of Agenda
2. Approval of Minutes of Previous Meeting (April 14, 2014)
3. Reports of Officers
4. Reports of Subcommittees
   Update of Pilgrim Nuclear Plant Emergency Planning Subcommittee
5. Superintendent's Report
   Storm Damage Repair Update
   National Park Service Centennial
   National Seashore Web site Update
   Smoking Ban on Guarded Beach Proposal
   Improved Properties/Town Bylaws
   Herring River Wetland Restoration
   Shorebird Management Planning
   Highlands Center Update
   Ocean Stewardship Topics—Shoreline Change
   Climate Friendly Parks
6. Old Business
   Continue Discussion of NSTAR Spraying Plans, Clearing Alternatives and Utility Right-of-Ways
   Live Lightly Campaign Progress Report
7. New Business
8. Date and Agenda for Next Meeting
9. Public comment
10. Adjournment

FOR FURTHER INFORMATION CONTACT: Further information concerning the meeting may be obtained from George E. Price, Jr., Superintendent, Cape Cod National Seashore, 99 Marconi Site Road, Wellfleet, MA 02667, or via telephone at (508) 771–2144.

SUPPLEMENTARY INFORMATION: The Commission was reestablished pursuant to Public Law 87–126 as amended by Public Law 105–280. The purpose of the Commission is to consult with the Secretary of the Interior, or her designee, with respect to matters relating to the development of Cape Cod National Seashore, and with respect to carrying out the provisions of sections 4 and 5 of the Act establishing the Seashore.

The meeting is open to the public. It is expected that 15 persons will be able to attend the meeting in addition to Commission members. Interested persons may make oral/written presentations to the Commission during the business meeting or file written statements. Such requests should be made to the park superintendent prior to the meeting. 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 may 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: May 19, 2014.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2014–12012 Filed 5–22–14; 8:45 am]

BILLING CODE 4310–WV–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX066A000 67F 134S180110; S2D2S SS08011000 SX066A00 33F 13xs501520]

Notice of Correction on the Draft Environmental Impact Statement for the Four Corners Power Plant and Navajo Mine Energy Project

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Notice; correction.

SUMMARY: On March 28, 2014 (79 FR 17569), OSMRE published a notice of availability (NOA) for the Four Corners Power Plant and Navajo Mine Energy Project draft environmental impact statement (DEIS). The DEIS included a copy of the United States Army Corps of Engineers (USACE) Preliminary Draft Permit Evaluation (Appendix C of the DEIS) with Attachments A through D omitted. OSMRE updated the online DEIS found at *http://www.wrcc.osmre.gov/initiatives/fourCorners.shtm* on May 2, 2014 to include the omitted Attachments A through D, and the USACE mailed Attachments A through D on May 5, 2014 to DEIS repositories identified in the March 28, 2014 (79 FR 17569) NOA for inclusion.

FOR FURTHER INFORMATION CONTACT: Marcelo Calle, 303–293–5035.

Dated: May 16, 2014.

Joseph G. Pizarchik,

Director.

[FR Doc. 2014–11898 Filed 5–22–14; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0001]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Information Collection Under Review; Report of Theft or Loss of Controlled Substances

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with

the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until July 22, 2014.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: This process is conducted in accordance with 5 CFR 1320.10. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and
—Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Report of Theft or Loss of Controlled Substances—DEA Form 106

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is DEA Form 106. Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Not-for-profit, State, local or tribal government.

Abstract: Title 21 CFR, 1301.74(c) and 1301.76(b) require DEA registrants to complete and submit DEA Form 106 upon discovery of a theft or significant loss of controlled substances. This provides accurate accountability and allows DEA to monitor substances diverted for illicit purposes.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates that 9,655 registrants submit 25,430 forms (24,189 electronic/1,241 paper) annually for this collection, taking .33 hours (20 minutes) to complete each form.

6. *An estimate of the total public burden (in hours) associated with the collection:* An estimate of the total public burden (in hours) associated with the collection: 8,477 hours annual burden hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: May 20, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–11953 Filed 5–22–14; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0009]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Information Collection Under Review; Controlled Substances Import/Export Declaration

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until July 22, 2014.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: This process is conducted in accordance with 5 CFR 1320.10. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and
—Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Controlled Substances Import/Export Declaration—DEA Form 236

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is DEA Form 236. Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: None.

Abstract: DEA Form 236 provides the DEA with control measures over the importation and exportation of controlled substances as required by United States drug control laws and international treaties.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that there are 278 respondents, 4,868 annual responses, and that each response takes 18 minutes to complete.

6. *An estimate of the total public burden (in hours) associated with the collection:* An estimate of the total public burden (in hours) associated with the collection: 1,460 annual burden hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: May 20, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–11955 Filed 5–22–14; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1117–0007]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Information Collection Under Review; Registrants Inventory of Drugs Surrendered

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until July 22, 2014.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: This process is conducted in accordance with 5 CFR 1320.10. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

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

—Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Registrants' Inventory of Drugs Surrendered—DEA Form 41

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is DEA Form 41. Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Not-for-profit institutions, federal government, state, local or tribal government.

Abstract: Title 21 CFR 1307.21 requires that any registrant desiring to voluntarily dispose of controlled substances shall list these controlled substances on DEA Form 41 and submit the form to the nearest DEA office. DEA Form 41 is used to account for destroyed controlled substances, and its use is mandatory.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 87,736 respondents will respond annually to this collection. The DEA estimates that it takes 30 minutes to complete each form.

6. *An estimate of the total public burden (in hours) associated with the collection:* An estimate of the total public burden (in hours) associated with the collection: 43,868 annual burden hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: May 20, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–11954 Filed 5–22–14; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Bureau of Labor Statistics Technical Advisory Committee; Notice of Meeting and Agenda

The Bureau of Labor Statistics Technical Advisory Committee will meet on Friday, June 20, 2014. The meeting will be held in the Postal Square Building, 2 Massachusetts Avenue NE., Washington, DC.

The Committee provides advice and makes recommendations to the Bureau of Labor Statistics (BLS) on technical aspects of the collection and formulation of economic measures. The BLS presents issues and then draws on the expertise of Committee members representing specialized fields within the academic disciplines of economics, statistics and survey design.

The meeting will be held in rooms 7 and 8 of the Postal Square Building Conference Center. The schedule and agenda for the meeting are as follows:

8:30 a.m. Commissioner's welcome and review of agency developments.

9:00 a.m. Current and Potential Uses of Big Data at BLS.

1:30 p.m. Discussion of future priorities.

2:00 p.m. Automated Coding of Survey of Occupational Illnesses and Injuries (SOII) Narratives.

3:30 p.m. Possible Addition of Certification/Licensure Questions to the Current Population Survey.
4:00 p.m. Approximate conclusion.

The meeting is open to the public. Any questions concerning the meeting should be directed to Lisa Fieldhouse, Bureau of Labor Statistics Technical Advisory Committee, on 202–691–5025. Individuals who require special accommodations should contact Ms. Fieldhouse at least two days prior to the meeting date.

Signed at Washington, DC, this 19th day of May, 2014.

Kimberley D. Hill,

Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 2014–11979 Filed 5–22–14; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0009]

Fire Brigades Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend OMB approval of the information collection requirements specified in the Fire Brigades Standard (29 CFR 1910.156).

DATES: Comments must be submitted (postmarked, sent, or received) by July 22, 2014.

ADDRESSES: *Electronically:* You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, OSHA Docket No. OSHA–2011–0009, U.S. Department of Labor, Occupational Safety and Health Administration, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and the OSHA docket number (OSHA–2011–0009) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov*. For further information on submitting comments see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (e.g., copyrighted material) is not publicly available to read or download from the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (i.e., employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accord with the Paperwork Reduction Act of 1995 (PRA–95) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires OSHA to obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

OSHA does not mandate that employers establish fire brigades; however, if they do so, they must comply with the provisions of the Fire Brigades Standard. The provisions of the Standard, including the paperwork requirements, apply to fire brigades, industrial fire departments, and private or contract fire departments, but not to airport crash rescue units or forest firefighting operations. Paragraphs (b)(1), (b)(2), and (c)(4) contain the paperwork requirements of the Standard.

Under paragraph (b)(1) of the Standard, employers must develop and maintain an organizational statement that establishes the: existence of a fire brigade; the basic organizational structure of the brigade; type, amount, and frequency of training provided to brigade members; expected number of members in the brigade; and functions that the brigade is to perform. This paragraph also specifies that the organizational statement must be available for review by workers, their designated representatives, and OSHA compliance officers. The organizational statement describes the functions performed by the brigade members and, thereby, determines the level of training and type of personal protective equipment (PPE) necessary for these members to perform their assigned functions safely. Making the statement available to workers, their designated representatives, and OSHA compliance officers ensures that the elements of the statement are consistent with the functions performed by the brigade members and the occupational hazards they experience, and that employers are providing training and PPE appropriate to these functions and hazards.

To permit a worker with known heart disease, epilepsy, or emphysema to participate in fire brigade emergency activities, paragraph (b)(2) of the Standard requires employers to obtain a physician's certificate of the worker's fitness to do so. This provision provides employers with a direct and efficient means of ascertaining whether or not they can safely expose workers with these medical conditions to the hazards of firefighting operations.

Paragraph (c)(4) of the Standard requires employers to inform fire

brigade members regarding special hazards such as the storage and use of flammable liquids and gases, toxic chemicals, radioactive sources, and water-reactive substances that may be present during fires and other emergencies, as well as about any changes in these special hazards. It also requires that employers develop written procedures describing the actions that brigade members are to take when special hazards are present, and to make these procedures available in the education and training program and for review by brigade members.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting an adjustment decrease of the previous estimate of 6,292 burden hours to 2,510 burden hours, a total decrease of 3,782 hours. The adjustment is primarily due to a decrease in the estimated number of manufacturing facilities with 100 or more workers.

Type of Review: Extension of a currently approved collection.

Title: Fire Brigades Standards (29 CFR 1910.156).

OMB Control Number: 1218–0075.

Affected Public: Business or other for-profits.

Number of Respondents: 23,247.

Total Responses: 3,487.

Frequency of Responses: On occasion.

Average Time per Response: Varies from five minutes (.08 hour) to obtain a physician's certificate to 2 hours to develop or revise an organizational plan.

Estimated Total Burden Hours: 2,510.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) electronically at *http://www.regulations.gov*, which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA–2011–0009). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (e.g., copyrighted material) is not publicly available to read or download from this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* Web site to submit comments and access the docket is available at the Web site's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available from this Web site and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC on May 20, 2014.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2014–12023 Filed 5–22–14; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2013–0028]

Nationally Recognized Testing Laboratory Program; Stakeholder Meeting

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: OSHA invites interested parties to attend an informal stakeholder meeting concerning the Nationally Recognized Testing Laboratory (NRTL) Program. The meeting will focus on the following NRTL Program topics: use of the private sector to increase the efficiency of the NRTL Program; certification marks; factory inspections; field inspections; fees; and, at OSHA's discretion and as time permits, other topics raised by participants or OSHA staff. OSHA plans to use the information gathered at this meeting to explore potential updates to NRTL Program policies and regulations.

DATES: The stakeholder meeting will be held on October 22, 2014, from 9:00 a.m. to 5:00 p.m., e.t., in Washington, DC. Attendees should arrive at least 30 minutes early to allow time for security access. Security-access information is available at *http://www.dol.gov/dol/aboutdol/visit.htm.*

The deadline to register to attend the meeting as a presenter, participant, or an observer is July 22, 2014. If space remains after this deadline, OSHA may accept additional presenters, participants, and observers until the meeting is full. Those who submit their registrations after July 22, 2014, may not receive confirmation of their attendance from OSHA. The deadline to submit written comments, information, and documents in response to the meeting topics found in Appendix A of this notice, to submit suggestions for additional topics for the meeting, or to request an extension of time to make a submission is July 22, 2014. All submissions must bear a postmark or provide other evidence of the submission date.

ADDRESSES:

1. Stakeholder Meeting

OSHA will hold the stakeholder meeting in the Francis Perkins Building, U.S. Department of Labor, at 200 Constitution Avenue NW., Washington, DC 20210. Information concerning the room number for the meeting will be available, no later than Wednesday, September 20, 2014, on OSHA's NRTL Program Web site at *http://www.osha.gov/nrtlpi*, in the docket for this meeting (Docket ID: OSHA–2013–0028, available at *http://www.regulations.gov,* and in the OSHA Docket Office). The nearest Metro station is Judiciary Square (Red Line), and private parking is available within walking distance of the building. Meeting attendees must have a valid form of government identification (e.g., driver's license), and will need to obtain a pass from our security desk to enter the building. Attendees should arrive at least 30 minutes early to allow time for security access. Security-access information is available at *http://www.dol.gov/dol/aboutdol/visit.htm.*

2. Registration to Attend

To register to attend as a presenter, during the presentation portion of the meeting, a participant, during the discussion portion of the meeting, or an observer of the meeting, you must use one of the three methods listed below. If you are registering as a presenter, you must include your presentation topic(s) and a synopsis of your presentation. OSHA will include, in the docket for this meeting (Docket No. OSHA–2013–0028, available at http://www.regulations.gov, and the OSHA Docket Office), the presentation topic(s) and synopses, and any additional information (including any comments, information, documents, or suggestions for additional topics) that it receives with individual registrations.

All presentation topics must address the NRTL Program, and presentations that address those topics described in Appendix A of this notice will have priority. *Once registered, OSHA will coordinate directly with presenters regarding the schedule of presentations.* For additional information about registering, see the ''Registration'' section of this notice under **SUPPLEMENTARY INFORMATION** below.

a. *Electronically:* Email your registration to attend to Ms. Kristin Webster at *webster.kristin@dol.gov*, and label the subject line of the email ''NRTL October 22, 2014, Stakeholder Meeting Registration.''

b. *Facsimile:* Fax your registration to attend to Ms. Webster at (202) 693–1644, and label it ''NRTL October 22, 2014, Stakeholder Meeting Registration.''

c. *Regular or express mail, hand delivery, or messenger (courier) service:* Send your registration to attend to: OSHA Directorate of Technical Support and Emergency Management, 200 Constitution Ave. NW., Room N–3655, Washington, DC 20210, Attention: Kristin Webster. On the outside of the envelope, write ''NRTL October 22, 2014, Stakeholder Meeting Registration.'' Note that security procedures may result in significant delays in receiving registrations by regular mail. If you have any questions about these instructions, contact Ms. Webster at (202) 693–2145.

3. Submitting Comments in Response to Listed Meeting Topics and Corresponding Questions, and Comments Suggesting Additional Topics

In addition to including comments, information, documents, or suggestions for additional topics in individual registrations (see Section 2 of this Notice, ''Registration to Attend,'' above), stakeholders and the general public may also submit written comments, information, and documents in response to the meeting topics and corresponding questions found in Appendix A of this notice, or suggestions for additional topics to address at the meeting, through one of the three methods listed below. For additional information about submissions to the docket, see the ''Submissions to the Docket'' section of this notice under **SUPPLEMENTARY INFORMATION,** below.

a. *Electronically:* Submit comments and any attachments electronically to Docket No. OSHA–2013–0028 at *http://www.regulations.gov*, which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions.

b. *Facsimile:* If submissions, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

c. *Regular or express mail, hand delivery, or messenger (courier) service:* Submit comments and any attachments to: OSHA Docket Office, Docket No. OHSA–2013–0028, Technical Data Center, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2350 (TTY number: (877) 889–5627). Note that security procedures may result in significant delays in receiving submissions and other written materials by regular mail. Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by regular or express mail, hand delivery, or messenger (courier) service. The hours of operation for the OSHA Docket Office are 8:15 a.m.–4:45 p.m., e.t.

4. Accessing the Docket

To read or download submissions or other material in the docket (e.g., public submissions of suggested topics), go to *http://www.regulations.gov* or to the OSHA Docket Office. You can reference all documents placed in the docket electronically at *http://www.regulations.gov* (Docket No. OSHA–2013–0028); however, some information (e.g., copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, will be available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press Inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3647, Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and Technical Information: Contact Mr. David Johnson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210; telephone: (202) 693–2145; email: *johnson.david.w@dol.gov.* OSHA's Web page includes information about the NRTL Program (see *http://www.osha.gov/otpca/nrtl/index.html*).

*Copies of the **Federal Register** Notice:* Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This **Federal Register** notice, as well as other relevant information, is also available on OSHA's Web page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nationally Recognized Testing Laboratory Program

Several OSHA standards require an NRTL to approve equipment as safe if used in the workplace (see *https://www.osha.gov/dts/otpca/nrtl/1910refs.html* (listing specific references to OSHA standards requiring NRTL approval)). NRTLs are independent laboratories that meet OSHA's requirements for performing safety

testing and certification of products used in the workplace. To obtain and retain OSHA recognition, an NRTL must meet the requirements in the NRTL Program regulations at 29 CFR 1910.7. Recognition is an acknowledgement by OSHA that an NRTL has the capability to perform independent safety testing and certification of the specific products covered within the NRTL's scope of recognition. Recognition also allows employers to use products certified by that NRTL to meet those OSHA standards that require approval by an NRTL.

OSHA's NRTL Program recognition process involves a thorough analysis of an NRTL applicant's policies and procedures, and a comprehensive on-site review of the applicant's testing and certification facilities, to ensure that the applicant meets the requirements of 29 CFR 1910.7. Once an NRTL obtains recognition from OSHA, OSHA's staff conducts on-site audits to ensure that existing NRTLs adequately perform their testing and certification activities and maintain the quality of their operations.

An NRTL's approval of a product generally consists of testing, inspection, and certification. Testing involves determining whether a sample or prototype of the product meets the applicable requirements of one or more specific consensus-based, U.S. product-safety test standards. If the product meets the requirements of the test standard, the NRTL then performs an initial inspection of the factory that manufactures, or will manufacture, the product to verify that the units of the product resulting from production runs are or will be in conformance with the test standard's requirements. Following a satisfactory initial inspection, the NRTL issues its certification, which provides assurance that the product conforms to the specific test standard(s). The NRTL also authorizes the manufacturer to apply the NRTL's mark to each unit of the manufactured product. After issuing its certification, the NRTL conducts periodic follow-up (i.e., quality-assurance and compliance) inspections of each manufacturing facility to provide assurance that the product currently manufactured at the facility and bearing the NRTL's mark is identical to the product that the NRTL tested, initially inspected, and certified. For more information about the NRTL Program, see the NRTL Program Web site (*www.osha.gov/dts/otpca/nrtl/index.html*).

B. Events Leading to This Stakeholder Meeting

In 2012, the Government Accountability Office (GAO) performed a study of OSHA's NRTL Program to examine the program's recognition process. GAO published its findings and recommendations from that study in December 2012, in a report entitled, *Product Safety Laboratories: OSHA's Accreditation Process Needs Reexamination* (Exhibit 14–1—GAO Report GAO–13–88). In the report, GAO recommended that OSHA review its current structure and procedures for recognizing NRTLs and implement alternatives that would maintain effectiveness while improving timeliness. More specifically, GAO suggested that OSHA explore various structural approaches for making decisions regarding recognition, including use of private accreditation bodies and/or contractors. GAO also recommended that OSHA review its current regulations and procedures to identify changes to existing regulations and program modifications, including increased alignment with international standards on accreditation.

As a result of GAO's report, in early 2013, OSHA staff began reexamining several aspects of the NRTL Program to determine how it could improve program operations without compromising the Agency's mission to protect worker safety and health. On March 15, 2013, OSHA held an informal stakeholder meeting to help OSHA staff assess the NRTL Program and make efforts to increase program effectiveness. At the March meeting, OSHA discussed and received feedback from stakeholders on several potential NRTL Program policy, procedure, and guideline changes.

Following the March 15 stakeholder meeting, OSHA began investigating the possibility of aligning the NRTL Program requirements with ISO/IEC 17025:2005 and ISO/IEC 17065:2012. As part of this effort, OSHA may propose developing NRTL Program-specific guidance that would permit NRTLs to obtain and maintain recognition under the NRTL Program regulation, 29 CFR 1910.7, by following specific provisions in ISO/IEC 17025 and ISO/IEC 17065 in conjunction with OSHA guidance that tailors the general criteria found in ISO/IEC 17025 and ISO/IEC 17065 to the specific NRTL Program requirements for testing and certification activities.

As part of its investigation into aligning the NRTL Program requirements with international standards, OSHA also is investigating the use of the private sector to improve the timeliness and efficiency of the NRTL recognition process, while still maintaining the integrity of the program. As part of its effort to explore the use of the private sector for this purpose, OSHA is holding this stakeholder meeting to gather more information on the topic. Moreover, after reviewing the NRTL Program requirements as part of its alignment investigation, OSHA developed potential modifications to existing policies and regulatory requirements with respect to certification marks, factory inspections, field inspections, and fees. OSHA also seeks to gather input on these potential policy and regulatory changes through this stakeholder meeting.

The stakeholder meeting will consist of stakeholder presentations concerning the topics described in Appendix A of this notice, and, at OSHA's discretion, other NRTL Program-related topics. A facilitated discussion will follow the presentations. OSHA determined that stakeholder presentations, in conjunction with informal discussion on specific topics related to the NRTL Program, will be beneficial to OSHA's further deliberations on developing, updating, and proposing new or revised NRTL Program policies, procedures, regulations, or guidelines.

II. Stakeholder Meeting

The stakeholder meeting will last approximately eight hours. The first part of the meeting will consist of stakeholder presentations on those topics described in Appendix A of this notice, and, at OSHA's discretion, other suggested topics related to the NRTL Program. Each presenter will have 10–20 minutes to make a presentation, depending on the number of people who request to make a presentation. A short period of 5–10 minutes will follow each presentation so that OSHA, other presenters, and registered participants can ask questions of, and request clarification from, the presenter. OSHA is limiting participation in these periods to OSHA and registered presenters and participants. Presenters may, at their discretion, submit written copies of their presentation to OSHA, either during the meeting or in written comments submitted to the docket in accordance with the procedures outlined in this notice. OSHA believes that having access to written copies of the presentations will facilitate its decisionmaking. OSHA will include copies of the presentations in the docket for this meeting (Docket No. OSHA–2013–0028, available at *http://www.regulations.gov* and the OSHA Docket Office).

OSHA is limiting the meeting to approximately 20 presentations, but may accommodate more presentations at its discretion and as time permits. OSHA will try to accommodate all presenters who respond in a timely fashion. To ensure all views are represented, OSHA encourages individuals and groups having similar interests to consolidate their information and present this information through a single representative. OSHA will try to accommodate, as space permits, all those who would like to observe the presentations.

If time permits, OSHA may hold an open-session portion of the meeting with facilitated discussion. OSHA is limiting the open-session portion of the meeting to approximately 30 participants. OSHA will try to accommodate all attendees who would like to participate. To ensure all views are represented, OSHA encourages individuals and groups having similar interests to consolidate their information and participate through a single representative. OSHA staff will be present to take part in the discussions.

The topics for the stakeholder meeting and related questions about these topics are in Appendix A of this notice. OSHA believes the discussion and related questions in Appendix A will provide the Agency with useful information, and will facilitate discussion during the meeting. If stakeholders and the public would like to provide input on the meeting topics and their corresponding questions prior to the stakeholder meeting, OSHA welcomes any available data, documentation, information, or comments related to those topics that might help facilitate the meeting. Stakeholders and the members of the public chosen to make presentations at the meeting and/or to participate during the open-session portion of the meeting, will also have an opportunity to provide information and comment on these topics and questions during the meeting. Any stakeholder or member of the public who chooses to provide data, documentation, information, or comments prior to the meeting should: identify any organization they are representing at the meeting; their position within that organization; and describe any qualifications they have that are relevant to their submission.

OSHA will provide the public with a copy of the final meeting agenda and any specific documents OSHA will use at the stakeholder meeting no later than five days prior to the meeting. These documents also will be available by that date at OSHA's NRTL Program Web site (*http://www.osha.gov/nrtlpi*) and in the docket for this notice (Docket No. OSHA–2013–0028, available at *http://www.regulations.gov* and the OSHA Docket Office).

OSHA will prepare a full transcript of the meeting and post this transcript on the NRTL Program Web site (*http://www.osha.gov/nrtlpi*) and in the docket (Docket No. OSHA–2013–0028, available at *http://www.regulations.gov* and the OSHA Docket Office).

III. Registration

Register to attend as a presenter, participant, or an observer in the stakeholder meeting by July 22, 2014, using one of the three methods described above in the ''Registration to Attend'' section of this notice under **ADDRESSES**. OSHA will accommodate attendees who do not register for the meeting if space permits. However, those who would like to make a presentation during the meeting must register as presenters and submit a copy of their presentation topic(s) and a synopsis of their presentations. Additionally, those who would like to participate during the open-session portion of the meeting must register as participants. OSHA will consider as an observer any attendee who does not register as a presenter or participant.

OSHA is limiting the number of attendees who may present or participate in the meeting; therefore, OSHA will grant priority to current or former NRTLs, and current NRTL applicants. Only one representative from each organization may make a presentation, and only one representative from each organization may attend as a participant; however, each organization may register one representative to be a presenter and a different representative to be a participant. Each organization may have more than one observer in attendance (space permitting).

Any individual or entity not affiliated with a current or former NRTL, or a current NRTL applicant, who would like to present and/or participate in the meeting must submit, with their registration to attend, a written statement that indicates their interest in the NRTL Program and the specific topic(s) they would like to present or discuss. If they would like to make a presentation, they must also submit a synopsis of their presentation. OSHA will enter these presentations and synopses into the docket for the meeting (Docket No. OSHA–2013–0028, available at *http://www.regulations.gov* and the OSHA Docket Office). However, if OSHA receives these documents after July 22, 2014 (the last day to timely submit topics), OSHA may not review the documents for the purpose of generating a meeting agenda (see the ''Submissions to the Docket'' section below).

Registrants not affiliated with a current or former NRTL, or with a current NRTL applicant, who would like to present a *specific topic* during the first portion of the meeting, and/or participate in the discussion during the open-session portion of the meeting, will be chosen as presenters and/or participants over similar attendees who would like to address broad topics only. OSHA cannot guarantee presenter and/or participation status to all those who register as presenters and/or participants; however, it will make every effort to accommodate registrants who want to present and/or participate, ensure a fair representation of interests, and facilitate the presentation of diverse viewpoints.

In registering to participate during the open-session portion of the meeting, current or former NRTLs, and current NRTL applicants, need not submit statements indicating their interest in the NRTL Program and the specific topic(s) they would like to discuss. However, if they would like to make a presentation during the first portion of the meeting, they must submit their presentation topic(s) and a synopsis of their presentation. Additionally, these organizations are welcome to submit, in writing, suggestions for additional topics for discussion (pursuant to the procedures described under **ADDRESSES** above and in the ''Submissions to the Docket'' section below).

When registering, please provide the following information:

a. Name, contact address, daytime phone, fax, and email address;

b. The organization for which you work or represent, if any;

c. Whether you are employed at, affiliated with, or represent a current or former NRTL or a current NRTL applicant;

d. Whether you are registering to be a presenter during the presentation portion of the meeting and/or a participant during the open-session portion of the meeting, or an observer;

e. If you registering to be a presenter during the presentation portion of the meeting, provide your presentation topic(s) and a synopsis of your presentation; and

f. If you are not affiliated with a current or former NRTL, or current NRTL applicant, and would like to make a presentation during the presentation portion of the meeting and/or be a participant during the open-session portion of the meeting, provide a written statement that indicates your

interest in the NRTL Program and the specific topic(s) you would like to present and/or discuss. Additionally, if you are registering to be a presenter, provide a synopsis of your presentation.

4. Submissions to the Docket

You must make all submissions to the docket using any of the methods listed above under **ADDRESSES**, and the submission must include the Agency name (i.e., OSHA) and the OSHA docket number (OSHA–2013–0028). You must make submissions to the docket by July 22, 2014.

Note that a submission to the docket does not constitute registration to attend the meeting as a presenter, participant, or observer. To register as a presenter, participant, or observer, you must follow the procedures described above in the section of this notice titled ''Registration'' under **SUPPLEMENTARY INFORMATION**.

OSHA will use the submissions it timely receives to establish the meeting agenda, which it will release no later than five days prior to the meeting on its NRTL Program Web site (*http://www.osha.gov/nrtlpi*) and in the docket for this notice (Docket No. OSHA–2013–0028, available at *http://www.regulations.gov* and the OSHA Docket Office). OSHA will consider submissions made after July 22, 2014 to be untimely and, therefore, may not use such submissions when establishing the meeting agenda.

OSHA will place all submissions, including any personal information, in the docket without revision, and these submissions and other material will be available online at *http://www.regulations.gov* and in the OSHA Docket Office (as described above in ''Accessing the Docket'' section under **ADDRESSES**). Therefore, OSHA cautions commenters about submitting statements they do not want made public, or submissions that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

IV. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2)), Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on May 20, 2014.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Appendix A

Topics for Informal Stakeholder Meeting Concerning the Nationally Recognized Testing Laboratory Program

OSHA presents here a discussion of the topics for the October 22, 2014, NRTL Program informal stakeholder meeting. OSHA believes the discussion and related questions presented here will assist commenters and presenters in narrowing their comments and presentations to topics about which OSHA has an interest in obtaining information, and facilitate discussion during the open-session portion of the meeting. OSHA numbered the individual topics below, and asks that commenters clearly delineate which number(s) (i.e., topics) each of their comments or other submissions is addressing.

A. Options for Using the Private Sector to Increase the Efficiency of the NRTL Program

OSHA is considering using private-sector accreditation bodies and/or independent contractors to increase the efficiency of the NRTL Program. As a result, OSHA is considering a number of different models to serve this purpose. This subsection of topics presents these models in general terms, and asks specific questions about each of these approaches.

OSHA is not endorsing any of these models at this time. Moreover, OSHA is open to considering other options or models for revising NRTL Program policies and regulations. OSHA invites stakeholders to provide any additional options, models, feedback, or suggestions that may assist OSHA in its decisionmaking.

1. OSHA is considering a model that uses private-sector accreditation as evidence of conformance to ISO/IEC 17025 and ISO/IEC 17065 to facilitate processing applications and performing on-site assessments. Although, OSHA would continue to conduct on-site assessments to NRTL Program-specific requirements, inclusion of accreditations may facilitate validation of generic ISO/IEC 17025 and ISO/IEC 17065 requirements. Under this approach, OSHA would deem NRTLs in compliance with the NRTL Program regulation, 29 CFR 1910.7, if along with OSHAs validation of compliance with NRTL Program specific requirements, a private-sector accreditation body accredits the NRTL headquarters to the appropriate scope of accreditation for ISO/IEC 17025 and ISO/IEC 17065, and the NRTL maintains this accreditation. In addition, under this approach, all of the NRTL's sites would require independent accreditation to ISO/IEC 17025.

a. Are you in favor of this approach? Please explain.

b. What are the benefits to this approach?

c. What are the weaknesses to this approach?

d. What resources and/or costs would be associated with this approach? Please explain.

e. Would there be any cost savings associated with this approach? Please explain.

f. As part of this approach, NRTLs would need to provide complete audit reports and final corrective actions to OSHA during OSHA's on-site assessments or upon request by OSHA. Note that such information could be subject to release by OSHA under the Freedom of Information Act (FOIA). Please explain the impact of this part of the approach.

2. OSHA is considering a model under which it makes use of one or more private-sector accreditation bodies as part of the NRTL recognition process. Under this approach, OSHA would delegate, to one or more private-sector accreditation bodies, the responsibility to assess NRTLs for recognition and perform NRTL Program on-site assessments. OSHA would maintain the official list of recognized NRTLs and still retain the authority to approve, deny, amend, or revoke NRTL recognition.

a. Are you in favor of this approach? Please explain.

b. What are the benefits to this approach?

c. What are the weaknesses to this approach?

d. What resources and/or costs would be associated with this approach? Please explain.

e. Would there be any cost savings associated with this approach? Please explain.

f. Are you in favor of using private-sector accreditation bodies in a manner not described in this approach? Please explain.

3. OSHA is considering a model under which it contracts with independent technical experts to perform specific functions for the NRTL Program. For example, OSHA may use independent technical experts to assess the technical requirements of NRTLs or applicants for purposes of NRTL applications and/or NRTL Program on-site assessments. OSHA would continue to perform all other aspects of the NRTL Program, and still would make all decisions regarding recognition.

a. Are you in favor of this approach? Please explain.

b. What are the benefits to this approach?

c. What are the weaknesses to this approach?

d. What resources and/or costs would be associated with this approach? Please explain.

e. Would there be any cost savings associated with this approach? Please explain.

f. Are you in favor of using independent technical experts in a manner not described in this approach? Please explain.

4. Under 29 CFR 1910.7, an NRTL must have the capability to perform both testing and certification functions. OSHA is considering a modification to the regulation that separates these two functions, thus allowing organizations to apply to the NRTL Program to perform testing only, certification only, or both testing and certification. If OSHA revises the regulation in this manner, it would also plan to use ISO/IEC 17025 and NRTL Program-specific policies to evaluate testing organizations, and ISO/IEC 17065 and

NRTL Program-specific policies to evaluate certification organizations. Under this approach, OSHA-recognized testing organizations would submit evaluation and testing results to OSHA-recognized certification organizations, and these organizations would authorize the certification of the product and conduct factory-surveillance on-site assessments.

a. Are you in favor of this approach? Please explain.

b. What are the benefits to this approach?

c. What are the weaknesses to this approach?

d. What resources and/or costs would be associated with this approach? Please explain.

e. Would there be any cost savings associated with this approach? Please explain.

f. If OSHA were to revise its regulation as described above, OSHA also may revise its regulation to require certification organizations authorized under the NRTL Program to accept test results from any testing organization authorized under the NRTL Program. Are you in favor of such a requirement? If OSHA had to adopt this requirement to successfully implement this model, would you be in favor of this requirement? Please explain.

B. Certification Marks for the NRTL Program

Under OSHA's current policy regarding certification marks, an NRTL is in compliance with the NRTL Program regulation, 29 CFR 1910.7, if it has a registered certification mark issued by the U.S. Patent and Trademark Office (USPTO) or by a national or international body under a registration system that requires ownership of the mark(s) and that is equivalent to the USPTO system of registration. Additionally, the NRTL can only use this certification mark(s) for its NRTL activities. OSHA is considering revising its policy to better account for ownership and use of certification marks for NRTL activities.

5. OSHA is considering making the following policy change: If an entity wholly owned by an NRTL owns a certification mark, and the NRTL uses that mark for its NRTL certifications, the entity owned by the NRTL could no longer use the mark for any purpose, including marketing or advertisement.

a. What impact would this policy change have on NRTLs? Please explain.

b. What resources and/or costs would be associated with this approach? Please explain.

6. OSHA is considering making the following policy change: Any mark owned by an NRTL, and used for its NRTL certifications, would need to be clearly distinguishable from the mark of another entity owned or affiliated with the NRTL (e.g., a mark used by an entity that is not a recognized NRTL would need to be clearly distinguishable from the mark used by the entity recognized as an NRTL, and a product certified by a non-NRTL could not appear to be a product certified by the NRTL).

a. What impact would this policy change have on NRTLs? Please explain.

b. What resources and/or costs would be associated with this approach? Please explain.

7. Under current OSHA policy, NRTLs need not add a unique identifier to their certification mark to signify work conducted under the NRTL Program and compliance to particular product-safety test standards (i.e.,, similar to the ''C'' mark for Canada). Some NRTLs voluntarily include the acronym ''NRTL'' with their regular certification marks. Under a policy change OSHA is considering, each NRTL would need to add a unique identifier to its certification mark to signify testing and certification conducted under the NRTL Program.

a. Are you in favor of requiring the NRTLs to add a unique identifier to their certification mark? Please explain.

b. What resources and/or costs would be associated with this approach? Please explain.

c. OSHA is considering delaying the effective date of this policy change for 2 years after it finalizes the policy change. Are you in favor of delaying the effective date of this policy change? If so, are you in favor of a 2 year delay? Please explain.

C. Factory Inspections

8. Under OSHA's current policy for factory inspections (OSHA Instruction CPL 01–00–003, NRTL Program Policies, Procedures, and Guidelines, App. C.III.A, ''*NRTL Follow-up Inspections at Manufacturing Facilities, Frequency of Inspections*'' (Dec. 2, 1999)), NRTLs need to perform more frequent inspections at facilities where heightened safety concerns exist regarding the manufacture of products certified by the NRTLs. As outlined in the existing policy, an NRTL needs to perform no fewer than four (4) inspections per year at facilities where heightened safety concerns exist, but needs to perform no fewer than two (2) inspections per year at facilities where heightened safety concerns or similar situations do not exist. OSHA is considering modifying its policy regarding the frequency of inspections to allow each NRTL to adopt its own risk-based approach [1] to determine the frequency with which it performs factory inspections.

a. Should OSHA allow each NRTL to adopt its own risk-based approach to determine the frequency with which it performs factory inspections or should OSHA keep its current policy in which NRTLs must perform a minimum number of inspections per year? Please explain.

b. What resources and/or costs would be associated with allowing NRTLs to adopt their own risk-based approach to determine the frequency with which they perform factory inspections? Please explain.

9. Under OSHA's current policy for factory inspections (OSHA Instruction CPL 01–00–003, NRTL Program Policies, Procedures, and Guidelines, App. C.III.B, ''*NRTL Follow-up Inspections at Manufacturing Facilities, Policies and Procedures for Inspections*'' (Dec. 2, 1999)), NRTLs need to determine the specific activities to undertake in performing each inspection, and document these activities. However, follow-up inspections activities (but not necessarily every inspection) need to at least include or address activities specified in the policy. OSHA is considering modifying its policy regarding factory inspections, and seeks input on the following questions:

a. Are you in favor of OSHA standardizing inspection content and processes for factory inspections? For example, should OSHA specify the activities NRTLs need to perform during each factory inspection and delineate how documentation should occur? Please explain.

b. Are you in favor of OSHA developing forms, with stakeholder involvement, for NRTLs to use during factoring inspections? Please explain.

c. What resources and/or costs would be associated with the modifications addressed in questions (a)–(c) above for your organization? Please explain.

D. Field Inspections

10. Under 29 CFR 1910.7(b)(2)(iii), an NRTL must conduct field inspections to monitor and assure proper use of its identifying mark or labels on products. OSHA is considering eliminating this requirement. Are you in favor of OSHA eliminating this requirement? Please explain.

E. Fees

11. OSHA currently requires NRTLs to pay all NRTL Program fees in U.S. dollars by check or money order. OSHA is considering allowing NRTLs to make online electronic payments only (e.g., through credit card or ACH), and disallowing payments made by check or money order.

a. What impact would such a change have? Please explain

b. What resources and/or costs would be associated with this approach? Please explain.

[FR Doc. 2014–12015 Filed 5–22–14; 8:45 am]

BILLING CODE 4510–26–P

[1] See, for example, ISO 31000:2009; *Risk management—Principles and guidelines on implementation; International Organization for Standardization.*

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2012–0036]

Tully/OHL USA Joint Venture: Grant of a Permanent Variance

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of grant of a permanent variance.

SUMMARY: In this notice, OSHA grants a permanent variance to Tully/OHL USA Joint Venture from the provisions of OSHA standards that regulate work in compressed-air environments at 29 CFR 1926.803.

DATES: The permanent variance specified by this notice becomes

effective on May 23, 2014 and shall remain in effect until March 31, 2015.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3647, Washington, DC 20210; telephone: (202) 693–1999; email: *Meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. David Johnson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210; telephone: (202) 693–2110; email: *johnson.david.w@dol.gov.* OSHA's Web page includes information about the Variance Program (see *http://www.osha.gov/dts/otpca/variances/index.html*).

SUPPLEMENTARY INFORMATION:

Copies of this Federal Register notice. Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This **Federal Register** notice and other relevant information are also available at OSHA's Web page at *http://www.osha.gov.*

I. Notice of Application

On July 12, 2012, Tully/OHL USA Joint Venture (''Tully'' or ''the applicant''), 355 Front Street, Construction Site, Staten Island, NY 10304, submitted under Section 6(d) of the Occupational Safety and Health Act of 1970 (''OSH Act''; 29 U.S.C. 655) and 29 CFR 1905.11 (''Variances and other relief under section 6(d)'') an application for a permanent variance from several provisions of the OSHA standard that regulates work in compressed air at 29 CFR 1926.803, as well as a request for an interim order pending OSHA's decision on the application for a variance (Document ID No. OSHA–2012–0036–0003). Specifically, Tully seeks a variance from the provisions of the standard that: (1) Prohibit compressed-air worker exposure to pressures exceeding 50 pounds per square inch (p.s.i.) except in an emergency (29 CFR 1926.803(e)(5)); [1] (2) require the use of the decompression values specified in decompression tables in Appendix A of the compressed-air standard for construction (29 CFR 1926.803(f)(1)); and (3) require the use of automated operational controls and a special decompression chamber (29 CFR 1926.803(g)(1)(iii) and .803(g)(1)(xvii), respectively).

Tully is a contractor that works on complex tunnel projects using recently developed equipment and procedures for soft-ground tunneling. Tully's workers engage in the construction of subaqueous tunnels using advanced shielded mechanical excavation techniques in conjunction with an Earth Pressure Balanced Tunnel Boring Machine (EPBTBM).

According to its application, Tully is currently the managing partner of Tully/OHL USA Joint Venture, the general contractor for the New York Economic Development Corporation's New York Siphon Tunnel Project. Tully is seeking the permanent variance solely for the duration of the New York Economic Development Corporation's New York Siphon Tunnel Project (hereafter, ''the project'').

The project consists of a 12-foot diameter tunnel beneath New York Harbor between Staten Island and Brooklyn. Tully will bore the tunnel below the water table through soft soils consisting of clay, silt, and sand. Tully employs specially trained personnel for the construction of the tunnel, and states that this construction will use shielded mechanical-excavation techniques. Tully asserts that its workers perform hyperbaric interventions at pressures greater than 50 p.s.i.g. in the excavation chamber of the EPBTBM; these interventions consist of conducting inspections and maintenance work on the cutter-head structure and cutting tools of the EPBTBM.

Tully asserts that innovations in tunnel excavation, specifically with EPBTBMs, have, in most cases, eliminated the need to pressurize the entire tunnel. This technology negates the requirement that all members of a tunnel-excavation crew work in compressed air while excavating the tunnel. These advances in technology modified substantially the methods used by the construction industry to excavate subaqueous tunnels compared to the caisson work regulated by the current OSHA compressed-air standard for construction at 29 CFR 1926.803. Such advances reduce the number of workers exposed, and the total duration of exposure, to hyperbaric pressure during tunnel construction.

Using shielded mechanical-excavation techniques, in conjunction with precast concrete tunnel liners and backfill grout, EPBTBMs provide methods to achieve the face pressures required to maintain a stabilized tunnel face through various geologies, and isolate that pressure to the forward section (the working chamber) of the EPBTBM. Interventions in the working chamber (the pressurized portion of the EPBTBM) take place only after halting tunnel excavation and preparing the machine and crew for an intervention. Interventions occur to inspect or maintain the mechanical-excavation components located in the working chamber. Maintenance conducted in the working chamber includes changing replaceable cutting tools and disposable wear bars, and, in rare cases, repairing structural damage to the cutter head.

In addition to innovations in tunnel-excavation methods, Tully asserts that innovations in hyperbaric medicine and technology improve the safety of decompression from hyperbaric exposures. According to Tully, the use of decompression protocols incorporating oxygen is more efficient, effective, and safer for tunnel workers than compliance with the decompression tables specified by the existing OSHA standard (29 CFR 1926, subpart S, Appendix A decompression tables). These hyperbaric exposures are possible due to advances in technology, a better understanding of hyperbaric medicine, and the development of a project-specific Hyperbaric Operations Manual (HOM) that requires specialized medical support and hyperbaric supervision to provide assistance to a team of specially trained man-lock attendants and hyperbaric or compressed-air workers.

OSHA initiated a technical review of the Tully's variance application and developed a set of follow-up questions that it sent to Tully on August 29, 2012 (Document ID No. OSHA–2012–0036–0004). On October 9, 2012, Tully submitted its response and a request for an interim order (Document ID No. OSHA–2012–0036–0005). In its response to OSHA's follow-up questions, Tully indicated that the maximum pressure to which it is likely to expose workers during interventions for the New York Economic Development Corporation's New York Siphon Tunnel Project is 58 p.s.i.g. Therefore, to work effectively on this project, Tully must perform hyperbaric interventions in compressed air at pressures higher than the maximum pressure specified by in the existing OSHA standard, 29 CFR 1926.803(e)(5), which states: ''No employee shall be

[1] The decompression tables in Appendix A of subpart S express the maximum working pressures as pounds per square inch gauge (p.s.i.g.), with a maximum working pressure of 50 p.s.i.g. Therefore, throughout this notice, OSHA expresses the 50 p.s.i. value specified by § 1926.803(e)(5) as 50 p.s.i.g., consistent with the terminology in Appendix A, Table 1 of subpart S.

subjected to pressure exceeding 50 p.s.i.g. except in emergency'' (see footnote 1 in this notice).

OSHA considered Tully's application for a permanent variance and interim order. On January 7, 2014, OSHA published a **Federal Register** notice announcing Tully's application for permanent variance and interim order, grant of an interim order, and request for comments (79 FR 844).

II. The Variance Application

A. Background

The applicant asserts that the advances in tunnel-excavation technology described in Section I of this notice modified significantly the equipment and methods used by contractors to construct subaqueous tunnels, thereby making several provisions of OSHA's compressed-air standard for construction at 29 CFR 1926.803 inappropriate for this type of work. These advances reduce both the number of employees exposed, and the total duration of exposure, to the hyperbaric conditions associated with tunnel construction.

Using shielded mechanical-excavation techniques, in conjunction with pre-cast concrete tunnel liners and backfill grout, EPBTBMs provide methods to achieve the pressures required to maintain a stabilized tunnel face, through various geologies, while isolating that pressure to the forward section (working or excavation chamber) of the EPBTBM.

Interventions involving the working chamber (the pressurized chamber at the head of the EPBTBM) take place only after the applicant halts tunnel excavation and prepares the machine and crew for an intervention. Interventions occur to inspect or maintain the mechanical-excavation components located in the forward portion of the working chamber. Maintenance conducted in the forward portion of the working chamber includes changing replaceable cutting tools and disposable wear bars, and, in rare cases, making repairs to the cutter head due to structural damage.

In addition to innovations in tunnel-excavation methods, research conducted after OSHA published its compressed-air standard for construction in 1971 resulted in advances in hyperbaric medicine. In this regard, the applicant asserts that the use of decompression protocols incorporating oxygen is more efficient, effective, and safer for tunnel workers than compliance with the existing OSHA standard (29 CFR 1926, subpart S, Appendix A decompression tables). According to the applicant, contractors routinely and safely expose employees performing interventions in the working chamber of EPBTBMs to hyperbaric pressures up to 75 p.s.i.g., which is 50% higher than the maximum pressure specified by the existing OSHA standard (see 29 CFR 1926.803(e)(5)). The applicant asserts that these hyperbaric exposures are possible because of advances in hyperbaric technology, a better understanding of hyperbaric medicine, and the development of a project-specific HOM that requires specialized medical support and hyperbaric supervision to provide assistance to a team of specially trained man-lock attendants and hyperbaric workers.

The applicant contends that the alternative safety measures included in its application provide its workers with a place of employment that is at least as safe and healthful as they would obtain under the existing provisions of OSHA's compressed-air standard for construction. The applicant certifies that it provided employee representatives of affected workers [2] with a copy of the variance application. The applicant also certifies that it notified its workers of the variance application by posting, at prominent locations where it normally posts workplace notices, a summary of the application and information specifying where the workers can examine a copy of the application. In addition, the applicant informed its workers and their representatives of their rights to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance application.

B. Variance From Paragraph (e)(5) of 29 CFR 1926.803, Prohibition of Exposure To Pressure Greater Than 50 p.s.i.g. (See Footnote 1 in This Notice)

The applicant states that it may perform hyperbaric interventions at pressures greater than 50 p.s.i.g. in the working chamber of the EPBTBM; this pressure exceeds the pressure limit of 50 p.s.i.g. specified for nonemergency purposes by 29 CFR 1926.803(e)(5). The EPBTBM has twin man locks, with each man lock having two compartments. This configuration allows workers to access the man locks for compression and decompression, and medical personnel to access the man locks if required in an emergency.

EPBTBMs are capable of maintaining pressure at the tunnel face, and stabilizing existing geological conditions, through the controlled use of propel cylinders, a mechanically driven cutter head, bulkheads within the shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. As noted earlier, the forward-most portion of the EPBTBM is the working chamber, and this chamber is the only pressurized segment of the EPBTBM. Within the shield, the working chamber consists of two sections: The staging chamber and the forward working chamber. The staging chamber is the section of the working chamber between the man-lock door and the entry door to the forward working chamber. The forward working chamber is immediately behind the cutter head and tunnel face.

The applicant will pressurize the working chamber to the level required to maintain a stable tunnel face. Pressure in the staging chamber ranges from atmospheric (no increased pressure) to a maximum pressure equal to the pressure in the working chamber. The applicant asserts that most of the hyperbaric interventions will be around 14.7 p.s.i.g. However, the applicant maintains that they may have to perform interventions at pressures up to 58 p.s.i.g.

During interventions, workers enter the working chamber through one of the twin man locks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward working chamber. The maximum crew size allowed in the forward working chamber is three. At certain hyperbaric pressures (i.e., when decompression times are greater than work times), the twin man locks allow for crew rotation. During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied man lock at its disposal.

The applicant developed a project-specific HOM (Document ID No. OSHA–2012–0036–0006) that describes in detail the hyperbaric procedures and required medical examinations used during the tunnel-construction project. The HOM is project specific, and discusses standard operating procedures and emergency and contingency procedures. The procedures include using experienced and knowledgeable man-lock attendants who have the training and experience necessary to recognize and treat decompression sickness and diving-related illnesses and injuries. The attendants are under the direct supervision of the hyperbaric supervisor and attending physician. In addition, procedures include medical screening and review of prospective

[2] See the definition of ''Affected employee or worker'' below in section VI. D of this notice.

compressed-air workers (CAWs). The purpose of this screening procedure is to vet prospective CAWs with medical conditions (e.g., deep vein thrombosis, poor vascular circulation, and muscle cramping) that could be aggravated by sitting in a cramped space (e.g., a man lock) for extended periods or by exposure to elevated pressures and compressed gas mixtures. A transportable recompression chamber (shuttle) is available to extract workers from the hyperbaric working chamber for emergency evacuation and medical treatment; the shuttle attaches to the topside medical lock, which is a large recompression chamber. The applicant believes that the procedures included in the HOM provide safe work conditions when interventions are necessary, including interventions above 50 p.s.i.g.

C. Variance From Paragraph (f)(1) of 29 CFR 1926.803, Requirement To Use OSHA Decompression Tables

OSHA's compressed-air standard for construction requires decompression in accordance with the decompression tables in Appendix A of 29 CFR 1926, subpart S (see 29 CFR 1926.803(f)(1)). As an alternative to the OSHA decompression tables, the applicant proposes to use newer decompression schedules that supplement breathing air used during decompression with pure oxygen. The applicant asserts that these decompression protocols are safer for tunnel workers than the decompression protocols specified in Appendix A of 29 CFR 1926, subpart S. Accordingly, the applicant proposes to use the 1992 French Decompression Tables to decompress CAWs after they exit the hyperbaric conditions in the working chamber.

Depending on the maximum working pressure and exposure time*s,* the 1992 French Decompression Tables provide for air decompression with or without oxygen. Tully asserts that oxygen decompression has many benefits, including reducing decompression time by about 33 percent, and significantly lowering the rate of decompression illness (DCI), compared to the air-decompression tables in Appendix A of 29 CFR 1926, subpart S. In addition, the HOM requires a physician certified in hyperbaric medicine to manage the medical condition of CAWs during hyperbaric exposures and decompression. A trained and experienced man-lock attendant also will be present during hyperbaric exposures and decompression. This man-lock attendant will operate the hyperbaric system to ensure compliance with the specified decompression table. A hyperbaric supervisor (competent person), trained in hyperbaric operations, procedures, and safety, directly oversees all hyperbaric interventions, and ensures that staff follow the procedures delineated in the HOM or by the attending physician.

The applicant asserts that at higher hyperbaric pressures, decompression times exceed 75 minutes. The HOM establishes protocols and procedures that provide the basis for alternate means of protection for CAWs under these conditions. Accordingly, based on these protocols and procedures, the applicant requests to use the 1992 French Decompression Tables for hyperbaric interventions up to 58 p.s.i.g. for the project. The applicant is committed to follow the decompression procedures described in the project-specific HOM during these interventions.

D. Variance From Paragraph (g)(1)(iii) of 29 CFR 1926.803, Automatically Regulated Continuous Decompression

According to the applicant, breathing air under hyperbaric conditions increases the amount of nitrogen gas dissolved in a CAW's tissues. The greater the hyperbaric pressure under these conditions, and the more time spent under the increased pressure, the greater the amount of nitrogen gas dissolved in the tissues. When the pressure decreases during decompression, tissues release the dissolved nitrogen gas into the blood system, which then carries the nitrogen gas to the lungs for elimination through exhalation. Releasing hyperbaric pressure too rapidly during decompression can increase the size of the bubbles formed by nitrogen gas in the blood system, resulting in DCI, commonly referred to as ''the bends.'' This description of the etiology of DCI is consistent with current scientific theory and research on the issue (see footnote 8 in this notice discussing a 1985 NIOSH report on DCI).

The 1992 French Decompression Tables proposed for use by the applicant provide for stops during worker decompression (i.e., staged decompression) to control the release of nitrogen gas from tissues into the blood system. Studies show that staged decompression, in combination with other features of the 1992 French Decompression Tables such as the use of oxygen, result in a lower incidence of DCI than the OSHA decompression requirements of 29 CFR 1926.803, which specify the use of automatically regulated continuous decompression (see footnotes 5 through 10 below for references to these studies).[3] In addition, the applicant asserts that staged decompression is at least as effective as an automatic controller in regulating the decompression process because:

A. A hyperbaric supervisor (a competent person experienced and trained in hyperbaric operations, procedures, and safety) directly supervises all hyperbaric interventions and ensures that the man-lock attendant, who is a competent person in the manual control of hyperbaric systems, follows the schedule specified in the decompression tables, including stops; and

B. The use of the 1992 French Decompression Tables for staged decompression offers an equal or better level of management and control over the decompression process than an automatic controller and results in lower occurrences of DCI.

Accordingly, the applicant is applying for a permanent variance from the OSHA standard at 29 CFR 1926.803(g)(1)(iii), which requires automatic controls to regulate decompression. As noted above, the applicant is committed to conduct the staged decompression according to the 1992 French Decompression Tables under the direct control of the trained man-lock attendant and under the oversight of the hyperbaric supervisor.

E. Variance From Paragraph (g)(1)(xvii) of 29 CFR 1926.803, Requirement of Special Decompression Chamber

The OSHA compressed-air standard for construction requires employers to use a special decompression chamber when total decompression time exceeds 75 minutes (see 29 CFR 1926.803(g)(1)(xvii)). Another provision

[3] In the study cited in footnote 6, starting at page 338, Dr. Eric Kindwall notes that the use of automatically regulated continuous decompression in the Washington State safety standards for compressed-air work (from which OSHA derived its decompression tables) was at the insistence of contractors and the union, and against the advice of the expert who calculated the decompression table, who recommended using staged decompression. Dr. Kindwall then states, ''Continuous decompression is inefficient and wasteful. For example, if the last stage from 4 psig . . . to the surface took 1 h, at least half the time is spent at pressures less than 2 psig . . ., which provides less and less meaningful bubble suppression . . . .'' In addition, the report referenced in footnote 5 under the section titled ''Background on the Need for Interim Decompression Tables'' addresses the continuous-decompression protocol in the OSHA compressed-air standard for construction, noting that ''[a]side from the tables for saturation diving to deep depths, no other widely used or officially approved diving decompression tables use straight line, continuous decompressions at varying rates. Stage decompression is usually the rule, since it is simpler to control.''

of OSHA's compressed-air standard calls for locating the special decompression chamber adjacent to the man lock on the atmospheric pressure side of the tunnel bulkhead (see 29 CFR 1926.803(g)(2)(vii)). However, since only the working chamber of the EPBTBM is under pressure, and only a few workers out of the entire crew are exposed to hyperbaric pressure, the man locks (which, as noted earlier, connect directly to the working chamber) are of sufficient size to accommodate the exposed workers. In addition, available space in the EPBTBM does not allow for an additional special decompression lock. Again, the applicant uses the man locks, each of which adequately accommodates a three-member crew, for this purpose when decompression lasts up to 75 minutes. When decompression exceeds 75 minutes, crews can open the door connecting the two compartments in each man lock during decompression stops or exit the man lock and move into the staging chamber where additional space is available. This alternative enables CAWs to move about and flex their joints to prevent neuromuscular problems during decompression.

F. State Plan Impact

Tully only applied for an interim order and variance for one site, the New York Siphon Tunnel Project, so the permanent variance OSHA is granting Tully is in effect in the State of New York solely during completion of the project. While the State of New York has an OSHA-approved safety and health program, that program covers only public-sector employers and not private-sector employers such as Tully; therefore, Federal OSHA continues to cover private-sector employers in the State of New York.

III. Description of the Conditions Specified for the Permanent Variance

This section describes the alternative means of compliance with 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii) and provides additional detail regarding the conditions that form the basis of Tully's permanent variance.

Condition A: Scope

The scope of the permanent variance limits coverage to the work situations specified under this condition. Clearly defining the scope of the permanent variance provides Tully, Tully's employees, and OSHA with necessary information regarding the work situations in which the permanent variance applies.

Condition B: Application

This condition specifies the circumstances under which the permanent variance is in effect, notably only for hyperbaric work performed during interventions. The condition places clear limits on the circumstances under which the applicant can expose its employees to hyperbaric pressure.

Condition C: List of Abbreviations

Condition C defines a number of abbreviations used in the permanent variance. OSHA believes that defining these abbreviations serves to clarify and standardize their usage, thereby enhancing the applicant's and its employees' understanding of the conditions specified by the permanent variance.

Condition D: Definitions

The condition defines a series of terms, mostly technical terms, used in the permanent variance to standardize and clarify their meaning. Defining these terms serves to enhance the applicant's and its employees' understanding of the conditions specified by the permanent variance.

Condition E: Safety and Health Practices

This condition requires the applicant to develop and submit to OSHA a project-specific HOM at least six months before using the EPBTBM for tunneling operations. This requirement ensures that the applicant develops hyperbaric safety and health procedures suitable for each specific project. The HOM enables OSHA to determine that the specific safety and health instructions and measures it specifies are appropriate and will adequately protect the safety and health of the CAWs. It also enables OSHA to enforce these instructions and measures. Additionally, the condition includes a series of related hazard prevention and control requirements and methods (e.g., decompression tables, job hazard analysis (JHA), operations and inspections checklists) designed to ensure the continued effective functioning of the hyperbaric equipment and operating system.

Condition F: Communication

Condition F requires the applicant to develop and implement an effective system of information sharing and communication. Effective information sharing and communication ensures that affected workers receive updated information regarding any safety-related hazards and incidents, and corrective actions taken, prior to the start of each shift. The condition also requires the applicant to ensure that reliable means of emergency communications are available and maintained for affected workers and support personnel during hyperbaric operations. Availability of such reliable means of communications enables affected workers and support personnel to respond quickly and effectively to hazardous conditions or emergencies that may develop during EPBTBM operations.

Condition G: Worker Qualification and Training

This condition requires the applicant to develop and implement an effective qualification and training program for affected workers. The condition specifies the factors that an affected worker must know to perform safely during hyperbaric operations, including how to enter, work in, and exit from hyperbaric conditions under both normal and emergency conditions. Having well-trained and qualified workers performing hyperbaric intervention work ensures that they recognize, and respond appropriately to, hyperbaric safety and health hazards. These qualification and training requirements enable affected workers to cope effectively with emergencies, as well as the discomfort and physiological effects of hyperbaric exposure, thereby preventing worker injury, illness, and fatalities.

Paragraph (2)(e) of this condition also requires the applicant to provide affected workers with information they can use to contact the appropriate healthcare professionals if they believe they are developing hyperbaric-related health effects. This requirement provides for early intervention and treatment of DCI and other health effects resulting from hyperbaric exposure, thereby reducing the potential severity of these effects.

Condition H: Inspections, Tests, and Accident Prevention

Condition H requires the applicant to develop, implement, and operate a program of frequent and regular inspections of the EPBTBM's hyperbaric equipment and support systems, and associated work areas. This condition helps to ensure the safe operation and physical integrity of the equipment and work areas necessary to conduct hyperbaric operations. The condition also enhances worker safety by reducing the risk of hyperbaric-related emergencies.

Paragraph (3) of this condition requires the applicant to document tests, inspections, corrective actions, and repairs involving the EPBTBM, and maintain these documents at the job site for the duration of the job. This

requirement provides the applicant with information needed to schedule tests and inspections to ensure the continued safe operation of the equipment and systems, and to determine that the actions taken to correct defects in hyperbaric equipment and systems were appropriate, prior to returning them to service.

Condition I: Compression and Decompression

This condition requires the applicant to consult with its designated medical advisor regarding special compression or decompression procedures appropriate for any unacclimated CAW. This provision ensures that the applicant consults with the medical advisor, and involves the medical advisor in the evaluation, development, and implementation of compression or decompression protocols appropriate for any CAW requiring acclimation to the hyperbaric conditions encountered during EPBTBM operations. Accordingly, CAWs requiring acclimation have an opportunity to acclimate prior to exposure to these hyperbaric conditions. OSHA believes this condition will prevent or reduce adverse reactions among CAWs to the effects of compression or decompression associated with the intervention work they perform in the EPBTBM.

Condition J: Recordkeeping

Condition J requires the applicant to maintain records of specific factors associated with each hyperbaric intervention. The information gathered and recorded under this provision, in concert with the information provided under Condition K, enables the applicant and OSHA to determine the effectiveness of the permanent variance in preventing DCI and other hyperbaric-related effects.

Condition K: Notifications

Under this condition, the applicant must, within specified periods: (1) Notify OSHA of any recordable injuries, illnesses, or fatalities that occur as a result of hyperbaric exposures during EPBTBM operations (using the OSHA 301 Incident Report form [4] to investigate and record hyperbaric recordable injuries as defined by 29 CFR 1904.4, and 1904.7 through 1904.12); (2) provide OSHA with a copy of the incident investigation report (using OSHA 301 form) of these events; (3) include on the 301 form information on the hyperbaric conditions associated with the recordable injury or illness, the root-cause determination, and preventive and corrective actions identified and implemented by the applicant; and (4) its certification that it informed affected workers of the incident and the results of the incident investigation. This condition also requires the applicant to: Notify OTPCA and the Manhattan Area Office within 15 working days should the applicant need to revise its HOM to accommodate changes in its compressed-air operations that affect its ability to comply with the conditions of the permanent variance; and provide OTPCA and the Manhattan Area Office, at the end of the project, with a report evaluating the effectiveness of the decompression tables.

These notification requirements enable the applicant, its employees, and OSHA to determine the effectiveness of the permanent variance in providing the requisite level of safety to the applicant's workers and, based on this determination, whether to revise or revoke the conditions of the permanent variance. Timely notification permits OSHA to take whatever action may be necessary and appropriate to prevent further injuries and illnesses. Providing notification to employees informs them of the precautions taken by the applicant to prevent similar incidents in the future.

This condition also requires the applicant to notify OSHA if it ceases to do business, has a new address or location for its main office, or transfers the operations covered by the permanent variance to a successor company. In addition, the condition specifies that OSHA must approve the transfer of the permanent variance to a successor company. These requirements allow OSHA to communicate effectively with the applicant regarding the status of the permanent variance, and expedite the Agency's administration and enforcement of the permanent variance. Stipulating that an applicant must have OSHA's approval to transfer a variance to a successor company provides assurance that the successor company has knowledge of, and will comply with, the conditions specified by permanent variance, thereby ensuring the safety of workers involved in performing the operations covered by the permanent variance.

IV. Comments on the Proposed Variance Application

OSHA received one public comment on the proposed variance application. Minda Nieblas, M.D. (occupational health physician), supported granting the permanent variance (Document ID No. OSHA–2012–0036–0012). In her comment, Dr. Nieblas proposed expanding and clarifying specific conditions of the proposed variance as follows: (1) Incorporating a clear definition of decompression illness (DCI) to include a broader range of hyperbaric health effects; (2) expanding the training provided to compressed air workers to improve their ability to recognize and report the signs and symptoms of decompression illness; (3) expanding the data collection associated with decompression illnesses experienced by CAWs to include a broader range of hyperbaric health effects; and (4) expanding the investigation and reporting criteria for hyperbaric incidents.

The remainder of this section describes the specific comments submitted by Dr. Nieblas and OSHA's responses to them.

Comment 1: The first comment addressed proposals to modify the definition of DCI and expand the training provided to compressed air workers. Regarding proposed conditions D and G (Definitions and Worker Qualification and Training), Dr. Nieblas recommended:

> It is important for CAW to recognize the signs and symptoms of decompression illness. However, it is also important that workers are trained about and how to recognize other adverse health effects from working at pressures. OSHA should consider adding requirements for training CAW regarding barotrauma, nitrogen narcosis, oxygen toxicity and any other health effects associated with work in compressed air or mixed gasses. It is not clear from the variance if the definition of DCI encompasses these adverse health effects.

OSHA's response: OSHA determined that the comments have merit and, therefore, is modifying the respective proposed conditions of the variance application. Tully's HOM provides the current decompression-illness definition, and the proposed variance did not include a distinct definition of this term. The HOM defines decompression illness as ''[an] illness caused by gas bubbles appearing in body compartments due to a reduction in ambient pressure.'' OSHA is adding a definition to proposed condition D that it adapted from the HOM's definition of DCI, as well as the National Institute for Occupational Safety and Health's (NOISH's) definition of

[4] See 29 CFR 1904 (Recording and Reporting Occupational Injuries and Illnesses) (*http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631);* recordkeeping forms and instructions (*http://www.osha.gov/recordkeeping/RKform300pkg-fillable-enabled.pdf*); and the OSHA Recordkeeping Handbook (*http://www.osha.gov/recordkeeping/handbook/index.html*).

decompression sickness or decompression illness.[5] OSHA is also adding DCI to the list of abbreviations found in proposed condition C. Additionally, OSHA is amending proposed condition G (specifically G(2)(c)) to include training in recognizing the symptoms of DCI and other hyperbaric intervention-related health effects (e.g., barotrauma, nitrogen narcosis, and oxygen toxicity).

Comment 2: The second comment focused on proposals to modify and improve the recordkeeping requirements included in proposed condition J. Regarding proposed condition J (Recordkeeping), Dr. Nieblas recommended:

> Section J (Recordkeeping) OSHA should consider requiring additional recordkeeping for hyperbaric interventions. OSHA should consider requiring recordkeeping information to include post-intervention assessment of each individual worker for signs and symptoms of decompression illness, barotrauma, nitrogen narcosis, oxygen toxicity or other health effects associated with work in compressed air or mixed gasses for each hyperbaric intervention. Lack of standardized data collection has made it difficult to evaluate the incidence of adverse health effects in these workers. It would be useful if OSHA, NIOSH, and experts from academia and industry developed standardized tools to assess CAW pre/post intervention. This data collection could be used to refine tables and practices across the industry.

OSHA's response: Proposed condition J requires Tully to identify, investigate, and record all cases of work-related injury and illness requiring medical treatment as specified by 29 CFR 1904 (Recording and Reporting Occupational Injuries and Illnesses). Thus, Tully must identify each compressed air worker who requires medical treatment when presenting with signs and symptoms of decompression illness, barotrauma, or other health effects associated with work in compressed air during or after hyperbaric interventions. Additionally, Tully must complete OSHA form 301 (Injury and Illness Incident Report) and OSHA form 300 (Log of Work-Related Injuries and Illnesses) for each such recordable (medical treatment) case.

OSHA finds that the recommendation to develop standardized tools for assessing CAWs for pre- and post-hyperbaric intervention health effects, while undoubtedly highly useful for analyzing and evaluating the incidence of adverse health outcomes, is well beyond the scope of this variance. However, OSHA added language to conditions J and K to clarify the hyperbaric conditions that Tully must identify and include on the OSHA 301 form as part of the recordable injury or illness investigation.

Comment 3: The last of Dr. Nieblas' comments addressed proposals to modify and expand the notifications requirements included in proposed condition K. Regarding proposed condition K (Notifications), Dr. Nieblas recommended:

> OSHA should clarify that the incident must be reported even if the worker did not require recompression. OSHA should also be notified about injuries and illness that may have been the result of impairment from elevated nitrogen or oxygen partial pressures since these are the result of exposure to hyperbaric conditions. The incident investigation report must include an estimate of employee workload, the composition of the gas mixture, temperature in the work and decompression environments, a medical summary of the illness or injury, and the contact information for the treating healthcare provider.

This information is needed to determine the root cause of the injury/illness.

OSHA's response: As noted in the response to comment 2, proposed condition J requires Tully to identify, investigate, and record all cases of work-related injury and illness requiring medical treatment. Proposed condition K requires Tully to notify OSHA (OTPCA and the Manhattan Area Office) of any injury, illness (including decompression illness as defined by revised condition D(5)), or fatality resulting from exposure of a CAW to hyperbaric conditions. Additionally, Tully must provide a copy of the incident-investigation report within 24 hours of the incident.

As a result of these comprehensive reporting and notification requirements, OSHA finds that the recommendation to expand the information requirements, while undoubtedly highly useful for evaluating and determining the root cause of hyperbaric incidents, is well beyond the scope of this proposed variance application. However, OSHA added language to condition K to clarify that recordable hyperbaric injuries or illnesses include those conditions that do not require recompression treatment (e.g., nitrogen narcosis, oxygen toxicity, barotrauma).

V. Decision

As noted earlier, on January 7, 2014, OSHA granted Tully an interim order (79 FR 844) to remain in effect until completion of the project or until the Agency makes a decision on its application for a permanent variance. During this period, the applicant had to comply fully with the conditions of the interim order (as an alternative to complying with the requirements of 29 CFR 1926.803 (hereafter, ''the standard'')) that:

A. Prohibit employers using compressed air under hyperbaric conditions from subjecting workers to pressure exceeding 50 p.s.i.g., except in an emergency (29 CFR 1926.803(e)(5));

B. Require the use of decompression values specified by the decompression tables in Appendix A of the compressed-air standard (29 CFR 1926.803(f)(1)); and

C. Require the use of automated operational controls and a special decompression chamber (29 CFR 1926.803(g)(1)(iii) and .803(g)(1)(xvii), respectively).

After reviewing the proposed alternatives OSHA determined that:

A. Tully developed, and proposed to implement, effective alternative measures to the prohibition of using compressed air under hyperbaric conditions exceeding 50 p.s.i.g. The alternative measures include use of engineering and administrative controls of the hazards associated with work performed in compressed-air conditions exceeding 50 p.s.i.g. while engaged in the construction of a subaqueous tunnel using advanced shielded mechanical-excavation techniques in conjunction with an EPBTBM. Prior to conducting interventions in the EPBTBM's pressurized working chamber, the applicant halts tunnel excavation and prepares the machine and crew to conduct the interventions. Interventions involve inspection, maintenance, or repair of the mechanical-excavation components located in the working chamber.

B. Tully developed, and proposed to implement, safe hyperbaric work procedures, emergency and contingency procedures, and medical examinations for the project's CAWs. The applicant compiled these standard operating procedures into a project-specific HOM. The HOM discusses the procedures and personnel qualifications for performing work safely during the compression and decompression phases of interventions. The HOM also specifies the decompression tables the applicant proposes to use. Depending on the maximum working pressure and exposure times during the interventions, the tables provide for decompression using air, pure oxygen, or a combination of air and oxygen. The decompression tables also include delays or stops for various time intervals at different pressure levels during the transition to atmospheric pressure (i.e., staged

[5] See NIOSH's Decompression Sickness and Tunnel Workers page at *http://www.cdc.gov/NIOSH/topics/Decompression/*.

decompression). In all cases, a physician certified in hyperbaric medicine will manage the medical condition of CAWs during decompression. In addition, a trained and experienced man-lock attendant, experienced in recognizing decompression sickness or illnesses and injuries, will be present. Of key importance, a hyperbaric supervisor (competent person), trained in hyperbaric operations, procedures, and safety, will directly supervise all hyperbaric operations to ensure compliance with the procedures delineated in the project-specific HOM or by the attending physician.

C. Tully developed, and proposed to implement, a training program to instruct affected workers in the hazards associated with conducting hyperbaric operations.

D. Tully developed, and proposed to implement, an effective alternative to the use of automatic controllers that continuously decrease pressure to achieve decompression in accordance with the tables specified by the standard. The alternative includes using the 1992 French Decompression Tables for guiding staged decompression to achieve lower occurrences of DCI, using a trained and competent attendant for implementing appropriate hyperbaric entry and exit procedures, and providing a competent hyperbaric supervisor and attending physician certified in hyperbaric medicine, to oversee all hyperbaric operations.

E. Tully developed, and proposed to implement, an effective alternative to the use of the special decompression chamber required by the standard. EPBTBM technology permits the tunnel's work areas to be at atmospheric pressure, with only the face of the EPBTBM (i.e., the working chamber) at elevated pressure. The applicant limits interventions conducted in the working chamber to performing required inspection, maintenance, and repair of the cutting tools on the face of the EPBTBM. The EPBTBM's man lock and working chamber provide sufficient space for the maximum crew of three CAWs to stand up and move around, and safely accommodate decompression times up to 360 minutes. Therefore, OSHA determined that the EPBTBM's man lock and working chamber function as effectively as the special decompression chamber required by the standard.

OSHA conducted a review of the scientific literature regarding decompression to determine whether the alternative decompression method (i.e., the 1992 French Decompression Tables) proposed by the applicant provide a workplace as safe and healthful as that provided by the standard. Based on this review, OSHA determined that tunneling operations performed with these tables [6] result in a lower occurrence of DCI than the decompression tables specified by the standard.[7] [8] [9]

The review conducted by OSHA found several research studies supporting the determination that the 1992 French Decompression Tables result in a lower rate of DCI than the decompression tables specified by the standard. For example, H. L. Anderson studied the occurrence of DCI at maximum hyperbaric pressures ranging from 4 p.s.i.g. to 43 p.s.i.g. during construction of the Great Belt Tunnel in Denmark (1992–1996); [10] this project used the 1992 French Decompression Tables to decompress the workers during part of the construction. Anderson observed 6 DCS cases out of 7,220 decompression events, and reported that switching to the 1992 French Decompression tables reduced the DCI incidence to 0.08%. The DCI incidence in the study by H. L. Andersen is substantially less than the DCI incidence reported for the decompression tables specified in Appendix A. OSHA found no studies in which the DCI incidence reported for the 1992 French Decompression Tables were higher than the DCI incidence reported for the OSHA decompression tables, nor did OSHA find any studies indicating that the 1992 French Decompression Tables were more hazardous to employees than the OSHA decompression tables.[11]

Based on a review of available evidence, the experience of State Plans that either granted variances (Nevada, Oregon, and Washington) [12] or promulgated a new standard (California) [13] for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, and the information provided in the applicant's variance application, OSHA is granting the permanent variance.

Under Section 6(d) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655), and based on the record discussed above, the Agency finds that when the employer complies with the conditions of the following order, the working conditions of the employer's workers are at least as safe and healthful as if the employer complied with the working conditions specified by paragraphs (e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii) of 29 CFR 1926.803. Therefore, Tully will: (1) Comply with the conditions listed below under ''Specific Conditions of the Permanent Variance'' for the period between the date of this notice and completion of the New York Siphon Tunnel Project, but no later than March 31, 2015; (2) comply fully with all other applicable provisions of 29 CFR part 1926; and (3) provide a copy of this **Federal Register** notice to all employees affected by the conditions, including the affected employees of other employers, using the same means it used to inform these employees of its application for a permanent variance. Additionally, this order will remain in effect until one of the following conditions occurs: (1) Completion of the New York Siphon Tunnel Project but no later than March 31, 2015; or (2) OSHA modifies or

[6] In 1992, the French Ministry of Labour replaced the 1974 French Decompression Tables with the 1992 French Decompression Tables, which differ from OSHA's decompression tables in Appendix A by using: (1) staged decompression as opposed to continuous (linear) decompression; (2) decompression tables based on air or both air and pure oxygen; and (3) emergency tables when unexpected exposure times occur (up to 30 minutes above the maximum allowed working time).

[7] Kindwall, EP (1997). Compressed air tunneling and caisson work decompression procedures: development, problems, and solutions. *Undersea and Hyperbaric Medicine,* 24(4), pp. 337–345. This article reported 60 treated cases of DCI among 4,168 exposures between 19 and 31 p.s.i.g. over a 51-week contract period, for a DCI incidence of 1.44% for the decompression tables specified by the OSHA standard.

[8] Sealey, JL (1969). Safe exit from the hyperbaric environment: medical experience with pressurized tunnel operations. *Journal of Occupational Medicine,* 11(5), pp. 273–275. This article reported 210 treated cases of DCI among 38,600 hyperbaric exposures between 13 and 34 p.s.i.g. over a 32-month period, for an incidence of 0.54% for the decompression tables specified by the Washington State safety standards for compressed-air work, which are similar to the tables in the OSHA standard. Moreover, the article reported 51 treated cases of DCI for 3,000 exposures between 30 and 34 p.s.i.g., for an incidence of 1.7% for the Washington State tables.

[9] In 1985, the National Institute for Occupational Safety and Health (NIOSH) published a report entitled ''Criteria for Interim Decompression Tables for Caisson and Tunnel Workers''; this report reviewed studies of DCI and other hyperbaric-related injuries resulting from use of OSHA's tables. This report is available on NIOSH's Web site: *http://www.cdc.gov/niosh/topics/decompression/default.html.*

[10] Anderson HL (2002). Decompression sickness during construction of the Great Belt tunnel, Denmark. *Undersea and Hyperbaric Medicine,* 29(3), pp. 172–188.

[11] Le Péchon JC, Barre P, Baud JP, Ollivier F (September 1996). Compressed air work—French tables 1992—operational results. *JCLP Hyperbarie Paris, Centre Medical Subaquatique Interentreprise, Marseille: Communication a l'EUBS,* pp. 1–5 (see Ex. OSHA–2012–0036–0005).

[12] These state variances are available in the docket: Exs. OSHA–2012–0035–0006 (Nevada), OSHA–2012–0035–0007 (Oregon), and OSHA–2012–0035–0008 (Washington).

[13] See California Code of Regulations, Title 8, Subchapter 7, Group 26, Article 154, available at *http://www.dir.ca.gov/title8/sb7g26a154.html.*

revokes this final order in accordance with 29 CFR 1905.13.

VI. Order

As of the effective date of this final order, OSHA is revoking the interim order granted to the employer on January 7, 2014.

OSHA issues this final order authorizing Tully/OHL USA Joint Venture (''the employer'') to comply with the following conditions instead of complying with the requirements of paragraphs 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii). This final order applies to Tully/OHL USA Joint Venture at the New York Siphon Tunnel Project. These conditions are:

A. Scope

The permanent variance applies only to work:

1. That occurs in conjunction with construction of the New York Siphon Tunnel Project, a subaqueous tunnel constructed using advanced shielded mechanical-excavation techniques and involving operation of an EPBTBM;
2. Performed under compressed-air and hyperbaric conditions up to 58 p.s.i.g.;
3. In the EPBTBM's forward section (the working chamber) and associated hyperbaric chambers used to pressurize and decompress employees entering and exiting the working chamber; and
4. Except for the requirements specified by 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii), Tully must comply fully with all other applicable provisions of 29 CFR part 1926.
5. This order will remain in effect until one of the following conditions occurs: (1) completion of the New York Siphon Tunnel Project, but no later than March 31, 2015; or (2) OSHA modifies or revokes this final order in accordance with 29 CFR 1905.13.

B. Application

The permanent variance applies only when Tully stops the tunnel-boring work, pressurizes the working chamber, and the CAWs either enter the working chamber to perform interventions (i.e., inspect, maintain, or repair the mechanical-excavation components), or exit the working chamber after performing interventions.

C. List of Abbreviations

Abbreviations used throughout this permanent variance include the following:

1. CAW—Compressed-air worker
2. CFR—Code of Federal Regulations
3. DCI—Decompression Illness
4. EPBTBM—Earth Pressure Balanced Tunnel Boring Machine
5. HOM—Hyperbaric Operations and Safety Manual
6. JHA—Job hazard analysis
7. OSHA—Occupational Safety and Health Administration
8. OTPCA—Office of Technical Programs and Coordination Activities

D. Definitions

The following definitions apply to this permanent variance. These definitions supplement the definitions in Tully's project-specific HOM.

1. *Affected employee or worker*—an employee or worker who is affected by the conditions of this permanent variance, or any one of his or her authorized representatives. The term ''employee'' has the meaning defined and used under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*)
2. *Atmospheric pressure*—the pressure of air at sea level, generally 14.7 p.s.i.a., 1 atmosphere absolute, or 0 p.s.i.g.
3. *Compressed-air worker*—an individual who is specially trained and medically qualified to perform work in a pressurized environment while breathing air at pressures up to 58 p.s.i.g.
4. *Competent person*—an individual who is capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.[14]
5. *Decompression illness (also called decompression sickness or the bends)*—an illness caused by gas bubbles appearing in body compartments due to a reduction in ambient pressure. Examples of symptoms of decompression illness include (but are not limited to): joint pain (also known as the ''bends'' for agonizing pain or the ''niggles'' for sight pain); areas of bone destruction (termed ''dysbaric osteonecrosis''); skin disorders (such as cutis marmorata, which causes a pink marbling of the skin); spinal cord and brain disorders (such as stroke, paralysis, paresthesia, and bladder dysfunction); cardiopulmonary disorders, such as shortness of breath; and arterial gas embolism (gas bubbles in the arteries that block blood flow).[15]

Note: Health effects associated with hyperbaric intervention, but not considered symptoms of DCI, can include: barotrauma (direct damage to air-containing cavities in the body such as ears, sinuses, and lungs); nitrogen narcosis (reversible alteration in consciousness that may occur in hyperbaric environments and caused by the anesthetic effect of certain gases at high pressure); and oxygen toxicity (a central nervous system condition resulting from the harmful effects of breathing molecular oxygen (O_2) at elevated partial pressures).

6. *Earth Pressure Balanced Tunnel Boring Machine*—the machinery used to excavate the tunnel.
7. *Hot work*—any activity performed in a hazardous location that may introduce an ignition source into a potentially flammable atmosphere.[16]
8. *Hyperbaric*—at a higher pressure than atmospheric pressure.
9. *Hyperbaric intervention*—a term that describes the process of stopping the EPBTBM and preparing and executing work under hyperbaric pressure in the working chamber for the purpose of inspecting, replacing, or repairing cutting tools and/or the cutterhead structure.
10. *Hyperbaric Operations Manual*—a detailed, project-specific health and safety plan developed and implemented by the employer for working in compressed air during the New York Siphon Tunnel Project.
11. *Job hazard analysis*—an evaluation of tasks or operations to identify potential hazards and to determine the necessary controls.
12. *Man lock*—an enclosed space capable of pressurization, and used for compressing or decompressing any employee or material when either is passing into or out of a working chamber.
13. *Pressure*—a force acting on a unit area; usually expressed as pounds per square inch (p.s.i.).
14. *p.s.i.*—pounds per square inch, a common unit of measurement of pressure; a pressure given in p.s.i. corresponds to absolute pressure.
15. *p.s.i.a*—pounds per square inch absolute, or absolute pressure, is the sum of the atmospheric pressure and gauge pressure. At sea level, atmospheric pressure is approximately 14.7 p.s.i. Adding 14.7 to a pressure expressed in units of p.s.i.g. will yield the absolute pressure, expressed as p.s.i.a.
16. *p.s.i.g.*—pounds per square inch gauge, a common unit of pressure; pressure expressed as p.s.i.g. corresponds to pressure relative to atmospheric pressure. At sea level,

[14] Adapted from 29 CFR 1926.32(f).

[15] See Appendix 10 of ''A Guide to the Work in Compressed Air Regulations 1996,'' published by the United Kingdom Health and Safety Executive and available from NIOSH at *http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH–254/compReg1996.pdf*

[16] Also see 29 CFR 1910.146(b).

atmospheric pressure is approximately 14.7 p.s.i. Subtracting 14.7 from a pressure expressed in units of p.s.i.a. yields the gauge pressure, expressed as p.s.i.g.

17. *Qualified person*—an individual who, by possession of a recognized degree, certificate, or professional standing, or who, by extensive knowledge, training, and experience, successfully demonstrates an ability to solve or resolve problems relating to the subject matter, the work, or the project.[17]

18. *Working chamber*—an enclosed space in the EPBTBM in which CAWs perform interventions, and which is accessible only through a man lock.

E. Safety and Health Practices

1. Tully must develop and implement a project-specific HOM, and submit the HOM to OSHA at least six months before using the EPBTBM. Tully must receive a written acknowledgement from OSHA regarding the acceptability of the HOM.[18] The HOM shall provide the governing safety and health requirements regarding hyperbaric exposures during the tunnel-construction project.

2. Tully must implement the safety and health instructions included in the manufacturer's operations manuals for the EPBTBM, and the safety and health instructions provided by the manufacturer for the operation of decompression equipment.

3. Tully must use air as the only breathing gas in the working chamber.

4. Tully must use the 1992 French Decompression Tables for air, air-oxygen, and oxygen decompression specified in the HOM, specifically the tables titled ''French Regulation Air Standard Tables.''

5. Tully must equip man-locks used by its employees with an oxygen-delivery system as specified by the HOM. Tully must not store oxygen or other compressed gases used in conjunction with hyperbaric work in the tunnel.

6. Workers performing hot work under hyperbaric conditions must use flame-retardant personal protective equipment and clothing.

7. In hyperbaric work areas, Tully must maintain an adequate fire-suppression system approved for hyperbaric work areas.

8. Tully must develop and implement one or more JHAs for work in the hyperbaric work areas, and review, periodically and as necessary (e.g., after making changes to a planned intervention that affects its operation), the contents of the JHAs with affected employees. The JHAs must include all the job functions that the risk assessment[19] indicates are essential to prevent injury or illness.

9. Tully must develop a set of checklists to guide compressed-air work and ensure that employees follow the procedures required by this permanent variance (including all procedures required by the HOM, which this permanent variance incorporates by reference). The checklists must include all steps and equipment functions that the risk assessment indicates are essential to prevent injury or illness during compressed-air work.

10. Tully must ensure that the safety and health provisions of the HOM adequately protect the workers of all contractors and subcontractors involved in hyperbaric operations.[20]

F. Communication

1. Prior to beginning a shift, Tully must implement a system that informs workers exposed to hyperbaric conditions of any hazardous occurrences or conditions that might affect their safety, including hyperbaric incidents, gas releases, equipment failures, earth or rock slides, cave-ins, flooding, fires, or explosions.

2. Tully must provide a power-assisted means of communication among affected workers and support personnel in hyperbaric conditions where unassisted voice communication is inadequate.

a. Tully must use an independent power supply for powered communication systems, and these systems must operate such that use or disruption of any one phone or signal location will not disrupt the operation of the system from any other location.

b. Tully must test communication systems at the start of each shift and as necessary thereafter to ensure proper operation.

G. Worker Qualifications and Training

Tully must:

1. Ensure that each affected worker receives effective training on how to safely enter, work in, exit from, and undertake emergency evacuation or rescue from, hyperbaric conditions, and document this training.

2. Provide effective instruction, before beginning hyperbaric operations, to each worker who performs work, or controls the exposure of others, in hyperbaric conditions, and document this instruction. The instruction must include topics such as:

a. The physics and physiology of hyperbaric work;

b. Recognition of pressure-related injuries;

c. Information on the causes and recognition of the signs and symptoms associated with decompression illness, and other hyperbaric intervention-related health effects (e.g., barotrauma, nitrogen narcosis, and oxygen toxicity).

d. How to avoid discomfort during compression and decompression; and

e. Information the workers can use to contact the appropriate healthcare professionals should the workers have concerns that they may be experiencing adverse health effects from hyperbaric exposure.

3. Repeat the instruction specified in paragraph (2) of this condition periodically and as necessary (e.g., after making changes to its hyperbaric operations).

4. When conducting training for its hyperbaric workers, make this training available to OSHA personnel and notify the OTPCA at OSHA's national office and OSHA's Manhattan Area Office before the training takes place.

H. Inspections, Tests, and Accident Prevention

1. Tully must initiate and maintain a program of frequent and regular inspections of the EPBTBM's hyperbaric equipment and support systems (such as temperature control, illumination, ventilation, and fire-prevention and fire-suppression systems), and hyperbaric work areas, as required under 29 CFR 1926.20(b)(2) by:

a. Developing a set of checklists to be used by a competent person in conducting weekly inspections of hyperbaric equipment and work areas; and

b. Ensuring that a competent person conducts daily visual checks, as well as weekly inspections of the EPBTBM.

2. If the competent person determines that the equipment constitutes a safety hazard, Tully must remove the equipment from service until it corrects the hazardous condition and has the correction approved by a qualified person.

3. Tully must maintain records of all tests and inspections of the EPBTBM, as well as associated corrective actions and repairs, at the job site for the duration of the job.

[17] Adapted from 29 CFR 1926.32(m).

[18] The previously granted interim order (79 FR 844) constitutes such acknowledgement by OSHA of the acceptability of the HOM provided by Tully for the New York Siphon Tunnel Project.

[19] See ANSI/AIHA Z10–2012, American National Standard for Occupational Health and Safety Management Systems, for reference.

[20] See ANSI/ASSE A10.33–2011, American National Standard for Construction and Demolition Operations—Safety and Health Program Requirements for Multi-Employer Projects, for reference.

I. Compression and Decompression

Tully must consult with its attending physician concerning the need for special compression or decompression exposures appropriate for CAWs not acclimated to hyperbaric exposure.

J. Recordkeeping

Tully must maintain a record of any recordable injury, illness, or fatality (as defined by 29 CFR part 1904 Recording and Reporting Occupational Injuries and Illnesses) resulting from exposure of an employee to hyperbaric conditions by completing the OSHA 301 Incident Report form and OSHA 300 Log of Work Related Injuries and Illnesses.

Note: Examples of important information to include on the OSHA 301 Incident Report form (along with the corresponding question on the form) are: the task performed (Question (Q) 14); an estimate of the CAW's workload (Q 14); the composition of the gas mixture (e.g., air or oxygen (Q 14)); the maximum working pressure (Q 14); temperatures in the work and decompression environments (Q 14); unusual occurrences, if any, during the task or decompression (Q 14); time of symptom onset (Q 15); duration between decompression and onset of symptoms (Q 15); type and duration of symptoms (Q 16); a medical summary of the illness or injury (Q 16); duration of the hyperbaric intervention (Q 17); possible contributing factors (Q 17); the number of prior interventions completed by the injured or ill CAW (Q 17); the number of prior interventions completed by the injured or ill CAW at this working pressure (Q 17); contact information for the treating healthcare provider (Q 17); and date and time of last hyperbaric exposure for this CAW.

In addition to completing the OSHA 301 Incident Report form and OSHA 300 Log of Work Related Injuries and Illnesses, the employer must maintain records of:

1. The date, times (e.g., began compression, time spent compressing, time performing intervention, time spent decompressing), and pressure for each hyperbaric intervention.

2. The name of each individual worker exposed to hyperbaric pressure and the decompression protocols and results for each worker.

3. The total number of interventions and the total hyperbaric exposure duration at each pressure.

4. The results of the post-intervention physical assessment of each CAW for signs and symptoms of decompression illness, barotrauma, nitrogen narcosis, oxygen toxicity or other health effects associated with work in compressed air or mixed gases for each hyperbaric intervention.

K. Notifications

1. To assist OSHA in administering the conditions specified herein, the employer must:

a. Notify the OTPCA and the Manhattan Area Office of any recordable injury, illness, or fatality (by submitting the completed OSHA 301 Incident Report form [21]) resulting from exposure of an employee to hyperbaric conditions, including those exposures that do not require recompression treatment (e.g., nitrogen narcosis, oxygen toxicity, barotrauma), but still meet the recordable injury or illness criteria of 29 CFR 1904. The employer shall provide the notification within 8 hours of the incident or 8 hours after becoming aware of a recordable injury, illness, or fatality, and submit a copy of the incident investigation (OSHA form 301) within 24 hours of the incident or 24 hours after becoming aware of a recordable injury, illness, or fatality. In addition to the information required by the OSHA form 301, the incident-investigation report must include a root-cause determination, and the preventive and corrective actions identified and implemented.

b. Provide certification within 15 days of the incident that the employer informed affected workers of the incident and the results of the incident investigation (including the root-cause determination and preventive and corrective actions identified and implemented).

c. Notify the OTPCA and the Manhattan Area Office within 15 working days in writing of any change in the compressed-air operations that affects the employer's ability to comply with the conditions specified herein.

d. Upon completion of the New York Siphon Tunnel Project, evaluate the effectiveness of the decompression tables used throughout the project, and provide a written report of this evaluation to the OTPCA and the Manhattan Area Office.

Note: The evaluation report is to contain summaries of: (1) The number, dates, durations, and pressures of the hyperbaric interventions completed; (2) decompression protocols implemented (including composition of gas mixtures (air and/or oxygen), and the results achieved; (3) the total number of interventions and the number of hyperbaric incidents (decompression illnesses and/or health effects associated with hyperbaric interventions as recorded on OSHA 301 and 300 forms, and relevant medical diagnoses and treating physicians' opinions); and (4) root causes of any hyperbaric incidents, and preventive and corrective actions identified and implemented.

e. To assist OSHA in administering the conditions specified herein, inform the OTPCA and the Manhattan Area Office as soon as possible after it has knowledge that it will:

i. Cease to do business;

ii. Change the location and address of the main office for managing the tunneling operations specified herein; or

iii. Transfer the operations specified herein to a successor company.

f. Notify all affected employees of this permanent variance by the same means required to inform them of its application for a variance.

2. OSHA must approve the transfer of this permanent variance to a successor company.

[21] See footnote 4.

VII. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to Section 29 U.S.C. 655(6)(d), Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1905.11.

Signed at Washington, DC on May 20, 2014.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2014–12016 Filed 5–22–14; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Institute of Museum and Library Services, The National Foundation for the Arts and the Humanities.

ACTION: 30-Day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, IMLS has submitted a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service

Delivery'' to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et. seq.).

DATES: Comments must be submitted by June 22, 2014.

ADDRESSES: Send comments regarding these information collections to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 Seventeenth Street NW., Washington, DC 20503, Attention: FRA Desk Officer. Alternatively, comments may be sent via email to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, at the following address: *oira_submissions@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Matthew Birnbaum, Ph.D., Evaluation and Research Officer, Planning, Research and Evaluation, Institute of Museum and Library Services, 1800 M St. NW., 9th Floor, Washington, DC 20036. Dr. Birnbaum can be reached by Telephone: 202–653–4760, Fax: 202– 653–4601, or by email at *mbirnbaum@imls.gov,* or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The Agency received no comments in response to the 60-day notice published in the **Federal Register** of February 14, 2014 (FR Vol. 79, No. 31, page 9003).

Below we provide the projected average estimates for the next three years:

Current Actions: Renew collection of information.

Type of Review: Renew Collection.

OMB Number: 0081.

Agency Number: 3137.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Average Expected Annual Number of activities: 5.

Annual responses: 4,900.

Frequency of Response: Once per request.

Average minutes per response: 55 minutes.

Burden hours: 3,900 hours.

Total Annual Costs: $38,102.

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 Office of Management and Budget control number.

Dated: May 19, 2014.

Kim A. Miller,

Management Analyst, Office of Planning, Research and Evaluation.

[FR Doc. 2014–11903 Filed 5–22–14; 8:45 am]

BILLING CODE 7036–01–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2014–49; Order No. 2079]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing requesting the addition of a Global Expedited Package Services 3 (MC2010–28) negotiated service agreement to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 27, 2014.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

On May 16, 2014, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2014–49 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than May 27, 2014. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints James F. Callow to serve as Public Representative in this docket.

[1] Notice of the United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, May 16, 2014 (Notice).

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2014–49 for consideration of the matters raised by the Postal Service's Notice.
2. Pursuant to 39 U.S.C. 505, James F. Callow is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).
3. Comments are due no later than May 27, 2014.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2014–11943 Filed 5–22–14; 8:45 am]

BILLING CODE 7710–FW–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

Summary: In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and purpose of information collection: Certification of Termination of Service and Relinquishment of Rights; OMB 3220–0016.

Under Section 2(e)(2) of the Railroad Retirement Act (RRA), an age and service annuity, spouse annuity, or divorced spouse annuity cannot be paid unless the Railroad Retirement Board (RRB) has evidence that the applicant has ceased railroad employment and relinquished rights to return to the service of a railroad employer. Under Section 2(f)(6) of the RRA, earnings deductions are required for each month an annuitant works in certain non-railroad employment termed Last Pre-Retirement Non-Railroad Employment.

Normally, the employee, spouse, or divorced spouse relinquishes rights and certifies that employment has ended as part of the annuity application process. However, this is *not always* the case. In limited circumstances, the RRB utilizes Form G–88, *Certification of Termination of Service and Relinquishment of Rights,* to obtain an applicant's report of termination of employment and relinquishment of rights. One response is required of each respondent. Completion is required to obtain or retain benefits. The RRB proposes no changes to Form G–88.

Estimate of Annual Respondent Burden

The estimated annual respondent burden is as follows:

Form No.	Annual responses	Time (minutes)	Burden (hours)
G–88	3,600	6	360

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV.* Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or emailed to *Charles.Mierzwa@RRB.GOV.* Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2014–11970 Filed 5–22–14; 8:45 am]

BILLING CODE 7905–01–P

RAILROAD RETIREMENT BOARD

Actuarial Advisory Committee with respect to the Railroad Retirement Account; Notice of Public Meeting

Notice is hereby given in accordance with Public Law 92–463 that the Actuarial Advisory Committee will hold a meeting on June 5, 2014, at 10:00 a.m. at the office of the Chief Actuary of the U. S. Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois, on the conduct of the 26th Actuarial Valuation of the Railroad Retirement System. The agenda for this meeting will include a discussion of the assumptions to be used in the 26th Actuarial Valuation. A report containing recommended assumptions and the experience on which the recommendations are based will have been sent by the Chief Actuary to the Committee before the meeting.

The meeting will be open to the public. Persons wishing to submit written statements or make oral presentations should address their communications or notices to the Actuarial Advisory Committee, c/o Chief Actuary, U. S. Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092.

Dated: May 16, 2014.

Martha P. Rico,

Secretary to the Board.

[FR Doc. 2014–11975 Filed 5–22–14; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31050; 812–14239]

Capitala Finance Corp., *et al.;* Notice of Application

May 19, 2014.

AGENCY: Securities and Exchange Commission (the ''Commission'').

ACTION: Notice of an application for an order under sections 6(c), 12(d)(1)(J), and 57(c) of the Investment Company Act of 1940 (''Act'') granting exemptions from sections 12(d)(1)(A), 18(a), 21(b), 57(a)(1)–(a)(3), and 61(a) of the Act; under section 57(i) of the Act and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by section 57(a)(4) of the Act; and under section 12(h) of the Securities Exchange Act of 1934 (''Exchange Act'') granting an exemption from section 13(a) of the Exchange Act.

Applicants: Capitala Finance Corp. (the ''Company''), CapitalSouth Partners Fund II Limited Partnership (''Fund II SBIC''), CapitalSouth Partners F–II, LLC (''Fund II SBIC General Partner''), CapitalSouth Partners SBIC Fund III,

L.P. (''Fund III SBIC''), CapitalSouth Partners SBIC F–III, LLC, (''Fund III SBIC General Partner''), CapitalSouth Partners Florida Sidecar Fund I, L.P., (''Florida Sidecar''), CSP-Florida Mezzanine Fund I, LLC, (''CSP-Florida'' together with Fund II SBIC General Partner and Fund III SBIC General Partner, the ''General Partners'') and Capitala Investment Advisors, LLC, (''Capitala Investment Advisors'').

SUMMARY: *Summary of Application:* Applicants request an order permitting the Company, a business development company (''BDC'') and its Subsidiaries (defined below) to operate effectively as one company, specifically allowing them to: (1) Engage in certain transactions with each other; (2) invest in securities in which the other is or proposes to be an investor that would otherwise be permitted if the Company and the Subsidiaries were one company; (3) be subject to modified consolidated asset coverage requirements for senior securities issued by a BDC and its small business investment company (''SBIC'') subsidiaries; and (4) file consolidated reports with the Commission.

DATES: *Filing Dates:* The application was filed on November 19, 2013, and amended on March 31, 2014, and April 17, 2014. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in this notice.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on June 9, 2014, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants, c/o Joseph B. Alala, III, Chief Executive Officer and President, Capitala Finance Corp., 4201 Congress Street, Suite 360, Charlotte, NC 28209.

FOR FURTHER INFORMATION CONTACT: Laura L. Solomon, Senior Counsel, at (202) 551–6915, or James M. Curtis, Branch Chief, at (202) 551–6712 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Company, a Maryland corporation, is an externally-managed, non-diversified, closed-end management investment company that has elected to be regulated as a BDC under the Act.[1] On September 24, 2013, the Company filed a registration statement on Form 8–A to register its common stock under section 12 of the Exchange Act and a notice of its election to be regulated as a BDC within the meaning of section 2(a)(48) of the 1940 Act on Form N–54A.[2] The Company intends to elect to be treated as a regulated investment company (''RIC'') as defined under Subchapter M of the Internal Revenue Code of 1986, as amended, and intends to continue to make such election in the future. The Company states that it expects to invest primarily in traditional mezzanine and senior subordinated debt, as well as senior and second-lien loans, and to a lesser extent, equity securities issued by smaller and lower middle-market companies. The Company's board of directors (''Board''), consists of five members, three of whom are not ''interested persons'' of the Company within the meaning of section 2(a)(19) of the Act (''Independent Directors''). The Company's investment objective is to generate both current income and capital appreciation through debt and equity investments.

2. On September 24, 2013, through a series of transactions, the Company acquired all of the interests in Fund II SBIC, Fund III SBIC and Florida Sidecar, as well as the General Partners (the ''Subsidiaries'').[3] After giving effect to these transactions, (a) the Company owns 100% of the membership interests in Fund II SBIC General Partner, Fund III SBIC General Partner and CSP-Florida, which are the sole general partners of Fund II SBIC, Fund III SBIC, and Florida Sidecar, respectively, and (b) the Company directly or indirectly owns 100% of the limited partnership interests in Fund II SBIC, Fund III SBIC and Florida Sidecar.

3. Fund II SBIC, a North Carolina limited partnership, and Fund III SBIC, a Delaware limited partnership, are SBICs licensed by the Small Business Administration (''SBA'') to operate under the Small Business Investment Act of 1958 (''SBA Act''). On September 24, 2013, Fund II SBIC and Fund III SBIC each filed an election to be regulated as a BDC within the meaning of section 2(a)(48) on Form N–54A under the Act, and each also filed a registration statement on Form 8–A to register its common stock under section 12 of the Exchange Act.

4. Fund II SBIC and Fund III SBIC are consolidated with the Company for financial reporting purposes.[4] Fund II SBIC and Fund III SBIC each have a board of directors (''Fund II SBIC Board'' and ''Fund III SBIC Board,'' respectively) consisting of three persons who are Independent Directors of Fund II SBIC and Fund III SBIC, respectively, and two persons who are ''interested persons'' of each of Fund II SBIC and Fund III SBIC. The members of Fund II SBIC Board and the Fund III SBIC Board are appointed each year by the equity owners of Fund II SBIC and Fund III SBIC, respectively. Fund II SBIC General Partner and Fund III SBIC General Partner, have irrevocably delegated the authority to manage the business affairs of Fund II SBIC and Fund III SBIC to the Fund II SBIC Board and Fund III SBIC Board. The SBA has approved the members of the Fund II SBIC Board and Fund III SBIC Board pursuant to SBA regulations.

5. Florida Sidecar, a Delaware limited partnership, is not registered under the Act under the exclusion from the definition of investment company contained in section 3(c)(7) of the Act,

[1] Section 2(a)(48) of the Act defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in sections 55(a)(1) through 55(a)(3) of the Act and makes available significant managerial assistance with respect to the issuers of such securities.

[2] The Company completed the initial public offering of its shares of common stock on September 30, 2013. The Company's common stock is traded on the NASDAQ Global Market under the symbol ''CPTA.''

[3] Subsidiary means Fund II SBIC, Fund III SBIC, Florida Sidecar and any direct or indirect wholly-owned subsidiary of the Company. References to ''Subsidiary'' include Subsidiaries currently in existence, as well as any future Subsidiaries. No Subsidiary other than Fund II SBIC and Fund III SBIC will be a BDC, and no Subsidiary will be a registered investment company.

[4] The Company may, in the future, create additional wholly-owned subsidiaries that may also be licensed by the SBA to operate under the SBA Act as SBICs (collectively, with Fund II SBIC and Fund III SBIC, the ''SBIC Subsidiaries''). Any existing entities that currently intend to rely on the order have been named as applicants, and any other existing or future entities that may rely on the order in the future will comply with its terms and conditions.

and its financial statements are consolidated with the Company's financial statements. Florida Sidecar's sole business purpose is to hold one or more investments on behalf of the Company. CSP-Florida is a limited liability company organized under the laws of the state of North Carolina. CSP-Florida serves as general partner to Florida Sidecar and its only role is to perform ministerial functions that result from decisions made by Capitala Investment Advisors; CSP-Florida is not able to prevent Capitala Investment Advisors from acting independently.[5]

6. Capitala Investment Advisors is a Delaware limited liability company and serves as the investment adviser to the Company, the SBIC Subsidiaries and Florida Sidecar. Capitala Investment Advisors is registered as an investment adviser under the Investment Advisers Act of 1940. Pursuant to an investment management agreement with the Company that satisfies the requirements under sections 15(a) and (c) of the Act, Capitala Investment Advisors manages the consolidated assets of the Company, including Fund II SBIC, Fund III SBIC and Florida Sidecar. The investment professionals of Capitala Investment Advisors are responsible for sourcing potential investments, conducting research and diligence on potential investments and equity sponsors, analyzing investment opportunities, structuring investments and monitoring the investments and portfolio companies of the Company and its wholly-owned subsidiaries, including Fund II SBIC, Fund III SBIC and Florida Sidecar. Applicants anticipate that Capitala Investment Advisors will also provide management and advisory services to all Subsidiaries.

Applicants' Legal Analysis

1. Applicants request an order under sections 6(c), 12(d)(1)(J), 57(c) and 57(i) of the Act and rule 17d–1 under the Act granting exemptions from sections 12(d)(1)(A), 18(a), 21(b), 57(a)(1), 57(a)(2), 57(a)(3), and 61(a) of the Act and permitting certain joint transactions otherwise prohibited by section 57(a)(4) of the Act to permit the Company and its Subsidiaries to operate effectively as one company, specifically to: (a) Engage in certain transactions with each other; (b) invest in securities in which the other is or proposes to be an investor that would otherwise be permitted if the Company and the Subsidiaries were one company; and (c) be subject to modified consolidated asset coverage requirements for senior securities issued by a BDC and its SBIC Subsidiaries. Applicants also request an order under section 12(h) of the Exchange Act for an exemption for Fund II SBIC and Fund III SBIC from section 13(a) of the Exchange Act, so as to allow filing of consolidated reports with the Commission.

2. Section 12 of the Act is made applicable to BDCs by section 60 of the Act. Section 12(d)(1)(A) makes it unlawful for any registered investment company to purchase or otherwise acquire the securities of another investment company, except to the extent permitted by sections 12(d)(1)(A)(i), (ii) and (iii). Rule 60a–1 exempts the acquisition by a BDC of the securities of an SBIC that is operated as a wholly-owned subsidiary of the BDC from section 12(d)(1)(A) of the Act. Accordingly, since the Company has elected BDC status, and since Fund II SBIC and Fund III SBIC are operated as wholly-owned subsidiaries of the Company, the transfer of assets from the Company to Fund II SBIC or Fund III SBIC should be exempt from the provisions of section 12(d)(1)(A) by virtue of rule 60a–1. However, the provisions of section 12(d)(1) also apply to the activities of Fund II SBIC and Fund III SBIC since each has elected BDC status under the Act. Any loans or advances by Fund II SBIC or Fund III SBIC to the Company might be deemed to violate section 12(d)(1)(A)(ii) or (iii) if the loans or advances are construed as purchases of the securities of the Company by Fund II SBIC or Fund III SBIC.

3. Applicants request an exemption under section 12(d)(1)(J) from section 12(d)(1)(ii) and (iii) of the Act to permit the acquisition by either of Fund II SBIC or Fund III SBIC of any securities of the Company representing indebtedness. Section 12(d)(1)(J) of the Act provides that the Commission may exempt persons or transactions from any provision of section 12(d)(1) if and to the extent such exception is consistent with the public interest and the protection of investors. Applicants state that the requested relief meets this standard because Fund II SBIC's or Fund III SBIC's wholly owned subsidiary status and consolidated financial reporting with the Company will both eliminate the possibility of overreaching and prevent confusion as to the financial status of the Company to the Company's stockholders, who are the investors that the Act is intended to protect.

4. Section 18(a) prohibits a registered closed-end investment company from issuing any class of senior security or selling any such security of which it is the issuer unless the company complies with the asset coverage requirements set forth in that section. Section 61(a) applies section 18, with certain modifications, to a BDC. Section 18(k), however, provides an exemption from sections 18(a)(1)(A) and (B) (relating to senior securities representing indebtedness) for SBICs.

5. Applicants state that a question exists as to whether the Company must comply with the asset coverage requirements of section 18(a) on a consolidated basis because the Company may be an indirect issuer of senior securities issued by either of the SBIC Subsidiaries. To do so would mean that the Company would treat as its own all assets held directly by the Company and the SBIC Subsidiaries and would also treat as its own any liabilities of the SBIC Subsidiaries, including senior securities as to which the SBIC Subsidiaries are exempt from the provisions of sections 18(a)(1)(A) and (B) by virtue of section 18(k). Accordingly, applicants request relief under section 6(c) of the Act from sections 18(a) and 61(a) of the Act to permit the Company to exclude from its consolidated asset coverage ratio any senior security representing indebtedness that is issued by either of the SBIC Subsidiaries.

6. Section 6(c) of the Act, in relevant part, permits the Commission to exempt any transaction or class of transactions from any provision of the Act if, and to the extent that, such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that, without the requested relief from sections 18(a) and 61(a), the ability of the SBIC Subsidiaries to obtain the kind of financing that would be available to the Company if it were to conduct the SBIC operations itself would be restricted. Applicants state that applying section 18(k) to the Company with respect to any senior security representing indebtedness that is issued by the SBIC Subsidiaries would not harm the public interest by exposing investors to risks of unconstrained leverage, because the SBA regulates the capital structure of the SBIC Subsidiaries. Companies operating under the SBA Act, such as the SBIC Subsidiaries, are subject to the SBA's substantial regulation of permissible

[5] The Company may in the future form one or more direct or indirect wholly-owned non-SBIC Subsidiaries each of whose sole business purpose is to hold one or more investments on behalf of the Company. Any such non-SBIC Subsidiary would be an investment company but for an exclusion in section 3(c) or in reliance on rule 3a-7 and its financial statements would be consolidated with the Company's financial statements.

leverage in their capital structure. An SBIC with outstanding SBA financial assistance may not incur any secured third-party debt or refinance any debt with secured third-party debt without prior written approval of the SBA.

7. Sections 57(a)(1) and (2) of the Act make it unlawful, with certain exceptions, for any person related to a BDC in the manner described in section 57(b), or any affiliated person of that person (a) to sell any security or other property to the BDC or to any company controlled by the BDC, or (b) to purchase from any BDC or from any company controlled by such BDC any security or other property. Section 57(b) includes any person who, directly or indirectly, controls, is controlled by, or is under common control with the BDC or any person who controls, is controlled by, or is under common control with that person. Applicants state that the Company is an affiliated person of Fund II SBIC, Fund III SBIC and Florida Sidecar by reason of its direct or indirect ownership of all of the limited partnership interests in each of Fund II SBIC, Fund III SBIC and Florida Sidecar and its indirect ownership of 100% of the general partnership interests in Fund II SBIC, Fund III SBIC and Florida Sidecar through its 100% ownership of the General Partners. Fund II SBIC, Fund III SBIC and Florida Sidecar each is a person related to each other in a manner described in section 57(b) because each is deemed to be under the control of the Company and thus under common control. Any Subsidiary would also each be a person related to Fund II SBIC and Fund III SBIC in a manner described in section 57(b) as long as it is under the common control of the Company.

8. Applicants state that there may be circumstances when one or more of the Company and a Subsidiary would purchase all or a portion of the portfolio investments held by one of the others in order to enhance the liquidity of the selling company or for other reasons, subject in each case to the requirements of the SBA and the regulations thereunder, as applicable. In addition, there may be circumstances when it is in the interest of the Company and/or its Subsidiaries for any non-BDC Subsidiary to invest in securities of an issuer that may be deemed to be a person related to either the Company or Fund II SBIC or Fund III SBIC in a manner described in section 57(b), or for the Company to invest in securities of an issuer that may be deemed to be a person related to a Subsidiary in a manner described in section 57(b).

9. Accordingly, applicants request relief under sections 57(a)(1) and (2) to permit any transaction in which one or more of the Company, Fund II SBIC, Fund III SBIC or any other Subsidiary would purchase all or a portion of the portfolio investments or other property held by one of the others. Applicants also request relief under sections 57(a)(1) and (2) to permit any transaction in which any non-BDC Subsidiary invests in securities of an issuer that may be deemed to be a person related to either the Company or Fund II SBIC or Fund III SBIC in a manner described in section 57(b), but only to the extent that any such transaction would not be prohibited if such Subsidiary were deemed to be part of the Company and not a separate company. Additionally, applicants request relief to permit the Company to invest in securities of an issuer that may be deemed to be a person related to a Subsidiary in a manner described in section 57(b) and permitting Fund II SBIC or Fund III SBIC to invest in securities of an issuer that may be deemed to be a person related to the Company or the Subsidiaries in a manner described in section 57(b). It is the intent of this request only to permit the Company and the Subsidiaries to do that which they otherwise would be permitted to do within the provisions of the Act if they were one company.

10. Section 57(c) directs the Commission to exempt a transaction from one or more provisions of sections 57(a)(1), (2) and (3) if the terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching of the BDC or its stockholders or partners on the part of any person concerned, the proposed transaction is consistent with the policy of the BDC concerned and the proposed transaction is consistent with the general purposes of the Act.

11. Applicants submit that the requested relief from sections 57(a)(1) and (2) meets this standard. Applicants represent that the proposed operations as one company will enhance the efficient operations of the Company and its wholly-owned Subsidiaries, and allow them to deal with portfolio companies as if the Company and its Subsidiaries were one company. Applicants contend that the terms of the proposed transactions are reasonable and fair and do not involve overreaching of the Company, its stockholders, or the Subsidiaries that are BDCs by any person, and that the requested order would permit the Company and the Subsidiaries to carry out more effectively their purposes and objectives of investing primarily in small business concerns. Applicants also state that since Fund II SBIC and Fund III SBIC and any Subsidiary are wholly-owned subsidiaries of the Company and since no officers or directors of Fund II SBIC and Fund III SBIC, any Subsidiary or of the Company, or any controlling persons or other ''upstream affiliates'' of the Company will have any prohibited financial interest in the transactions described, there can be no overreaching on the part of any persons and no harm to the public interest in transactions solely between the Company and Fund II SBIC and Fund III SBIC. Finally, applicants note that the proposed transactions are consistent with the policy of the Company and Fund II SBIC and Fund III SBIC as specified in filings with the Commission and reports to stockholders, as well as consistent with the policies and provisions of the Act.

12. Section 57(a)(3) of the Act makes it unlawful for certain affiliated persons of a BDC, and certain affiliated persons of those persons, set out in section 57(b) to borrow money or other property from such BDC or from any company controlled by the BDC, except as permitted by section 21(b) or section 62. Section 21(b) of the Act (made applicable to BDCs by section 62) provides that it shall be unlawful for a BDC to lend any money or property, directly or indirectly, to any person that controls or is under common control with the BDC, except to any company that owns all of the outstanding securities of the BDC other than directors' qualifying shares.

13. The Company is an affiliated person of Fund II SBIC and Fund III SBIC by reason of its direct or indirect ownership of all of the limited partnership interests in Fund II SBIC and Fund III SBIC and its indirect ownership of all of the general partnership interests in Fund II SBIC and Fund III SBIC through its 100% ownership of the Fund II SBIC General Partner and Fund III SBIC General Partner. The Company does not directly own all of the outstanding securities of Fund II SBIC or Fund III SBIC because Fund II SBIC General Partner holds a 1.03% general partnership interest in Fund II SBIC and Fund III SBIC General Partner holds a 0.95% general partnership interest in Fund III SBIC and both SBIC Subsidiaries have issued SBA guaranteed debentures and, in the future, may have other outstanding securities in the form of indebtedness. Fund II SBIC and Fund III SBIC are affiliated persons of the Company because they are deemed to be under the control of the Company. Accordingly, the Company is related to Fund II SBIC and Fund III SBIC in the manner set

forth in section 57(b) and Fund II SBIC and Fund III SBIC are related to the Company in the manner set forth in section 57(b).

14. Applicants state that there may be instances when it would be in the best interests of the Company and its stockholders for the Company to make loans to its Subsidiaries that are BDCs. There may also be instances when it would be in the best interests of the Company and its stockholders for its Subsidiaries that are BDCs to make loans to the Company. Applicants note that, in the case of loans from Fund II SBIC or Fund III SBIC to the Company, the loans would be prohibited by section 21(b) and section 57(a)(3) because the borrower controls the lender and the lender may have outstanding securities not owned by the borrower. Accordingly, applicants request an order under section 6(c) exempting from the provisions of section 21(b) the lending of money or other property by Fund II SBIC or Fund III SBIC to the Company and by the Company to Fund II SBIC or Fund III SBIC. Applicants argue that because these transactions are solely between the Company and Fund II SBIC, Fund III SBIC, or its wholly-owned subsidiaries, they will have no substantive economic effect and there is be no basis for overreaching or harm to the public interest. Applicants also request an order under section 57(c) exempting from the provisions of section 57(a)(3) the borrowing of money or property by the Company from Fund II SBIC or Fund III SBIC. Applicants submit that the requested relief meets the standards of section 57(c).

15. Section 57(a)(4) of the Act makes it unlawful for certain persons related to a BDC in the manner set forth in section 57(b), acting as principal, to knowingly effect any transaction in which the BDC or a company controlled by the BDC is a joint or joint and several participant with that person in contravention of such rules and regulations as the Commission may prescribe for the purpose of limiting or preventing participation by the BDC or controlled company on a basis less advantageous than that of the other participant. Section 57(i) of the Act provides that rules and regulations under section 17(d) of the Act, *e.g.,* rule 17d–1, will apply to transactions subject to section 57(a) in the absence of rules under that section. The Commission has not adopted rules under section 57(a)(4) with respect to joint transactions and, accordingly, the standards set forth in rule 17d–1 govern applicants' request for relief. Rule 17d–1(a) prohibits an affiliate or, when applying rule 17d–1 to implement section 57(a)(4), a person related to a BDC in a manner described in section 57(b) acting as principal, from participating in, or effecting any transaction in connection with any joint enterprise or joint arrangement or profit-sharing plan in which any such BDC, or a company controlled by such BDC, is a participant.

16. Applicants request relief under section 57(i) and rule 17d-1 to permit any joint transaction that would otherwise be prohibited by section 57(a)(4) between the Company and either or both of Fund II SBIC or Fund III SBIC with respect to any transaction involving investments by the Company or Fund II SBIC or Fund III SBIC in portfolio companies in which any is or is proposed to become an investor, but only to the extent that the transaction would not be prohibited if Fund II SBIC and Fund III SBIC (and all of their respective assets and liabilities) were deemed to be part of the Company, and not separate companies.

17. In determining whether to grant an order under section 57(i) and rule 17d-1, the Commission considers whether the participation of the BDC in the joint transaction is consistent with the provisions, policies, and purposes of the Act, and the extent to which such participation is on a basis different from or less advantageous than that of other participants. Applicants state that the proposed transactions are consistent with the policy and provisions of the Act and will enhance the interests of the Company and the Subsidiaries while retaining the important protections afforded by the Act. In addition, because the joint participants will conduct their operations as though they comprise one company, the participation of one will not be on a basis different from or less advantageous than the others. Accordingly, applicants submit that the standard for relief under section 57(i) and rule 17d-1 is satisfied.

18. Section 54 of the Act provides that a closed-end company may elect BDC treatment under the Act if the company has either a class of equity securities registered under section 12 of the Exchange Act or has filed a registration statement pursuant to section 12 of the Exchange Act for a class of its equity securities. Section 12(g) of the Exchange Act requires issuers with specified assets and a specified number of security holders to register under the Exchange Act. As a BDC, the Company has registered its common stock under section 12(b) of the Exchange Act. In order to elect BDC treatment under the Act, Fund II SBIC and Fund III SBIC voluntarily registered their securities under the Exchange Act.

19. By filing a registration statement under section 12 of the Exchange Act, absent an exemption, Fund II SBIC and Fund III SBIC would be required to make periodic filings with the Commission, even though Fund II SBIC and Fund III SBIC have only one equity holder. Section 13 of the Exchange Act is the primary section requiring such filings. Accordingly, applicants request an order under section 12(h) of the Exchange Act exempting Fund II SBIC and Fund III SBIC from the reporting requirements of section 13(a) of the Exchange Act.

20. Section 12(h) of the Exchange Act provides that the Commission may exempt an issuer from section 13 of the Exchange Act if the Commission finds that by reason of the number of public investors, amount of trading interest in the securities, the nature and extent of the activities of the issuer, income or assets of the issuer, or otherwise, that such action is not inconsistent with the public interest or the protection of investors. Fund II SBIC and Fund III SBIC each have only one investor, which is itself a reporting company, and no public investors. There will be no trading in Fund II SBIC or Fund III SBIC securities, so no public interest or investor protective purpose will be served by separate Fund II SBIC and Fund III SBIC reporting. Further, applicants state that the nature and extent of each of Fund II SBIC's and Fund III SBIC's activities are such that its activities will be fully reported through consolidated reporting in accordance with normal accounting rules. Accordingly, applicants believe that the requested exemption meets the standards of section 12(h) of the Exchange Act.

Applicants' Conditions

Applicants agree that the requested order will be subject to the following conditions:

1. The Company will at all times own and hold, beneficially and of record, all of the outstanding limited partnership interests in any Subsidiary and all of the outstanding membership interests in the General Partners, or otherwise own and hold beneficially all of the outstanding voting securities and equity interests of such Subsidiary.

2. The Subsidiaries will have investment policies not inconsistent with those of the Company, as set forth in the Company's registration statement.

3. No person shall serve as a member of any of the Subsidiaries' board of directors, including as a manager under a different form of legal organization that might perform the function of a director, unless such person shall also

be a member of the Company's Board. The board of directors or the managers, as applicable, of any Subsidiary will be appointed by the equity owners of that Subsidiary.

4. The Company shall not issue or sell any senior security and the Company shall not cause or permit any SBIC Subsidiaries to issue or sell any senior security of which the Company or such SBIC Subsidiary is the issuer except to the extent permitted by section 18 (as modified for BDCs by section 61) of the Act; provided that, immediately after the issuance or sale by either of the Company or any SBIC Subsidiary of any such senior security, the Company, individually and on a consolidated basis, shall have the asset coverage required by section 18(a) of the Act (as modified by section 61(a)). In determining whether the Company has the asset coverage on a consolidated basis required by section 18(a) of the Act, (as modified by section 61(a)), any senior securities representing indebtedness of an SBIC Subsidiary if that SBIC Subsidiary has issued indebtedness that is held or guaranteed by the SBA shall not be considered senior securities and, for purposes of the definition of ''asset coverage'' in section 18(h), shall be treated as indebtedness not represented by senior securities.

5. The Company will acquire securities of any SBIC Subsidiary representing indebtedness only if, in each case, the prior approval of the SBA has been obtained. In addition, the Company and the SBIC Subsidiaries will purchase and sell portfolio securities between themselves only if, in each case, the prior approval of the SBA has been obtained.

6. No person shall serve or act as investment adviser to the Subsidiaries unless the Board and the stockholders of the Company shall have taken such action with respect thereto that is required to be taken pursuant to the Act by the functional equivalent of the Subsidiary's Board and the equity holders of the Subsidiary, including as if such Subsidiary were a BDC.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–11965 Filed 5–22–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–31051; 812–14313]

Credit Suisse Asset Management, LLC, et al.; Notice of Application and Temporary Order

May 19, 2014.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Temporary order and notice of application for a permanent order under section 9(c) of the Investment Company Act of 1940 (''Act'').

SUMMARY: Applicants have received a temporary order exempting them from section 9(a) of the Act, with respect to a guilty plea entered on May 19, 2014, by Credit Suisse AG (''CSAG'') in the U.S. District Court for the Eastern District of Virginia (''District Court'') in connection with a plea agreement between CSAG and the U.S. Department of Justice (''DOJ''), until the Commission takes final action on an application for a permanent order. Applicants have also applied for a permanent order.

APPLICANTS: Credit Suisse Asset Management, LLC (''CSAM''), Credit Suisse Asset Management Limited (''CSAML''), Credit Suisse Hedging-Griffo Servicos Internacionais S.A. (''CSHG''), Credit Suisse Securities (USA) LLC (''CSSU''), and CSAG (each an ''Applicant'' and collectively, the ''Applicants''),[1] and Credit Suisse Group AG (''CS Group'').[2]

DATES: *Filing Date:* The application was accepted on EDGAR on May 19, 2014, with a filing date of May 20, 2014.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on June 13, 2014, and should be accompanied by proof of service on Applicants, in the form of an affidavit, or for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: c/o Credit Suisse Asset Management, LLC, Eleven Madison Avenue, New York, NY 10010.

FOR FURTHER INFORMATION CONTACT: Courtney S. Thornton, Senior Counsel, at (202) 551–6812 or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a temporary order and a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. Each of the Applicants is a direct or indirect wholly owned subsidiary of CS Group, the parent company of CSAG. CSAM, a limited liability company formed under Delaware law, is registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). CSAML, a corporation formed under the laws of the United Kingdom, is registered as an investment adviser under the Advisers Act. CSHG, a corporation formed under the laws of Brazil, is registered as an investment adviser under the Advisers Act. CSSU, a limited liability company formed under Delaware law, is registered as a broker-dealer under the Securities Exchange Act of 1934 and as an investment adviser under the Advisers Act, and is registered as a member of the Financial Industry Regulatory Authority. CSAM, CSAML, CSHG, and CSSU serve either as investment adviser (as defined in section 2(a)(20) of the Act) to investment companies (or series thereof) registered under the Act (''Funds'') and employees' securities companies (''ESCs''), or as principal underwriter (as defined in section 2(a)(29) of the Act) to open-end management investment companies registered under the Act (''Open-End Funds'') (such activities, collectively, ''Fund Service Activities''). CSAG is the principal operating subsidiary of CS Group, which operates as a holding company. Both CSAG and CS Group are corporations organized under the laws of Switzerland; both are engaged in the private banking,

[1] Applicants request that any relief granted pursuant to the application also apply to any existing or future company of which CSAG is or may become an affiliated person within the meaning of section 2(a)(3) of the Act (together with the Applicants, the ''Covered Persons'') with respect to any activity contemplated by section 9(a) of the Act.

[2] CS Group is a party to the application solely for purposes of agreeing to the portion of condition 4 that applies to it.

investment banking, and asset management businesses.

2. On May 19, 2014, the DOJ filed a one-count criminal information (the ''Information'') in the District Court charging CSAG with conspiracy to commit tax fraud related to accounts CSAG established for cross-border clients in violation of Title 18, United States Code, Section 371. CASG has agreed to resolve the action brought by DOJ through a plea agreement dated May 19, 2014 (the ''Plea Agreement''). Under the Plea Agreement, CSAG pleaded guilty to the charge set out in the Information (the ''Guilty Plea''). Applicants expect that the District Court will enter a judgment against CSAG that will require remedies that are materially the same as set forth in the Plea Agreement. Pursuant to the Plea Agreement, CSAG agreed to comply with the undertakings described in the application and to pay substantial criminal penalties and restitution.

3. In addition to the Plea Agreement with DOJ, on February 21, 2014, CS Group reached a settlement with the Commission that resolved its investigation into the provision of unregistered broker-dealer and investment adviser services to U.S. clients during the time period between 2002–2008 (the ''Commission Settlement''). The conduct that was the subject of the Commission investigation related to the conduct charged in the Information. As part of the Commission Settlement, CS Group agreed to pay $196,511,014, which includes $82,170,990 in disgorgement, $64,340,024 in interest and a $50,000,000 penalty. CS Group also retained an independent consultant in connection with the Commission Settlement.

4. CSAG will enter a settlement with the Board of Governors of the Federal Reserve System (the ''Federal Reserve'') to resolve certain findings by the Federal Reserve, including that the activities of CSAG regarding opening of foreign accounts for U.S. taxpayers, provision of investment services to U.S. clients, and operation of CSAG's New York representative office prior to 2009 lacked adequate enterprise-wide risk management and compliance policies and procedures sufficient to ensure that all of its activities comply with U.S. laws and regulations (the ''Federal Reserve Order'').

5. CSAG also will enter into a consent order with the New York State Department of Financial Services (''DFS'') to resolve DFS's investigation into the Conduct, as defined below (the ''DFS Order'').

6. Ten individuals who have been identified as having been responsible for the conduct underlying the Plea Agreement (including the conduct described in any of the exhibits to the Plea Agreement) (the ''Conduct'') are current employees of CSAG or a Covered Person. All other employees of CSAG and any Covered Person who were identified as having been responsible for the Conduct have either resigned or been terminated. Of the individuals identified as having been responsible for the Conduct that remain employees of CSAG or a Covered Person, all but one (the ''December Employee'') will be notified no later than May 31, 2014 that their employment with CSAG or a Covered Person will be terminated no later than August 31, 2014.[3]

7. Additionally, beginning in 2008, CSAG commenced a remediation program to ensure that only U.S. clients who established compliance with U.S. tax laws could remain clients of CSAG. U.S. clients that could not demonstrate tax compliance had to terminate their relationship with CSAG. As part of that program, CSAG moved the securities business with U.S. residents into U.S.-regulated subsidiaries or terminated those relationships.

Applicants' Legal Analysis

1. Section 9(a)(1) of the Act provides, in pertinent part, that a person may not serve or act as an investment adviser or depositor of any registered investment company or a principal underwriter for any registered open-end investment company or registered unit investment trust, if such person within ten years has been convicted of any felony or misdemeanor arising out of such person's conduct, as, among other things, an investment adviser, a broker or dealer, or a bank. Section 2(a)(10) of the Act defines the term ''convicted'' to include a plea of guilty. Section 9(a)(3) of the Act extends the prohibitions of section 9(a)(1) to a company any affiliated person of which has been disqualified under the provisions of section 9(a)(1). Section 2(a)(3) of the Act defines ''affiliated person'' to include, among others, any person directly or indirectly controlling, controlled by, or under common control with, the other person. Applicants state that CSAG is an affiliated person of each of the other Applicants within the meaning of section 2(a)(3). Applicants state that the Guilty Plea would result in a disqualification of each Applicant for ten years under section 9(a) of the Act because CSAG would become the subject of a conviction described in 9(a)(1).

2. Section 9(c) of the Act provides that the Commission shall grant an application for exemption from the disqualification provisions of section 9(a) if it is established that these provisions, as applied to Applicants, are unduly or disproportionately severe or that the Applicants' conduct has been such as not to make it against the public interest or the protection of investors to grant the exemption. Applicants have filed an application pursuant to section 9(c) seeking temporary and permanent orders exempting the Applicants and other Covered Persons from the disqualification provisions of section 9(a) of the Act.

3. Applicants believe they meet the standard for exemption specified in section 9(c). Applicants state that the prohibitions of section 9(a) as applied to them would be unduly and disproportionately severe and that the conduct of Applicants has been such as not to make it against the public interest or the protection of investors to grant the exemption from section 9(a).

4. Applicants assert that the Conduct did not involve any of Applicants acting as an investment adviser or depositor of any Fund, ESC or business development company or principal underwriter for any Open-End Fund, unit investment trust registered under the Act, or face amount certificate company registered under the Act. The Conduct similarly did not involve any Fund, ESC or business development company with respect to which Applicants engaged in Fund Service Activities.[4] Applicants further assert that (i) none of the current or former directors, officers or employees of the Applicants (other than certain personnel of CSAG who were not involved in any of the Applicants' Fund Service Activities) had involvement in the Conduct; (ii) except as noted above, no current or former employee of CSAG or any Covered Person who previously has been or who subsequently may be identified by CSAG or any U.S. or non-U.S. regulatory or enforcement agencies as having been responsible for the Conduct will be an officer, director, or employee of CSAM, CSAML, CSHG, CSSU, or of any other Covered Person; (iii) those identified

[3] The employment of the December Employee will be terminated at the earlier of December 31, 2014 or the date that the December Employee's services are no longer needed by CSAG. The sole activity of the December Employee as an employee will be to perform compliance-related services in a specific area. The activity of the December Employee will be subject to direct supervision by senior legal personnel.

[4] CSAG does not engage, has not engaged, and will not engage in Fund Service Activities.

employees have had no, and will not have any future, involvement in the Covered Persons' activities in any capacity described in section 9(a) of the Act; and (iv) because the personnel of the Applicants (other than certain personnel of CSAG who were not involved in any of the Applicants' Fund Service Activities) did not have any involvement in the Conduct, shareholders of the Funds and ESCs were not affected any differently than if those Funds and ESCs had received services from any other non-affiliated investment adviser or principal underwriter.

5. Except as discussed above, Applicants have agreed that neither they nor any of the other Covered Persons will employ any of the current or former employees of CSAG or any Covered Person who previously have been or who subsequently may be identified by CSAG or any U.S. or non-U.S. regulatory or enforcement agencies as having been responsible for the Conduct in any capacity without first making a further application to the Commission pursuant to section 9(c). Applicants also have agreed that each Applicant (and any Covered Person that acts in any capacity described in section 9(a) of the Act) will adopt and implement policies and procedures reasonably designed to ensure compliance with the terms and conditions of the order granted under section 9(c). In addition, CSAG has agreed to comply in all material respects with the material terms and conditions of the Plea Agreement and the material terms of the Federal Reserve Order and the DFS Order, and CS Group has agreed to comply in all material respects with the material terms and undertakings of the Commission Settlement.

6. Applicants further represent that the inability of CSAM, CSAML, CSHG, and CSSU to continue providing Fund Service Activities would result in potential hardships for both the Funds and the ESCs and their shareholders. Applicants state that they will distribute written materials, including an offer to meet in person to discuss the materials, to the board of trustees of the Funds, including the directors who are not ''interested persons,'' as defined in section 2(a)(19) of the Act, of such Funds, and their independent legal counsel as defined in rule 0–1(a)(6) under the Act, regarding the Plea Agreement, any impact on the Funds, and the application. The Applicants will provide the Funds with all information concerning the Plea Agreement and the application that is necessary for the Funds to fulfill their disclosure and other obligations under the federal securities laws.

7. Applicants also state that, if CSAM, CSAML, CSHG, and CSSU were barred from providing Fund Service Activities to the Funds and the ESCs, the effect on their business and employees would be severe.

8. Applicants state that certain of the Applicants and their affiliates have received exemptive orders under section 9(c), as described in greater detail in the application.

Applicants' Conditions

Applicants agree that any order granted by the Commission pursuant to the application will be subject to the following conditions:

1. Any temporary exemption granted pursuant to the application will be without prejudice to, and shall not limit the Commission's rights in any manner with respect to, any Commission investigation of, or administrative proceedings involving or against, Covered Persons, including, without limitation, the consideration by the Commission of a permanent exemption from section 9(a) of the Act requested pursuant to the application or the revocation or removal of any temporary exemptions granted under the Act in connection with the application.

2. Except as set out in the second paragraph of Section IV.E of the application, neither the Applicants nor any of the other Covered Persons will employ any of the current or former employees of CSAG or any Covered Person who previously have been or who subsequently may be identified by CSAG or any U.S. or non-U.S. regulatory or enforcement agencies as having been responsible for the Conduct in any capacity without first making a further application to the Commission pursuant to section 9(c).

3. Each Applicant and Covered Person will adopt and implement policies and procedures reasonably designed to ensure that they will comply with the terms and conditions of the requested orders within 60 days of the date on which any permanent order is granted or, with respect to condition 4, such later date as may be contemplated by the Federal Reserve Order, the DFS Order, or the Commission Settlement, as applicable.

4. CSAG will comply in all material respects with the material terms and conditions of the Plea Agreement and with the material terms of the Federal Reserve Order and the DFS Order, and CS Group will comply in all material respects with the material terms and undertakings of the Commission Settlement.

5. Applicants will provide written notification to the Chief Counsel of the Commission's Division of Investment Management, with a copy to the Chief Counsel of the Commission's Division of Enforcement, of a material violation of the terms and conditions of the requested orders within 30 days of discovery of the material violation.

Temporary Order

The Commission has considered the matter and finds that the Applicants have made the necessary showing to justify granting a temporary exemption.

Accordingly

It is hereby ordered, pursuant to section 9(c) of the Act, that the Applicants and the other Covered Persons are granted a temporary exemption from the provisions of section 9(a), effective forthwith, solely with respect to the Guilty Plea, subject to the representations and conditions in the application, until the date the Commission takes final action on their application for a permanent order.

By the Commission.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–11929 Filed 5–22–14; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–72184; File No. SR–FICC–2014–02]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Request To Extend the Pilot Program for Certain Government Securities Division Rules Relating to the GCF Repo® Service

May 19, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 5, 2014, the Fixed Income Clearing Corporation (''FICC'' or the ''Corporation'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes[3] as described in Items I, II and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission temporarily approved the changes that are the subject of this filing in 2011, and renewed this temporary approval most recently in 2013. Securities Exchange Act Release No. 70068 (July 30, 2013), 78 FR 47453 (August 5, 2013) (SR–FICC–2013–06). Thus, while the Exhibit 5 attached to this filing is marked to indicate that new text is being added to the rulebook of FICC's Government

III below, which Items have been prepared by FICC. The Commission is publishing this notice to solicit comments on the proposed rule changes from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule changes consist of modifications to the Rulebook of the Government Securities Division (''GSD'') in connection with the GCF Repo® service.[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, FICC 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. FICC 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.

(i) Purpose of the Proposed Rule Change

FICC is seeking the Commission's approval to extend the current pilot program (the ''2013 Pilot Program'') that is currently in effect for the GCF Repo® service. FICC is requesting that the 2013 Pilot Program be extended for one year following the Commission's approval of the present filing.[5]

By way of background, on July 12, 2011, FICC submitted a rule filing to the Commission (SR–FICC–2011–05) proposing to make certain changes to its GCF Repo service in order to comply with the recommendations that had been made by the Task Force on Triparty Reform (''TPR''), an industry group formed and sponsored by the Federal Reserve Bank of New York.[6] Because the GCF Repo service operates as a triparty mechanism, FICC was requested to incorporate changes to the GCF Repo service to align the service with the other TPR recommended changes for the overall triparty market.

The rule change described in SR–FICC–2011–05 was proposed to be run as a pilot program for one year starting from the date on which the filing was approved by the Commission (the ''2011 Pilot Program'').[7] Throughout 2011 and the earlier half of 2012, FICC implemented a portion of the rule changes that were included in SR–FICC–2011–05. As the expiration date of the 2011 Pilot Program approached, FICC elected to have certain aspects of the 2011 Pilot Program continue, however, FICC also proposed to make certain modifications to the 2011 Pilot Program. As a result, on June 8, 2012, FICC submitted a rule filing for the 2012 Pilot Program (SR–FICC–2012–05).[8] On June 5, 2013, FICC then submitted a rule filing to extend the Pilot Program for an additional year (SR–FICC–2013–06)[9]. Because the latest extension is now approaching its expiry date, FICC is seeking the Commission's approval to extend the Pilot Program for an additional year while the final phase of the tri-party reform is put in to place.[10]

Background: Description of the GCF Repo Service and History

(1) Creation of the GCF Repo Service

The GCF Repo service allows GSD dealer members to trade general collateral repos[11] throughout the day without requiring intra-day, trade-for-trade settlement on a delivery-versus-payment (DVP) basis. The service allows the dealers to trade such general collateral repos, based on rate and term, throughout the day with inter-dealer broker netting members on a blind basis. Standardized, generic CUSIP numbers have been established exclusively for GCF Repo processing and are used to specify the acceptable type of underlying Fedwire book-entry eligible collateral, which includes Treasuries, Agencies and certain mortgage-backed securities.

The GCF Repo service was developed as part of a collaborative effort among GSCC (FICC's predecessor), its two clearing banks (The Bank of New York Mellon (''BNY'') and JPMorgan Chase Bank, National Association (''Chase''))—and industry representatives. GSCC introduced the GCF Repo service on an *intra*-clearing bank basis in 1998.[12] Under the intrabank service, dealers could only engage in GCF Repo transactions with other dealers that cleared at the *same* clearing bank.

(2) Creation of the Interbank Version of the GCF Repo Service

In 1999, GSCC expanded the GCF Repo service to permit dealer participants to engage in GCF Repo trading on an *inter*-clearing bank basis, meaning that dealers using *different* clearing banks could enter into GCF Repo transactions (on a blind brokered basis).[13] Because dealer members that participate in the GCF Repo service do not all clear at the same clearing bank, introducing the service as an interbank service necessitated the establishment of a mechanism to permit after-hours movements of securities between the two clearing banks to deal with the fact that GSCC would likely have unbalanced net GCF securities and cash positions within each clearing bank (that is, it is likely that at the end of GCF Repo processing each business day, the dealers in one clearing bank will be net funds borrowers, while the dealers at the other clearing bank will be net funds lenders). To address this issue, GSCC and its clearing banks established, and the Commission approved, a legal mechanism by which securities would ''move'' across the clearing banks without the use of the securities Fedwire.[14] (Movements of cash do not present the same issue because the cash Fedwire is open later than the securities Fedwire.) Therefore, at the end of the

Services Division (''GSD''), this text already appears in the GSD's rulebook pursuant to the Commission's prior approvals. The current filing seeks the Commission's approval to retain this text in the GSD's rulebook for one additional year.

[4] GCF Repo is a registered trademark of FICC/DTCC.

[5] If FICC determines to change the parameters of the service during the one-year Pilot Program extension period, it will submit a rule filing to the Commission. If FICC seeks to extend the Pilot Program beyond the one-year period or proposes to make the Pilot Program permanent, it will also submit a rule filing to the Commission.

[6] The main purpose of the TPR was to develop recommendations to address the risk presented by triparty repo transactions due to the current morning reversal or ''unwind'' process and to move to a process by which transactions are collateralized all day.

[7] Securities Exchange Act Release No. 34–65213 (August 29, 2011), 76 FR 54824 (September 2, 2011)(SR–FICC–2011–05).

[8] *See* Securities Exchange Release No. 34–67621 (August 8, 2012); 77 FR 48572 (August 14, 2012) (SR–FICC–2012–05)

[9] *See* Securities Exchange Act Release No. 34–70068 (July 30, 2013) 78 FR 47453 (August 5, 2013) (SR–FICC–2013–06)

[10] The final phase includes the development interactive messages for the interbank collateral substitution automation. If FICC determines to change the parameters of the service during the one-year Pilot Program extension period, it will submit a rule filing to the Commission. If FICC seeks to extend the Pilot Program beyond the one-year period or proposes to make the Pilot Program permanent, it will also submit a rule filing to the Commission.

[11] A general collateral repo is a repo in which the underlying securities collateral is nonspecific, general collateral whose identification is at the option of the seller. This is in contrast to a specific collateral repo.

[12] *See* Securities Exchange Act Release No. 34–40623 (October 30, 1998) 63 FR 59831 (November 5, 1998) (SR–GSCC–98–02).

[13] *See* Securities Exchange Act Release No. 34–41303 (April 16, 1999) 64 FR 20346 (April 26, 1999) (SR–GSCC–99–01).

[14] *See id.* for a detailed description of the clearing bank and FICC accounts needed to effect the after-hour movement of securities.

day, after the GCF net results are produced, securities are pledged via a tri-party-like mechanism and the interbank cash component is moved via Fedwire. In the morning, the pledges are unwound, that is, funds are returned to the net funds lenders and securities are returned to the net funds borrowers.

The following simplified example illustrates the manner in which the GCF Repo services works on an interbank basis:

Assume that Dealer B clears at BNY and Dealer C clears at Chase. Further assume that: (i) outside of FICC, Dealer B engages in a triparty repo transaction with Party X to obtain funds and seeks to invest such funds via a GCF Repo transaction, (ii) outside of FICC, Dealer C engages in a DVP repo with Party Y to buy securities and seeks to finance these securities via a GCF Repo transaction, and (iii) Dealer B and Dealer C enter into a GCF Repo transaction (on a blind basis via a GCF Repo broker) and submit the trade details to FICC.

At the end of ''Day 1'', GCF Repo collateral must be allocated, i.e., Dealer B must receive the securities. However, the securities that Dealer B is to receive are at Chase and the securities Fedwire is closed. The after-hours movement mechanism permits the securities to be ''sent'' to Dealer B as follows: FICC will instruct Chase to allocate to a special FICC clearance account at Chase securities in an amount equal to the net short securities position.

FICC has established on its own books and records two ''securities accounts'' as defined in Article 8 of the New York Uniform Commercial Code, one in the name of Chase (''FICC Account for Chase'') and one in the name of BNY (''FICC Account for BNY''). The FICC Account for Chase is comprised of the securities in FICC's special clearance account maintained by BNY (''FICC Special Clearance Account at BNY for Chase''), and the FICC Account for BNY is comprised of the securities in FICC's special clearance account maintained by Chase (''FICC Special Clearance Account at Chase for BNY'').[15] The establishment of these securities accounts by FICC in the name of the clearing banks enables the bank that is in the net long securities position to ''receive'' securities by pledge after the close of the securities Fedwire. Once the clearing bank has ''received'' the securities by pledge, it can credit them by book-entry to a FICC GCF Repo account at that clearing bank and then to the dealers that clear at that bank that are net long the securities in connection with GCF Repo trades.

In our example, Chase, as agent for FICC, will transmit to BNY a description of the securities in the FICC Special Clearance Account at Chase for BNY. Based on this description, BNY will transfer funds equal to the funds borrowed position to the FICC GCF Repo account at Chase. Upon receipt of the funds by Chase, Chase will release any liens it may have on the FICC Special Clearance Account at Chase for BNY, and FICC will release any liens it may have on FICC Account for BNY (both of these accounts being comprised of the same securities). BNY will credit the securities in the FICC Account for BNY to FICC's GCF Repo account at BNY, and BNY will further credit these securities to Dealer B, who, as noted, is in a net long securities position. In the morning of ''Day 2,'' all securities and funds movements occurring on Day 1, are reversed (''unwind'').

(3) Issues with Morning Unwind Process

In 2003, FICC shifted the GCF Repo service back to intrabank status only.[16] By that time, the service had grown significantly in participation and volume. However, with the increase in use of the interbank service, certain payments systems risk issues arose from the inter-bank funds settlements related to the service, namely, the large interbank funds movement in the morning. FICC shifted the service back to intrabank status to enable management to study the issues presented and identify a satisfactory solution for bringing the service back to interbank status.

(4) The NFE Filing and Restoration of Service to Interbank Status

In 2007, FICC submitted a rule filing to address the issues raised by the interbank morning funds movement and return the GCF Repo service to interbank status (the ''2007 NFE Filing'').[17] The 2007 NFE Filing addressed these issues by using a hold against a dealer's ''net free equity'' (''NFE'') at the clearing bank to collateralize its GCF Repo cash obligation to FICC on an intraday basis.[18]

The 2007 NFE Filing replaced the Day 2 morning unwind process with an alternate process, which is currently in effect. Specifically, in lieu of making funds payments, the interbank dealers grant to FICC a security interest in their NFE-related collateral equal to their prorated share of the total interbank funds amount. FICC, in turn, grants to the other clearing bank (that was due to receive the funds) a security interest in the NFE-related collateral to support the debit in the FICC account at the clearing bank. The debit in the FICC account (''Interbank Cash Amount Debit'') occurs because the dealers who are due to receive funds in the morning must receive those funds at that time in return for their release of collateral. The debit in the FICC account at the clearing bank gets satisfied during the end of day GCF Repo settlement process. Specifically, that day's new activity yields a new interbank funds amount that will move at end of day—however, this amount gets netted with the amount that would have been due in the morning, thus further reducing the interbank funds movement. The NFE holds are released when the interbank funds movement is made at end of day. The 2007 NFE Filing did not involve any changes to the after-hours movement of securities occurring at the end of the day on Day 1. Using our simplified example:

On the morning of Day 2, Dealer C who needs to return funds in the unwind, instead of returning the funds in the morning, grants to FICC a security interest in Dealer C's NFE-related collateral equal to its funds movement (we have assumed only one GCF Repo transaction took place in this simplified example). FICC, in turn, grants BNY (that was due to receive the funds) a security interest in the NFE-related collateral to support the debit in the FICC account at BNY. As noted above, the debit in FICC's account at BNY arises because, under the current processing, Dealer B must receive its funds during the morning unwind. The FICC debit is then satisfied during the end of day GCF Repo settlement process.

As part of the 2007 NFE Filing, FICC imposed certain additional risk management measures with respect to the GCF Repo service. First, FICC imposed a collateral premium (called ''GCF Premium Charge'') on the GCF Repo portion of the Clearing Fund

[15] FICC has appointed Chase as its agent to maintain FICC's books and records with respect to the BNY securities account, and FICC has appointed BNY as its agent to maintain FICC's books and records with respect to the Chase securities account.

[16] *See* Securities Exchange Act Release No. 34–48006 (June 10, 2003), 68 FR 35745 (June 16, 2003) (SR–FICC–2003–04).

[17] *See* Securities Exchange Act Release No. 34–57652 (April 11, 2008), 73 FR 20999 (April 17, 2008) (SR–FICC–2007–08).

[18] NFE is a methodology that clearing banks use to determine whether an account holder (such as a dealer) has sufficient collateral to enter a specific transaction. NFE allows the clearing bank to place a limit on its customer's activity by calculating a value on the customer's balances at the bank. Bank customers have the ability to monitor their NFE balance throughout the day.

deposits of all GCF participants to further protect FICC in the event of an intra-day default of a GCF Repo participant. FICC requires GCF Repo participants to submit a quarterly ''snapshot'' of their holdings by asset type to enable Risk Management staff to determine the appropriate Clearing Fund premium. Members who do not submit this required information by the deadlines established by FICC are subject to fine and an increased Clearing Fund premium, as with all other instances of late submission of required information.

Second, the 2007 NFE Filing addressed the situation where FICC becomes concerned about the volume of interbank GCF Repo activity. Such a concern might arise, for example, if market events were to cause dealers to turn to the GCF Repo service for increased funding at levels beyond normal processing. The 2007 NFE Filing provides FICC with the discretion to institute risk mitigation and appropriate disincentive measures in order to bring GCF Repo levels to a comfortable level from a risk management perspective.[19]

2011 Pilot Program—Proposed Changes to the GCF Repo Service to Implement the TPR's Recommendations

In SR–FICC–2011–05, FICC proposed the following rule changes with respect to the GCF Repo service to address the TPR's Recommendations:

(1) (a) To move the Day 2 unwind from 7:30 a.m. to 3:30 p.m., (b) to move the NFE process[20] from morning to a time established by the Corporation as announced by notice to all members[21], (c) to move the cut-off time of GCF Repo submissions from 3:35 p.m. to 3:00 p.m., and (d) to move the cut-off time for dealer affirmation or disaffirmation from 3:45 p.m. to 3:00 p.m.

(2) To establish rules for intraday GCF Repo collateral substitutions (i.e., SR–FICC–2011–05 stated that with respect to interbank GCF Repo transactions, the substitution process will only permit cash as an initial matter to accommodate current processing systems, however, as noted below, the substitution process will permit cash and/or securities).

During the term of the 2011 Pilot Program, FICC implemented the proposed changes referred to in subsections 1(c) and 1(d) above and during the term of the 2012 Pilot Program, FICC implemented the proposed changes referred to in subsections 1(a), 1(b) and 2 above.

(1) Proposed Change Regarding the Morning Unwind and Related Rule Changes

The TPR recommended that the Day 2 unwind for all triparty transactions be moved from the morning to 3:30 p.m. The TPR made this recommendation in order to achieve the benefit of reducing the clearing banks' intraday exposure to the dealers. As stated, because the GCF Repo service is essentially a triparty mechanism, the TPR requested that FICC accommodate this time change. For the GSD rules, this necessitated a change to the GSD's ''Schedule of GCF Timeframes.'' Specifically, the 7:30 a.m. time in the Schedule was deleted and the language therein was moved to a new time of 3:30 p.m.

Because the Day 2 unwind moved from the morning to 3:30 p.m. and because the NFE process established by the 2007 NFE Filing is tied to the moment of the unwind, the NFE process also was required to move. During 2012, when the systems processing for the tri-party reform effort continued on the part of the clearing banks, the unwind moved to 3:30 p.m. and the funds continued to move between the two clearing banks at 5:00 p.m.; the NFE hold which applies to dealers moved to between 3:30 p.m. and 5:00 p.m. Because the NFE process is a legal process and not an operational process, it is not reflected on the Schedule of GCF Timeframes and therefore no change to the Schedule was required to accommodate the move of the NFE process. A change was needed in Section 3 of GSD Rule 20 to delete the reference to the ''morning'' timeframe on Day 2 with respect to the NFE process and to add language referencing ''at the time established by the Corporation.''

(2) Proposed Change Regarding Intraday GCF Repo Securities Collateral Substitutions

As a result of the time change of the unwind (i.e., the reversal on Day 2 of collateral allocations established by FICC for each netting member's GCF net funds borrower positions and GCF net funds lender positions on Day 1) to 3:30 p.m., the provider of GCF Repo securities collateral in a GCF Repo transaction on Day 1 no longer has possession of such securities at the beginning of Day 2. Therefore, during Day 2 prior to the unwind of the Day 1 collateral allocations, the provider of GCF Repo securities collateral (in our simple example, Dealer C) needs a substitution mechanism for the return of its posted GCF Repo securities collateral in order to make securities deliveries for utilization of such securities in its business activities. (In our example, Dealer C may need to return the securities to Party Y depending upon the terms of their transaction.) In the 2012 Pilot Program, FICC established a substitution process for this purpose in conjunction with its clearing banks. The language for the substitution mechanism was added to Section 3 of GSD Rule 20. It provides that all requests for substitution for the GCF Repo securities collateral must be submitted by the provider of the GCF Repo securities collateral (i.e., Dealer C) by the applicable deadline on Day 2 (the ''substitution deadline'').[22]

Substitutions on Intrabank GCF Repos

If the GCF Repo transaction is between dealer counterparties effecting the transaction through the same clearing bank (i.e., on an intra-clearing bank basis and in our example Dealer C and other dealers clearing at Chase), on Day 2 such clearing bank will process each substitution request of the provider of GCF Repo securities collateral (i.e., Dealer C) submitted prior to the substitution deadline promptly upon

[19] Specifically, the 2007 NFE Filing introduced the term ''GCF Repo Event'', which will be declared by FICC if either of the following occurs: (i) the GCF interbank funds amount exceeds five times the average interbank funds amount over the previous ninety days for three consecutive days; or (ii) the GCF interbank funds amount exceeds fifty percent of the amount of GCF Repo collateral pledged for three consecutive days. FICC reviews these figures on a semi-annual basis to determine whether they remain adequate. FICC also has the right to declare a GCF Repo Event in any other circumstances where it is concerned about GCF Repo volumes and believes it is necessary to declare a GCF Repo Event in order to protect itself and its members. FICC will inform its members about the declaration of the GCF Repo Event via important notice. FICC will also inform the Commission about the declaration of the GCF Repo Event.

[20] No other changes are being proposed to the NFE process that was in place by the 2007 NFE Filing; the risk management measures that were put in place by the 2007 NFE Filing remain in place with the present proposal.

[21] SR–FICC–2011–05 noted that the possible time range would be 8 a.m. to 1 p.m. to coincide with the collateral substitution mechanism that was being developed between FICC and its clearing banks. In rule filing SR–FICC–2012–05, FICC clarified that the 8:00 a.m. to 1:00 p.m. proposed time range in SR–FICC–2011–05 referred to the clearing bank hold on the FICC interest in the NFE (i.e., as part of the NFE process, FICC grants to the other clearing bank (that was due to receive the funds) a security interest in the NFE—related collateral to support the debit in the FICC account at the clearing bank). At present, given the move of the NFE process (as discussed in more detail below), this proposed time range has now moved from 8:00am to 3:30pm.

[22] As noted in SR–FICC–2012–05, FICC will establish such deadline prior to the implementation of the changes to this service in conjunction with the clearing banks and the Federal Reserve in light of market circumstances. As noted in Important Notice GOV088.12, once delivery has been made to GSD on the new obligations for that business day, no substitutions will be permitted for the remainder of the day.

receipt of such request. The return of the GCF Repo securities collateral in exchange for cash and/or eligible securities of equivalent value can be effected by simple debits and credits to the accounts of the GCF Repo dealer counterparties at the clearing agent bank (i.e., in our example, Chase). Eligible securities for this purpose will be the same as what is currently permitted under the GSD rules for collateral allocations, namely, Comparable Securities,[23] (ii) Other Acceptable Securities,[24] or (iii) U.S. Treasury bills, notes or bonds maturing in a time frame no greater than that of the securities that have been traded (except where such traded securities are U.S. Treasury bills, substitution may be with Comparable Securities and/or cash only).

Substitutions on Interbank GCF Repos

For a GCF Repo that was processed on an interbank basis and to accommodate a potential substitution request, FICC initiates a debit of the securities in the account of the lender through the FICC GCF Repo accounts at the clearing bank of the lender and the FICC GCF Repo account at the clearing bank of the borrower (''Interbank Movement''). This Interbank Movement is done so that a borrower who elects to substitute collateral will have access to the collateral for which it is substituting. The Interbank Movement occurs in the morning, though the clearing banks and FICC have the capability to have the Interbank Movement occur at any point during the day up until 2:30 p.m. During the 2012 Pilot Program, FICC and the clearing banks implemented a change to unwind the intrabank GCF Repo transactions at 3:30 p.m.

In the example above, the GCF Repo securities collateral will be debited from the securities account of the receiver of the collateral (i.e., Dealer B) at its clearing bank (i.e., BNY), and from the FICC Account for BNY. If a substitution request is received by the clearing bank (i.e., Chase) of the provider of GCF Repo securities collateral, prior to the substitution deadline at a time specified in FICC's procedures,[25] that clearing bank will process the substitution request by releasing the GCF Repo securities collateral from the FICC GCF Repo account at Chase and crediting it to the account of the provider of GCF Repo securities collateral (i.e., Dealer C). All cash and/or securities substituted for the GCF Repo securities collateral being released will be credited to FICC's GCF Repo account at the clearing bank (i.e., Chase).

Simultaneously, with the debit of the GCF Repo securities collateral from the account at the clearing bank (i.e., BNY) of the original receiver of GCF Repo securities collateral (i.e., Dealer B), for purposes of making payment to the original receiver of securities collateral (i.e., Dealer B), such clearing bank will effect a cash debit equal to the value of the securities collateral in FICC's GCF Repo account at such clearing bank and will credit the account of the original receiver of securities collateral (i.e., Dealer B) at such clearing bank with such cash amount. (This is because when Dealer B is debited the securities, Dealer B must receive the funds.) In order to secure FICC's obligation to repay the balance in FICC's GCF Repo account at such clearing bank (i.e., BNY), FICC will grant to such clearing bank a security interest in the cash and/or securities substituted for the GCF securities collateral in FICC's GCF repo account at the other clearing bank (i.e., Chase).

Using the example from above, assume the Dealer C submits a substitution notification—it requires the securities collateral that has been pledged to Dealer B and will substitute cash and/or securities. BNY will debit the securities from Dealer B's account and the relevant liens will be released so that the securities are in FICC's account at Chase. Chase will credit the securities to Dealer C's account and the cash and/or securities that Dealer C uses for its collateral substitution will be credited by Chase to FICC's account at Chase. From Dealer B's perspective, when BNY debits the securities from Dealer B's account, Dealer B is supposed to receive the funds—but as noted, the funds are at Chase. BNY will credit the funds to Dealer B's account and debit FICC's account at BNY.

At this point in our example, FICC is running a credit at Chase and a debit at BNY. In order to secure FICC's debit at BNY, FICC will grant a security interest in the funds in the FICC account at Chase.

For substitutions that occur with respect to GCF Repo transactions that were processed on an inter-clearing bank basis, FICC and the clearing banks permit cash and/or securities for the substitutions. The proposed rule change provided FICC with flexibility in this regard by referring to FICC's procedures.

As noted above, each of the above-referenced changes were approved in connection with SR–FICC–2011–05[26], SR–FICC–2012–05[27], and SR–FICC–2013–06[28]. FICC proposes to extend the pilot program reflecting these changes for an additional one year. The changes referenced above are reflected in Exhibit 5.

(ii) Statutory Basis for the Proposed Rule Change

The proposed rule change is consistent with the Securities and Exchange Act of 1934, as amended (the ''Act'') and the rules and regulations promulgated thereunder because it will align the GCF Repo service with recommendations being made by the TPR to address risks in the triparty market overall and therefore will serve to further safeguard the securities and funds for which FICC is responsible.

B. Self-Regulatory Organization's Statement on Burden on Competition

FICC does not believe that the proposed rule change will have any negative impact, or impose any burden, on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments relating to the proposed rule changes have not yet been solicited or received. FICC will notify the Commission of any written comments received by FICC.

D. Advance Notices Filed Pursuant to Section 806(e) of the Payment, Clearing and Settlement Supervision Act

(a) Not applicable.
(b) Not applicable.

[23] The GSD rules define ''Comparable Securities'' as follows: The term ''Comparable Securities'' means, with respect to a security or securities that are represented by a particular Generic CUSIP Number, any other security or securities that are represented by the same Generic CUSIP Number.

[24] The GSD rules define ''Other Acceptable Securities'' as follows:

The term ''Other Acceptable Securities'' means, with respect to:

(an) adjustable-rate mortgage-backed security or securities issued by Ginnie Mae, any fixed-rate mortgage-backed security or securities issued by Ginnie Mae, or (an) adjustable-rate mortgage-backed security or securities issued by either Fannie Mae or Freddie Mac: (a) any fixed-rate mortgage-backed security or securities issued by Fannie Mae and Freddie Mac, (b) any fixed-rate mortgage-backed security or securities issued by Ginnie Mae, or (c) any adjustable-rate mortgage-backed security or securities issued by Ginnie Mae.

[25] Rule filing SR–FICC–2012–05 noted that this timeframe would also be established in consultation with the clearing banks and the Federal Reserve. At that time, the parties were considering whether to have the substitution process be accomplished in two batches during the day depending upon the time of submission of the notifications for substitution. The clearing banks, however, developed a real-time substitution mechanism for both tri-party and GCF collateral making batch processing unnecessary.

[26] Securities Exchange Act Release No. 34–65213 (August 29, 2011) 76 FR 54824 (September 2, 2011)

[27] Securities Exchange Act Release No. 34–67277 (June 20, 2012) 77 FR 38108 (June 26, 2012)

[28] Securities Exchange Act Release No. 34–70068 (July 30, 2013) 78 FR 47453 (August 5, 2013)

(c) Not applicable.
(d) Not applicable.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove 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–FICC–2014–02 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FICC–2014–02. 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 of submission. 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 FICC and on FICC's Web site at *http://www.dtcc.com/~/media/Files/Downloads/legal/rule-filings/2014/ficc/SR-FICC%202014-02.ashx.* 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 the File Number SR–FICC–2014–02 and should be submitted on or before June 13, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–11964 Filed 5–22–14; 8:45 am]

BILLING CODE 8011–01–P

[29] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

China Green Lighting Limited, China Kangtai Cactus Bio-Tech, Inc., Gemco Minerals, Inc., Perfectenergy International Limited, and Rodobo International, Inc.; Order of Suspension of Trading

May 21, 2014.

China Green Lighting Limited (CIK No. 1421378) is a delinquent Colorado corporation located in Jiangshan City, China with a class of securities registered with the Commission pursuant to Exchange Act Section 12(g). China Green Lighting Limited is delinquent in its periodic filings with the Commission, having not filed any periodic reports since it filed a Form 10–Q for the period ended September 30, 2011, which reported a net loss of $1,252,940 for the prior nine months. As of May 8, 2014, the company's stock (symbol ''CHGL'') was quoted on OTC Link (previously, ''Pink Sheets'') operated by OTC Markets Group, Inc. (''OTC Link''), had three market makers, and was eligible for the ''piggyback'' exception of Exchange Act Rule 15c2–11(f)(3). It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of China Green Lighting Limited because it has not filed any periodic reports since the period ended September 30, 2011.

China Kangtai Cactus Bio-Tech, Inc. (CIK No. 1017699) is a revoked Nevada corporation located in Harbin, China with a class of securities registered with the Commission pursuant to Exchange Act Section 12(g). China Kangtai Cactus Biotech, Inc. is delinquent in its periodic filings with the Commission, having not filed any periodic reports since it filed a Form 10–Q for the period ended September 30, 2011. As of May 8, 2014, the company's stock (symbol ''CKGT'') was quoted on OTC Link, had eight market makers, and was eligible for the ''piggyback'' exception of Exchange Act Rule 15c2–11(f)(3). It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of China Kangtai Cactus Biotech, Inc. because it has not filed any periodic reports since the period ended September 30, 2011.

Gemco Minerals, Inc. (CIK No. 1338118) is a Florida corporation located in Langley, British Columbia, Canada, with a class of securities registered with the Commission pursuant to Exchange Act Section 12(g). Gemco Minerals, Inc. is delinquent in its periodic filings with the Commission, having not filed any periodic reports since it filed a Form 10–Q for the period ended November 30, 2009, which reported a net loss of $3,394,046 since the company's August 21, 1997 inception. As of May 8, 2014, the company's stock (symbol ''GMML'') was quoted on OTC Link, had three market makers, and was eligible for the ''piggyback'' exception of Exchange Act Rule 15c2–11(f)(3). It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Gemco Minerals, Inc. because it has not filed any periodic reports since the period ended November 30, 2009.

Perfectenergy International Limited (CIK No. 1345432) is a revoked Nevada corporation located in Shanghai, China with a class of securities registered with the Commission pursuant to Exchange Act Section 12(g). Perfectenergy International Limited is delinquent in its periodic filings with the Commission, having not filed any periodic reports since it filed a Form 10–K for the fiscal year ended September 30, 2011, which reported a net loss of $7,627,177 for the prior eleven months. As of May 8, 2014, the company's stock (symbol ''PFGY'') was quoted on OTC Link, had six market makers, and was eligible for the ''piggyback'' exception of Exchange Act Rule 15c2–11(f)(3). It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Perfectenergy International Limited because it has not filed any periodic reports since the period ended September 30, 2011.

Rodobo International, Inc. (CIK No. 1177274) is a revoked Nevada corporation located in Harbin, China with a class of securities registered with the Commission pursuant to Exchange

Act Section 12(g). Rodobo International, Inc. is delinquent in its periodic filings with the Commission, having not filed any periodic reports since it filed a Form 10–Q for the period ended June 30, 2011, which reported a net loss of $6,892,633 for the prior three months. As of May 8, 2014, the company's stock (symbol ''RDBO'') was quoted on OTC Link, had four market makers, and was eligible for the ''piggyback'' exception of Exchange Act Rule 15c2–11(f)(3). It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Rodobo International, Inc. because it has not filed any periodic reports since the period ended June 30, 2011.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. e.d.t. on May 21, 2014, through 11:59 p.m. e.d.t. on June 4, 2014.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2014–12111 Filed 5–21–14; 11:15 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13986 and #13987]

Florida Disaster # FL–00101

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of FLORIDA (FEMA—4177—DR), dated 05/14/2014.

Incident: Severe Storms, Tornadoes, Straight-line Winds, and Flooding.

Incident Period: 04/28/2014 through 05/06/2014.

Effective Date: 05/14/2014.

Physical Loan Application Deadline Date: 07/14/2014.

Economic Injury (EIDL) Loan Application Deadline Date: 02/16/2015.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 05/14/2014, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: ESCAMBIA, OKALOOSA, SANTA ROSA, WALTON.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.625
Non-Profit Organizations without Credit Available Elsewhere	2.625
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.625

The number assigned to this disaster for physical damage is 13986B and for economic injury is 13987B.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2014–11987 Filed 5–22–14; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law (Pub. L.) 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions and one extension of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB)

Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA)

Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

I. The information collection below is pending at SSA. SSA will submit it to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than July 22, 2014. Individuals can obtain copies of the collection instruments by writing to the above email address.

Medical Permit Parking Application—41 CFR 101–20—104.2—0960–0624. SSA employees and contractors with a qualifying medical condition who park at SSA-owned and leased facilities may apply to receive a medical parking permit. SSA uses three forms for this program: (1) SSA–3192, the Application and Statement, which an individual completes when first applying for the medical parking space; (2) SSA–3193, the Physician's Report, which the applicant's physician completes to verify the medical condition; and (3) SSA–3194, Renewal Certification, which medical parking permit holders complete to verify their continued need for the permit. The respondents are SSA employees and contractors seeking medical parking permits and their physicians.

Note: Because SSA employees are Federal workers exempt from the requirements of the Paperwork Reduction Act, the burden below is only for SSA contractors and physicians (of both SSA employees and contractors).

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–3192	290	1	30	145
SSA–3193	580	1	90	870
SSA–3194	93	1	5	8
Totals	963			1,023

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding the information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than June 23, 2014. Individuals can obtain copies of the OMB clearance packages by writing to *OR.Reports.Clearance@ssa.gov*.

1. Disability Update Report—20 CFR 404.1589–404.1595 and 416.988–416.996—0960–0511. As part of our statutory requirements, SSA periodically uses Form SSA–455, the Disability Update Report, to evaluate current Title II disability beneficiaries' and Title XVI disability payment recipients' continued eligibility for Social Security disability payments. Specifically, SSA uses the form to determine if: (1) There is enough evidence to warrant referring the respondent for a full medical Continuing Disability Review (CDR); (2) the respondent's impairment(s) is still present and is indicative of no medical improvement, precluding the need for a CDR; or (3) there are unresolved work-related issues for the respondent. SSA mails Form SSA–455 to specific disability recipients, whom we select as possibly qualifying for the continuing disability review process. SSA pre-fills the form with data specific to the disability recipient, except for the sections we ask the beneficiary to complete. When SSA receives the completed form, we scan it into SSA's system. This allows us to gather the information electronically to enable SSA to process the returned forms through automated decision logic to decide the proper course of action to take. The respondents are recipients of Title II and Title XVI Social Security disability payments.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–455	1,500,000	1	15	375,000

2. Request for Evidence from Doctor and Request for Evidence from Hospital—20 CFR 404 Subpart P and 20 CFR 416 Subpart I—0960–0722. Sections 223(d)(5) and 1614(a)(3)(H)(i) of the Social Security Act require claimants to furnish medical evidence of their disability when filing a disability claim. SSA uses Forms HA–66 and HA–67 to obtain evidence from medical sources identified by the claimants as having information relative to their impairments or ability to do work-related activities. In addition to accepting manual paper responses, SSA sends a barcode with the HA–66 and HA–67, allowing respondents to fax the information directly into the electronic claims folder rather than submitting it manually. SSA uses the information to determine eligibility for benefits. The respondents are medical sources, doctors, and hospitals that evaluate the claimants. Type of Request: Extension of an OMB-approved information collection.

Note: This is a correction notice. When we published the 60-day Notice for this collection on 3/3/14 at 79 FR 11852 we listed it as a revision; however, this is an extension of a currently approved information collection.

Modality of completion	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)
HA–66—Paper	3,060	22	67,320	15	16,830
HA–66—Electronic	8,940	22	196,680	15	49,170
HA–67—Paper	3,060	22	67,320	15	16,830
HA–67—Electronic	8,940	22	196,680	15	49,170
Totals	24,000		528,000		132,000

Dated: May 20, 2014.

Faye Lipsky,

Reports Clearance Director, Social Security Administration.

[FR Doc. 2014–11928 Filed 5–22–14; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 8744]

International Security Advisory Board (ISAB) Meeting Notice;

Closed Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App 10(a)(2), the Department of State announces a meeting of the International Security Advisory Board (ISAB) to take place on June 26, 2014, at the Department of State, Washington, DC.

Pursuant to section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. App 10(d), and 5 U.S.C. 552b(c)(1), it has been determined that this Board meeting will be closed to the public because the Board will be reviewing and discussing matters properly classified in accordance with Executive Order 13526. The purpose of the ISAB is to provide the Department with a continuing source of independent advice on all aspects of arms control, disarmament, nonproliferation, political-military affairs, international security, and related aspects of public diplomacy. The agenda for this meeting will include classified discussions related to the Board's studies on current U.S. policy and issues regarding arms control, international security, nuclear proliferation, cyber stability, energy security, and diplomacy.

For more information, contact Richard W. Hartman II, Executive Director of the International Security Advisory Board, U.S. Department of State, Washington, DC 20520, telephone: (202) 736–4290.

Dated: May 9, 2014.

Richard W. Hartman, II,

Executive Director, International Security Advisory Board, U.S. Department of State.

[FR Doc. 2014–11998 Filed 5–22–14; 8:45 am]

BILLING CODE 4710–27–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice before Waiver With Respect to Land at Richmond International Airport, Richmond, Virginia

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent of waiver with respect to land.

SUMMARY: The FAA is publishing notice of proposed release of 1.318 acres of land at the Richmond International Airport, Richmond, Virginia to the Henrico County for construction of the widening of Charles City Road. An additional 0.622 Acres will be permanently utilized by Henrico County within utility, and drainage easements. There are no adverse impacts to the Airport and the land is not needed for airport development as shown on the Airport Layout Plan. Fair Market Value of the land has been established. The Airport will benefit from the improvements to Charles City Road with the more efficient intersection at Airport Drive. The east and west bound through lanes and dedicated right and left turn lanes will provide a more efficient entry to the Airport. These intangible benefits will offset the value of the released property.

DATES: Comments must be received on or before *June 23, 2014.*

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Terry J. Page, Manager, FAA Washington Airports District Office, 23723 Air Freight Lane, Suite 210, Dulles, VA 20166.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Jon E. Mathiasen, President & CEO, Capital Region Airport Commission, at the following address: Jon E. Mathiasen, President & CEO, Capital Region Airport Commission, 1 Richard E. Byrd Terminal Drive, Richmond International Airport, VA 23250.

FOR FURTHER INFORMATION CONTACT: Mr. Terry Page, Manager, Washington Airports District Office, 23723 Air Freight Lane, Suite 210, Dulles, VA 20166; telephone (703) 661–1354, fax (703) 661–1370, email *Terry.Page@faa.gov.*

SUPPLEMENTARY INFORMATION: The Wendell H. Ford Aviation investment and Reform Act for the 21st Century, public Law 10–181 (Apr. 5, 2000; 114 Stat. 61) (AIR 21), as amended, requires that a 30 day public notice must be provided before the Secretary may waive any condition imposed on an interest in surplus property.

Issued in Dulles, Virginia on May 16, 2014.

Terry J. Page,

Manager, Washington Airports District Office, Eastern Region.

[FR Doc. 2014–11982 Filed 5–22–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in the City of Cleveland, Ohio

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA.

SUMMARY: This notice announces actions taken by the FHWA that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to a proposed project to connect Interstate 480 (I–480) to University Circle area in Cleveland, Ohio, Cuyahoga County, with a new boulevard. Those actions grant approvals for the project.

DATES: A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before October 20, 2014. If this date falls on a Saturday, Sunday, or legal holiday, parties are advised to file their claim no later than the business day preceding this date. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Ms. Naureen Dar, PE, Transportation Engineer, Federal Highway Administration, 200 North High Street, Columbus, Ohio, 43215; telephone: (614) 280–6846; or Mr. Gary Benesh, PE, Ohio Department of Transportation (ODOT), 5500 Transportation Blvd., Garfield Heights, Ohio 44125 telephone: (216) 584–2108.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA has taken final agency actions by issuing approvals for the following major highway improvements in the State of Ohio: The Cleveland Opportunity Corridor project. The project meets purpose of improving the roadway network within a historically underserved, economically depressed area within the City of Cleveland. It will also address the identified transportation need elements, including improving system linkage, improving mobility and supporting planned economic development. The length of the Opportunity Corridor is approximately 3.6 miles, and the project involves building an urban boulevard with traffic lights at intersections from the I–490-East 55th Street intersection to the East 105th Street-Chester Avenue intersection. The proposed boulevard will have two westbound through-lanes, but the number of eastbound through-lanes will vary. Left-turn lanes will also be added at many of the intersections. Additional amenities and mitigation measures are also provided. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Draft Environmental Impact Statement (DEIS) the project, approved on August 8, 2013, and the Final Environmental Impact Statement/Record of Decision (FEIS/ROD), approved on May 1st, 2014 and in other documents in the FHWA administrative record. The DEIS, FEIS/ROD and other documents in the FHWA administrative record are available by contacting the FHWA or ODOT at the addresses provided above or at

http://www.dot.state.oh.us/projects/ClevelandUrbanCoreProjects/OpportunityCorridor/Pages/default.aspx. This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (NEPA) [42 USC 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].
2. Air: Clean Air Act, 42 U.S.C. 7401–7671(q).
3. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers), 23 U.S.C. 319.
4. Wildlife: Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536], Marine Mammal Protection Act [16 U.S.C. 1361], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712].
5. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–11]; Archeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].
6. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].
7. Wetlands and Water Resources: Clean Water Act, 33 U.S.C. 1251–1377 (Section 404, Section 401, Section 319); Land and Water Conservation Fund (LWCF), 16 U.S.C. 4601–4604; Safe Drinking Water Act (SDWA), 42 U.S.C. 300(f)–300(j)(6); Rivers and Harbors Act of 1899, 33 U.S.C. 401–406; Wild and Scenic Rivers Act, 16 U.S.C. 1271–1287; Emergency Wetlands Resources Act, 16 U.S.C. 3921, 3931; TEA–21 Wetlands Mitigation, 23 U.S.C. 103(b)(6)(m), 133(b)(11); Flood Disaster Protection Act, 42 U.S.C. 4001–4128.
8. Executive Orders: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

Catalog of Federal Domestic Assistance Number and Title: FHWA 20.205, Highway Planning and Construction (A, B). The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Authority: 23 U.S.C. 139(l)(1); Sec. 1308, Public Law 112–141, 126 Stat. 405.

Issued on: May 9th, 2014.

Laura S. Leffler,

Division Administrator, Columbus, Ohio.

[FR Doc. 2014–11758 Filed 5–22–14; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA–2013–0470]

Hours of Service of Drivers: American Trucking Associations (ATA); Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that it has received an application from the ATA for an exemption from the 14-hour provision of the Agency's hours-of-service regulations to enable certain drivers to exclude waiting time at a natural gas or oil well site from their calculations of on-duty time. Currently, only specially trained drivers of commercial motor vehicles (CMVs) that are specially constructed to service oil and natural gas extraction sites may employ this provision. ATA proposes that FMCSA by a limited 2-year exemption that may be renewed, permit exclusion of such waiting time by drivers of CMVs who are exclusively engaged in servicing oil and natural gas extraction sites and have the opportunity to obtain rest while waiting at such sites. FMCSA requests public comment on ATA's application for exemption.

DATES: Comments must be received on or before July 7, 2014.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA–2013–0470 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the Agency name and docket number. For detailed instructions on submitting comments and additional information on the exemption process, see the **Public Participation** heading below. Note that all comments received will be posted without change to www.regulations.gov, including any personal information provided. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments received, go to www.regulations.gov, and follow the online instructions for accessing the dockets, or go to the street address listed above.

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

Public Participation: The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can get electronic submission and retrieval help and guidelines under the ''help'' section of the Federal eRulemaking Portal Web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online. Comments received after the comment closing date will be included in the docket, and we will consider late comments to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Yager, Chief, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4325. Email: *MCPSD@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations (FMCSRs) (49

CFR part 350 *et seq.*). FMCSA must publish a notice of each exemption request in the **Federal Register** [49 CFR 381.315(a)]. The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed [49 CFR 381.300(b)].

ATA Application for an Exemption

Part 395 of the FMCSRs contains the hours of service (HOS) rules for drivers of CMVs in interstate commerce. Section 395.8 of the FMCSRs requires most interstate CMV drivers to maintain a handwritten or electronic record of duty status, or log, on a 24-hour grid. They must record their duty status as either ''off duty,'' ''sleeper berth,'' ''on duty/not driving'' or ''on duty/driving.'' Drivers must keep their log up to date to the most recent change of duty status, and have their log for the current date and the preceding 7 days on board the CMV.

Generally, a driver may not record time as ''off duty'' unless he or she has been relieved of all duty and responsibility for the care and custody of the CMV, its accessories, and its cargo, and is free to pursue activities of his or her own choosing. Thus, drivers who are waiting, whether at a loading dock or at a natural gas or oil well site, are generally considered to be ''on duty.'' Section 395.3(a)(2) of the FMCSRs provides that ''a driver may drive only during a period of 14 consecutive hours after coming on duty following 10 consecutive hours off duty.'' However, the FMCSRs provide a special exception to the 14-hour rule for the waiting time of a specific classification of driver. Section 395.1(d)(2) provides, ''In the case of specially trained drivers of commercial motor vehicles that are specially constructed to service oil wells, on-duty time shall not include waiting time at a natural gas or oil well site'' (waiting-time rule). These drivers may record such waiting time as off duty time, making note of the waiting-time rule on their log. Section 395.1(d)(2) also provides that the waiting time of these drivers ''shall not be included in calculating the 14-hour period. . . .''

ATA asks that FMCSA, by a limited 2-year exemption that may be renewed, permit similar treatment of waiting time at such locations to drivers ''exclusively engaged in servicing oil and natural gas extraction sites'' who are able to establish ''a method to adequately ensure a rest opportunity while waiting.'' ATA suggests that ''trucks equipped with sleeper berths'' and ''on-site bunking or resting facilities'' would satisfy the ''rest opportunity'' standard. ATA believes the proposed exemption would encourage these drivers to obtain quality rest at extraction sites and would provide an improved standard for State officials enforcing waiting time requirements.

FMCSA can only grant an exemption if an FMCSR prevents a motor carrier from ''implementing more efficient or effective operations that would maintain a level of safety equivalent to, or greater than, the level achieved without the exemption'' [381.305(a)]. ATA asserts that its proposed exemption would maintain or exceed the level of safety of the current waiting-time rule.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315(b)(4), FMCSA requests public comment on ATA's application for an exemption from section 395.1(d)(2) (the waiting-time rule) of the FMCSRs. The Agency will consider all comments received by close of business on July 7, 2014. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will consider to the extent practicable comments received in the public docket after the closing date of the comment period.

Issued on: May 16, 2014.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2014–11957 Filed 5–22–14; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35826]

Geaux Geaux Railroad, LLC—Acquisition and Operation Exemption—Illinois Central Railroad Company

Geaux Geaux Railroad, LLC (GGRL), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire from Illinois Central Railroad Company (ICR) and to operate approximately 21.95 miles of rail line (the Line) between: (1) milepost 9.69 at or near Zee and milepost 0.00 at or near Slaughter, and (2) milepost 345.84 at or near Slaughter and milepost 358.10 at or near Maryland, in East Baton Rouge Parish, La. GGRL states it will also operate over ICR between mileposts 358.10 and 363.60 solely for purposes of interchanging traffic at ICR's Baton Rouge yard.[1]

The transaction may be consummated on or after June 7, 2014 (30 days after the notice of exemption was filed).

GGRL certifies that its projected annual revenues as a result of this transaction will not exceed those that would qualify it as a Class III rail carrier and will not exceed $5 million.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than May 30, 2014 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35826, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Beatriz Beltranena, One Federal Highway, Suite 400, Boca Raton, FL 33432, and Thomas F. McFarland, 208 South LaSalle St., Suite 1890, Chicago, IL 60604.

Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV*''.

Decided: May 19, 2014.

[1] GGRL states that it intends to contract with a rail operator to operate the Line and that the operator will seek Board authority or an exemption for such operation. GGRL further states that it will retain a residual common carrier obligation to operate the Line.

By the Board,

Rachel D. Campbell,

Director, Office of Proceedings.

Raina S. White,

Clearance Clerk.

[FR Doc. 2014–11984 Filed 5–22–14; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35828]

The Apache Railroad Company, LLC—Corporate Family Transaction Exemption—the Apache Railway Company

The Apache Railroad Company, LLC (APA), and The Apache Railway Company (Apache) (collectively, applicants) have jointly filed a verified notice of exemption under 49 CFR 1180.2(d)(3) for a corporate family transaction.

According to the applicants, APA is a noncarrier and a limited liability company established for the purpose of owning and operating a common carrier short line railroad. Apache is an existing Class III railroad. Both are wholly owned subsidiaries of Snowflake Community Foundation (Snowflake), a noncarrier entity that, according to the applicants, was established to acquire Apache's common stock to preserve the railroad's track, facilities, and operations. Applicants state that APA would acquire all of the assets, franchises, rights, obligations, and operations of Apache, which would be merged into APA. Consequently, APA would become a Class III railroad upon the consummation of this transaction.[1] According to the applicants, the purpose of this transaction is to enable Snowflake to obtain a federal loan in order to finance the acquisition of Apache's assets and operations.

Unless stayed, the exemption will be effective on June 7, 2014 (30 days after the verified notice was filed). Applicants state that they intend to consummate the proposed transaction on or about mid-June 2014.

Applicants state that the transaction qualifies for the class exemption for corporate family transactions under 49 CFR 1180.2(d)(3) and have not indicated that the transaction would result in adverse changes in service levels, significant operational changes, or any changes in the competitive balance with carriers outside the corporate family.

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under §§ 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because the only carrier involved is a Class III rail carrier.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later May 30, 2014 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35828, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on John D. Heffner, Strasburger & Price, LLP, 1025 Connecticut Ave. NW., Suite 717, Washington, DC 20036.

Board decisions and notices are available on our Web site at ''WWW.STB.DOT.GOV.''

Decided: May 19, 2014.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2014–12005 Filed 5–22–14; 8:45 am]

BILLING CODE 4915–01–P

[1] Pursuant to 49 CFR 1180.6(a)(7)(ii), applicants are required to submit ''a copy of any contract or other written instrument entered into, or proposed to be entered into, pertaining to the proposed transaction.'' According to the applicants, an agreement has not yet been prepared. Applicants are directed to file a copy of the agreement as soon as it is available.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35789]

Pacific Harbor Line, Inc.—Lease and Operation Exemption—Union Pacific Railroad Company

Pacific Harbor Line, Inc. (PHL), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to lease from Union Pacific Railroad Company (UP), and to operate, pursuant to a lease agreement, approximately 30,820 feet of rail line, known as the Santa Ana Bypass Track, extending from milepost 21.7 at CP Compton to milepost 15.9 at Firestone Park in Los Angeles County, Cal.

This transaction is related to a concurrently filed verified notice of exemption in *Pacific Harbor Line, Inc.—Operation Exemption—Union Pacific Railroad Company,* Docket No. FD 35814, wherein PHL seeks Board approval to operate, also pursuant to the above lease agreement, approximately 5.75 miles of rail line that UP currently operates in Los Angeles County, Cal. This line is owned by the City of Los Angeles, Cal., acting by and through its Board of Harbor Commissioners, and the City of Long Beach, Cal., acting by and through its Board of Harbor Commissioners.

According to PHL, the agreement between PHL and UP does not contain any provision that may limit future interchange of traffic with any third-party connecting carrier. PHL states that, under the terms of the lease, UP will retain the exclusive common carrier obligation to provide service over the line.

PHL intends to consummate the proposed transaction 30 days or more after the exemption was filed (May 7, 2014), or 60 days or more after filing its certification with the Board pursuant to 49 CFR 1150.42(e).

PHL certifies that its projected annual revenues as a result of this transaction will not result in the creation of a Class II or Class I rail carrier. Because PHL's projected annual revenues will exceed $5 million, PHL certified to the Board on April 30, 2014, that it had complied with the requirements of 49 CFR 1150.32(e) by providing notice to employees and their labor unions on the affected 30,820 feet of rail line. Under 49 CFR 1150.32(e), this exemption cannot become effective until 60 days after the date notice was provided, which would be June 29, 2014.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than June 20, 2014 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35789, must be filed with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Rose-Michele Nardi, Transport Counsel PC, 1701 Pennsylvania Avenue NW., Suite 300, Washington, DC 20006.

Board decisions and notices are available on our Web site at ''*www.stb.dot.gov.*''

Decided: May 19, 2014.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Raina S. White,

Clearance Clerk.

[FR Doc. 2014–11988 Filed 5–22–14; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35814]

Pacific Harbor Line, Inc.—Operation Exemption—Union Pacific Railroad Company

Pacific Harbor Line, Inc. (PHL), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to operate, pursuant to a lease agreement, approximately 5.75 miles of track owned by the City of Los Angeles, Cal., acting by and through its Board of Harbor Commissioners (POLA), and the City of Long Beach, Cal., acting by and through its Board of Harbor Commissioners (POLB), and over which Union Pacific Railroad Company (UP) currently operates. Specifically, the 5.75 miles of rail line consists of: (1) approximately 5.5 miles extending from milepost 10.6 (CP Compton) to milepost 16.1 (CP West Thenard), known as the Rail Corridor Portion; and (2) an industrial lead (no known mileposts), known as the Drill Track Portion, extending less than a quarter mile in length and located on the west side of the Rail Corridor Portion in Los Angeles County, Cal. (the Subject Track).

This transaction is related to a concurrently filed verified notice of exemption in *Pacific Harbor Line, Inc.—Lease and Operation Exemption—Union Pacific Railroad Company,* Docket No. FD 35789, wherein PHL seeks Board approval to lease and operate approximately 30,820 feet of rail line, known as the Santa Ana Bypass Track, extending from milepost 21.7 at CP Compton to milepost 15.9 at Firestone Park in Los Angeles County, Cal.

According to PHL, the proposed grant of authority to operate over the Subject Track is necessary because it will allow PHL to access a line of railroad it is seeking to lease and operate in its verified notice of exemption filed in Docket No. FD 35789. PHL states that, pursuant to an agreement among themselves, POLA, POLB, and the Alameda Corridor Transportation Authority (ACTA), have consented to UP's grant of certain operating rights to PHL over the Subject Track.

PHL states that the agreement between PHL and UP does not contain any provision that may limit future interchange of traffic with any third-party connecting carrier.

PHL intends to consummate the proposed transaction 30 days or more after the exemption was filed (May 7, 2014), or 60 days or more after filing its certification with the Board pursuant to 49 CFR 1150.42(e).

PHL certifies that its projected annual revenues as a result of this transaction will not result in the creation of a Class II or Class I rail carrier. Because PHL's projected annual revenues will exceed $5 million, PHL certified to the Board on April 30, 2014, that it had complied with the requirements of 49 CFR 1150.32(e) by providing notice to employees and their labor unions on the affected 5.75-mile line. Under 49 CFR 1150.32(e), this exemption cannot become effective until 60 days after the date notice was provided, which would be June 29, 2014.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than June 20, 2014 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35814, must be filed with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Rose-Michele Nardi, Transport Counsel PC, 1701 Pennsylvania Avenue NW., Suite 300, Washington, DC 20006.

Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV.*''

Decided: May 19, 2014.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2014–12006 Filed 5–22–14; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35827]

Union Pacific Railroad Company—Temporary Trackage Rights Exemption—Dallas Area Rapid Transit and Fort Worth Transportation Authority

Trinity Railway Express (TRE),[1] pursuant to a written trackage rights agreement dated May 2, 2014, has agreed to grant Union Pacific Railroad Company (UP) temporary overhead trackage rights over approximately 1.4 miles of the TRE Rail Corridor in Ft. Worth, Tex., between milepost 610.5 (the T&P Station) and milepost 611.9 (the 6th Street Junction).

The transaction may be consummated on or after June 7, 2014, the effective date of the exemption (30 days after the verified notice of exemption was filed). The temporary trackage rights are scheduled to expire on December 30, 2014. The purpose of the temporary trackage rights is to allow UP to continue providing rail service between adjacent UP lines during outages on connecting UP lines caused by construction of improvements to Tower 55.

As a condition to the exemption, any employees affected by the acquisition of the temporary trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc., 354 I.C.C. 605 (1978),* as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad,* 360 I.C.C. 653 (1980), and any employees affected by the discontinuance of those trackage rights will be protected by the conditions set out in *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

The verified notice of exemption is filed under 49 CFR 1180.2(d)(8). If it contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the

[1] Dallas Area Rapid Transit (DART) and the Fort Worth Transportation Authority (the T) are regional transportation authorities established under Chapter 452 of the Texas Transportation Code. *See Dall. Area Rapid Transit—Acquis. & Operation Exemption—Certain Lines of the Atchison, Topeka & Santa Fe Ry.,* FD 32611 (ICC served Mar. 17, 1995). DART and the T are collectively referred to as Trinity Railway Express.

effectiveness of the exemption. Petitions for stay must be filed no later than May 30, 2014 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35827, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Jeremy Berman, 1400 Douglas Street, Union Pacific Railroad Company, STOP 1580, Omaha, NE 68179.

Board decisions and notices are available on our Web site at ''WWW.STB.DOT.GOV.''

Decided: May 19, 2014.

By the Board,

Rachel D. Campbell,

Director, Office of Proceedings.

Raina S. White,

Clearance Clerk.

[FR Doc. 2014–11985 Filed 5–22–14; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

May 20, 2014.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before June 23, 2014 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at *PRA@treasury.gov,* or the entire information collection request may be found at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

OMB Number: 1545–0002.

Type of Review: Revision of a currently approved collection.

Title: Employee Representative's Quarterly Railroad Tax Return.

Form: CT–2.

Abstract: Employee representatives file Form CT–2 quarterly to report compensation on which railroad retirement taxes are due. IRS uses this information to ensure that employee representatives have paid the correct tax. Form CT–2 also transmits the tax payment.

Affected Public: Individuals or Households.

Estimated Burden Hours: 132.

OMB Number: 1545–0200.

Type of Review: Extension without change of a currently approved collection.

Title: Application for Determination for Adopters of Master or Prototype or Volume Submitter Plans.

Form: 5307.

Abstract: This form is filed by employers or plan administrators who have adopted a prototype plan approved by the IRS National Office or a regional prototype plan approved by the IRS District Director to obtain a ruling that the plan adopted is qualified under IRC sections 401(a) and 501(a). It may not be used to request a letter for a multiple employer plan.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 5,139,000.

OMB Number: 1545–1083.

Type of Review: Revision of a currently approved collection.

Title: TD 8434—Treatment of Dual Consolidated Losses (INTL–399–88).

Abstract: Section 1503(d) denies use of the losses of one domestic corporation by another affiliated domestic corporation where the loss corporation is also subject to the income tax of another country. The regulation allows an affiliate to make use of the loss if the loss has not been used in the foreign group, to take the loss into income upon future use of the loss in the foreign country. The regulation also requires separate accounting for a dual consolidated loss where the dual resident corporation files a consolidated return.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 1,620.

OMB Number: 1545–1205.

Type of Review: Extension without change of a currently approved collection.

Title: Disabled Access Credit.

Form: 8826.

Abstract: Code section 44 allows eligible small businesses to claim a non-refundable income tax credit of 50 percent of the amount of eligible access expenditures for any tax year that exceed $250 but do not exceed $10,250. Form 8826 figures the credit and the tax limit.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 89,027.

OMB Number: 1545–1476.

Type of Review: Extension without change of a currently approved collection.

Title: TD 8687—Source of Income From Sales of Inventory and Natural Resources Produced in One Jurisdiction and Sold in Another Jurisdiction (INTL–3–95).

Abstract: The information requested is necessary for the Service to audit taxpayers' returns to ensure taxpayers have properly determined the source of income from sales of inventory produced in one country and sold in another.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 1,250.

OMB Number: 1545–1634.

Type of Review: Extension without change of a currently approved collection.

Title: TD 9595—Consolidated Overall Foreign Losses, Separate Limitation Losses, and Overall Domestic Losses (REG–141399–07).

Abstract: These regulations provide rules for the apportionment of a consolidated group's overall domestic loss (CODL), overall foreign loss (COFL) and separate limitation loss (CSLL) accounts to a departing member. The regulations affect consolidated groups of corporations that compute the foreign tax credit limitation or that dispose of property used in a foreign trade or business.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 3,000.

OMB Number: 1545–1756.

Type of Review: Extension without change of a currently approved collection.

Title: Revenue Procedure 2001–56, Demonstration Automobile Use.

Abstract: This revenue procedure provides optional simplified methods for determining the value of the use of demonstration automobiles provided to employees by automobile dealerships.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 100,000.

OMB Number: 1545–1931.

Type of Review: Extension without change of a currently approved collection.

Title: TD 9237—Designated Roth Contributions to Cash or Deferred Arrangements Under Section 401(k).

Abstract: The regulations provide special rules relating to designed Roth contributions under a section 401(k) plan. Under section 1.401(k)-l(f)(1) or the regulations, one of the requirements that must be met for contributions to be considered designated Roth contribution is that they must be maintained by the plan in a separate account. Section 1.401(k)-l(f)(2) of the regulations provides that, under the separate accounting requirement, contributions and withdrawals of designated Roth contributions must be credited and debited to a designated Roth contribution account maintained for the employee who made the designation and the plan must maintain a record of the employee's investment in the contract employee's designated Roth contribution account.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Annual Burden Hours: 157,500.

OMB Number: 1545–2024.

Type of Review: Extension without change of a currently approved collection.

Title: Limited Payability Claim Against the United States For Proceeds of an Internal Revenue Refund Check.

Form: 13818.

Abstract: This form is used by taxpayers for completing a claim against the United States for the proceeds of an Internal Revenue refund check.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 4,000.

OMB Number: 1545–2190.

Type of Review: Extension without change of a currently approved collection.

Title: IRS Paid Preparer Tax Identification Number (PTIN) Application and Renewal.

Form: W–12.

Abstract: Paid tax return preparers are required to obtain a preparer tax identification number (PTIN) by completing Form W–12, IRS Paid Preparer Tax Identification Number (PTIN) Application and Renewal, and to pay the fee required with the application. A third party will administer the PTIN application process. Most applications will be filled out on-line. Form W–12 will be used to collect the information required by § 1.6109–2 and to collect the information the third party needs to administer the PTIN application process.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 1,464,000.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2014–12007 Filed 5–22–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Additional Identifying Information Associated With Persons Whose Property and Interests in Property Are Blocked Pursuant to Executive Order 13667 of May 12, 2014, ''Blocking Property of Certain Persons Contributing to the Conflict in the Central African Republic''

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (''OFAC'') is publishing additional identifying information associated with the five individuals listed in the Annex to Executive Order 13667 of May 12, 2014, ''Blocking Property of Certain Persons Contributing to the Conflict in the Central African Republic,'' whose property and interests in property are therefore blocked.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Compliance Outreach & Implementation, Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Avenue NW., (Treasury Annex), Washington, DC 20220, Tel.: 202/622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*http://www.treasury.gov/about/organizational-structure/offices/Pages/Office-of-Foreign-Assets-Control.aspx*) or via facsimile through a 24-hour fax-on-demand service, Tel.: 202/622–0077.

Background

On May 12, 2014, the President issued Executive Order 13667 ''Blocking Property of Certain Persons Contributing to the Conflict in the Central African Republic'' (the ''Order'') pursuant to, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701–06). The Order was effective at 12:01 a.m. eastern daylight time on May 13, 2014.

Section 1 of the Order blocks, with certain exceptions, all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any United States person, of persons listed in the Annex to the Order and of persons determined by the Secretary of the Treasury, in consultation with the Secretary of State, to satisfy certain criteria set forth in the Order.

The Annex to the Order lists five individuals whose property and interests in property are blocked pursuant to the Order. OFAC is publishing additional identifying information associated with those individuals.

The listings for these individuals on OFAC's list of Specially Designated Nationals and Blocked Persons appear as follows:

Individuals

1. ADAM, Noureddine (a.k.a. ADAM, Nourreddine; a.k.a. ADAM, Nourredine; a.k.a. ADAM, Nourreldine; a.k.a. ADAM, Nureldine); DOB 1969 to 1971; POB Ndele, Central African Republic; nationality Central African Republic; General; Former Minister of Public Security (individual) [CAR].
2. BOZIZE, Francois (a.k.a. BOZIZE, Francois Yangouvonda; a.k.a. YANGOUVONDA, Bozize); DOB 14 Oct 1946; POB Gabon; Former President of the Central African Republic (individual) [CAR].
3. DJOTODIA, Michel (a.k.a. DJOTODIA, Michel Am-Nondroko), Benin; DOB 1949; POB Vakaga Region, Central African Republic; nationality Central African Republic (individual) [CAR].
4. MISKINE, Abdoulaye (a.k.a. KOUMTAMADJI, Martin Nadingar; a.k.a. NKOUMTAMADJI, Martin); DOB 05 Oct 1965; alt. DOB 03 Mar 1965; POB Kobo, Central African Republic; alt. POB Ndinaba, Chad; nationality Chad; General (individual) [CAR].
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Dated: May 15, 2014.

Barbara C. Hammerle,

Acting Director, Office of Foreign Assets Control.

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Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, *et al.*

Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 424

[CMS–4159–F]

RIN 0938–AR37

Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

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

ACTION: Final rule.

SUMMARY: The final rule will revise the Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement statutory requirements; improve program efficiencies; and clarify program requirements. The final rule also includes several provisions designed to improve payment accuracy.

DATES: *Effective Dates:* These regulations are effective on July 22, 2014 except for the amendment in instruction 27 to § 423.100, the amendment in instruction 30 to § 423.501, and the amendment in instruction 34 to § 423.505, which are effective on January 1, 2016.

Applicability Dates: In the **SUPPLEMENTARY INFORMATION** section of this final rule, we provide a table (Table 1) which lists key changes in this final rule that have an applicability date other than the effective date of this final rule.

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SUPPLEMENTARY INFORMATION: Table 1 lists key changes that have an applicability date other than 60 days after the date of publication of this final rule. The applicability dates are discussed in the preamble for each of these items.

TABLE 1—APPLICABILITY DATE OF KEY PROVISIONS OTHER THAN 60 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE

Preamble section	Section title	Applicability date
III.A.4	Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C)).	01/01/2016
III.A.7	Agent/Broker Compensation Requirements (§§ 422.2274 and 423.2274)	01/01/2015
III.A.20	Enrollment Requirements for the Prescribers of Part D Covered Drugs (§ 423.120(c)(6))	06/01/2015
III.A.24	Eligibility of Enrollment for Incarcerated Individuals (§§ 417.1, 417.460(b)(2)(i), 417.460(f)(1)(i)(A) through (C), 422.74(d)(4)(i)(A), 422.74(d)(4)(v), 423.44(d)(5)(iii) and (iv)).	01/01/2015

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Acronyms

ADS Automatic Dispensing System
AEP Annual Enrollment Period
AHFS American Hospital Formulary Service
AHFS–DI American Hospital Formulary Service–Drug Information
AHRQ Agency for Health Care Research and Quality

ALJ Administrative Law Judge
ANOC Annual Notice of Change
AO Accrediting Organization
AOR Appointment of Representative
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA [Medicare, Medicaid, and SCHIP] Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
BLA Biologics License Application
CAHPS Consumer Assessment Health Providers Survey
CAP Corrective Action Plan
CCIP Chronic Care Improvement Program
CC/MCC Complication/Comorbidity and Major Complication/Comorbidity
CCS Certified Coding Specialist
CDC Centers for Disease Control
CHIP Children's Health Insurance Programs
CMP Civil Money Penalty
CMR Comprehensive Medical Review
CMS Centers for Medicare & Medicaid Services
CMS–HCC CMS Hierarchal Condition Category
CTM Complaints Tracking Module
COB Coordination of Benefits
CORF Comprehensive Outpatient Rehabilitation Facility
CPC Certified Professional Coder
CY Calendar year
DAB Departmental Appeals Board
DEA Drug Enforcement Administration
DIR Direct and Indirect Remuneration
DME Durable Medical Equipment
DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
D–SNPs Dual Eligible SNPs
DOL U.S. Department of Labor
DUA Data Use Agreement
DUM Drug Utilization Management
EAJR Expedited Access to Judicial Review
EGWP Employer Group/Union-Sponsored Waiver Plan
EOB Explanation of Benefits
EOC Evidence of Coverage
ESRD End-Stage Renal Disease
FACA Federal Advisory Committee Act
FDA Food and Drug Administration
FEHBP Federal Employees Health Benefits Plan
FFS Fee-For-Service
FIDE Fully-integrated Dual Eligible
FIDE SNPs Fully-integrated Dual Eligible Special Needs Plans
FMV Fair Market Value
FY Fiscal year
GAO Government Accountability Office
HAC Hospital-Acquired Conditions
HCPP Health Care Prepayment Plans
HEDIS HealthCare Effectiveness Data and Information Set
HHS [U.S. Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HMO Health Maintenance Organization
HOS Health Outcome Survey
HPMS Health Plan Management System
ICL Initial Coverage Limit
ICR Information Collection Requirement
ID Identification
IVC Initial Validation Contractor
LCD Local Coverage Determination
LEP Late Enrollment Penalty
LIS Low Income Subsidy
LPPO Local Preferred Provider Organization
LTC Long Term Care
MA Medicare Advantage
MAAA Member of the American Academy of Actuaries
MA–PD Medicare Advantage–Prescription Drug Plan
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MOC Medicare Options Compare
MOOP Maximum Out-of-Pocket
MPDPF Medicare Prescription Drug Plan Finder
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MS–DRG Medicare Severity Diagnosis Related Group
MSA Metropolitan Statistical Area
MSAs Medical Savings Accounts
MSP Medicare Secondary Payer
MTM Medication Therapy Management
MTMP Medication Therapy Management Program
NAIC National Association of Insurance Commissioners
NCD National Coverage Determination
NCPDP National Council for Prescription Drug Programs
NCQA National Committee for Quality Assurance
NDA New Drug Application
NDC National Drug Code
NGC National Guideline Clearinghouse
NIH National Institutes of Health
NOMNC Notice of Medicare Non-Coverage
NPI National Provider Identifier
NWS National Weather Service
OIG Office of Inspector General
OMB Office of Management and Budget
OPM Office of Personnel Management
OTC Over the Counter
Part C Medicare Advantage
Part D Medicare Prescription Drug Benefit Program
PBM Pharmacy Benefit Manager
PDE Prescription Drug Event
PDP Prescription Drug Plan
PFFS Private Fee For Service Plan
POA Present on Admission (Indicator)
POS Point-of-Sale
PPO Preferred Provider Organization
PPS Prospective Payment System
P&T Pharmacy & Therapeutics
QIC Qualified Independent Contractor
QIO Quality Improvement Organization
QRS Quality Review Study
PACE Programs of All Inclusive Care for the Elderly
RADV Risk Adjustment Data Validation
RAPS Risk Adjustment Payment System
RPPO Regional Preferred Provider Organization
SCORM Sharable Content Object Reference Model
SEP Special Election Period
SHIP State Health Insurance Assistance Programs
SNF Skilled Nursing Facility
SNP Special Needs Plan
SPAP State Pharmaceutical Assistance Programs
SSA Social Security Administration
SSI Supplemental Security Income
T&C Terms and Conditions
TPA Third Party Administrator
TrOOP True Out-Of-Pocket
U&C Usual and Customary
UPIN Uniform Provider Identification Number
USP U.S. Pharmacopoeia

I. Executive Summary

A. Purpose

The purpose of this final rule is to make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain provisions of the Affordable Care Act. This final rule is necessary to—(1) clarify various program participation requirements; (2) improve payment accuracy; and (3) make other clarifications and technical changes.

B. Summary of the Major Provisions

1. Modifying the Agent/Broker Requirements, Specifically Agent/Broker Compensation

The former regulatory compensation structure was comprised of a 6-year cycle that ended December 31, 2013. Under that structure, MA organizations and Part D sponsors provided an initial compensation payment to independent agents for new enrollees (Year 1), and paid a renewal rate (equal to 50 percent of the initial year compensation) for Years 2 through 6. MA organizations and Part D sponsors had the option to pay the 50 percent renewal rate for CY2014 (year 1). This compensation structure proved to be complicated to implement and monitor, and also created an incentive for agents to move beneficiaries as long as the fair market value (FMV) continued to increase each year. To resolve these issues, we proposed to revise the compensation structure. Under our proposal, MA organizations and Part D sponsors would continue to have the discretion to decide, on an annual basis, whether or not to use independent agents. Also, for new enrollments, MA organizations and Part D sponsors could determine what their initial rate would be, up to the CMS designated FMV amount. For renewals in Year 2 and subsequent years, with no end date, the MA organization or Part D sponsor could pay up to 35 percent of the current FMV amount for that year. We believed that revising the existing compensation

structure to allow MA organizations or Part D sponsors to pay up to 35 percent of the FMV for year 2 and subsequent years was appropriate based on a couple of factors. First, we believed that a 2 tiered payment system (that is, initial and renewal) would be significantly less complicated than a 3-tiered system (that is, initial, 50 percent renewal for years 2 through 6, and 25 percent residual for years 7 and subsequent years), and would reduce administrative burden and confusion for plan sponsors. Second, our analysis determined that 35 percent was the renewal compensation level at which the present value of overall payments under a 2-tiered system would be relatively equal to the present value of overall payments under a 3-tiered system (taking into account the estimated life expectancy for several beneficiary age cohorts). In addition to revising the agent and broker compensation structures, we proposed to amend the training and testing requirements as well as setting limits on referral fees ($100) for agents and brokers.

We received more than 140 comments from agents, health plans, and trade associations opposing the 35 percent renewal rate, and instead suggesting that CMS maintain the 50 percent renewal rate. A number of commenters expressed concerns that the proposed reduction in compensation would represent a significant decrease from the current compensation limit, and a rate set at 50 percent of FMV would be in line with industry standard. They noted that the higher compensation amount would be particularly important for stand-alone prescription drug plans, as 35 percent would be insufficient to cover an agent's costs associated with the renewal transaction and could discourage agents from assisting in the annual evaluation of a Medicare beneficiary's options. Commenters also stated that, compared to current practice, the proposed 35 percent renewal rate is a reduction since a number of MA plans began offering a renewal rate of 50 percent for 10 years or more at the end of the 6-year cycle (2013). The majority of commenters also stated that agents play an important role in educating beneficiaries about Medicare and the proposed reduction in the renewal rate could reduce the level and quality of services provided to beneficiaries, thereby resulting in less information sharing and poorer plan choices by beneficiaries. Many commenters also stated that agents spend a significant amount of time in training, preparing, and educating beneficiaries and that the compensation is already low relative to the hours spent. Some commenters also expressed concern that the lower compensation rate would discourage new agents from entering the MA market. Many agents stated they would have to stop selling MA products and instead sell other more profitable products. No plans strongly supported the 35 percent renewal rate. Therefore, we are modifying the compensation renewal rate from up to 35 percent to up to 50 percent. These changes will be applicable for enrollments effective January 2015. Because the proposed rate is similar to previous regulatory requirements, present CMS guidance, and industry practice, we believe this implementation timeframe is reasonable and appropriate. We are not finalizing the proposed changes to agent and broker training and testing at this time. We are finalizing limits on referral fees for agents as proposed.

2. Drug Categories or Classes of Clinical Concern

We are not finalizing any new criteria and will maintain the existing six protected classes.

3. Improving Payment Accuracy—Implementing Overpayment Provisions of Section 1128J(d) of the Social Security Act (§§ 422.326 and 423.360)

These proposed regulatory provisions codify the Affordable Care Act requirement establishing section 1128J(d) of the Act that MA organizations and Part D sponsors report and return identified Medicare overpayments.

We proposed to adopt the statutory definition of overpayment for both Part C and Part D, which means any funds that an MA organization or Part D sponsor has received or retained under Title XVIII of the Act to which the MA organization or Part D sponsor, after applicable reconciliation, is not entitled under such title. To reflect the unique structure of Part C and Part D payments to plan sponsors, we also propose to define two terms included in the statutory definition of overpayments: ''funds'' and ''applicable reconciliation.'' We proposed to define funds as payments an MA organization or Part D sponsor has received that are based on data that these organizations submitted to CMS for payment purposes. For Part C we proposed that applicable reconciliation occurs on the annual final risk adjustment data submission deadline. For Part D, we proposed that applicable reconciliation occurs on the date that is the later of either the annual deadline for submitting prescription drug event (PDE) data for the annual Part D payment reconciliations referred to in § 423.343(c) and (d) or the annual deadline for submitting DIR data.

In addition, we proposed to state in regulation that an MA organization or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. An MA organization or Part D sponsor must report and return any identified overpayment it received no later than 60 days after the date on which it identified it received an overpayment. The MA organization or Part D sponsor must notify CMS, using a notification process determined by CMS, of the amount and reason for the overpayment. Finally, we proposed a look-back period with an exception for overpayments resulting from fraud, whereby MA organizations and Part D sponsors would be held accountable for reporting overpayments within the 6 most recent completed payment years for which the applicable reconciliation has been completed.

We received approximately 30 comments from organizations and individuals. Generally, commenters supported establishing separate applicable reconciliation dates for Part C and Part D. Many commenters questioned when the 60-day period for reporting and returning begins, and what activities constitute reporting and returning an overpayment to CMS, including questions about estimating an amount of overpayment. A number of commenters also requested to clarify the standards for ''identifying'' an overpayment, including questions about the meaning of reasonable diligence. Finally, a few commenters recommended that we impose the same limitation on the look-back period for all overpayments, even those relating to fraud.

We are finalizing the provisions at §§ 422.326 and 423.360, with the following modifications. First, we add at the end of paragraph § 422.326(d) the phrase ''unless otherwise directed by CMS for the purpose of § 422.311.'' Also, to increase clarity we revise §§ 422.326(c) and 423.360(c) regarding identified overpayments. Finally, we strike the following sentence in the proposed paragraphs on the 6-year look-back period: ''Overpayments resulting from fraud are not subject to this limitation of the lookback period.''

4. Risk Adjustment Data Requirements

We proposed several amendments to § 422.310 to strengthen existing regulations related to the accuracy of

risk adjustment data, including: (1) A requirement that medical record reviews, if used, be designed to determine the accuracy of diagnoses submitted under §§ 422.308(c)(1) and 422.310(g)(2); (2) a revision in the deadlines for submission of risk adjustment data; and (3) a limitation on the type and purpose of late data submissions. We also proposed a restructuring of subparagraph (g)(2) as part of the revisions. We received approximately 25 comments from organizations and individuals regarding these proposals; many of the comments were concerned and critical of the proposals, highlighting vagueness and the potential for operational instability. For reasons discussed in more detail below in section III.B.2 of the preamble, we are not finalizing the proposed amendment regarding the scope of medical reviews and we are not finalizing at this time the proposal to change the date for final risk adjustment data submission. We are finalizing as proposed the restructuring of §§ 422.310(g)(2) and the 422.310(g)(2)(ii) provision to prohibit submission of diagnoses for additional payment after the final risk adjustment data submission deadline.

C. Summary of Costs and Benefits

TABLE 2—SUMMARY OF COSTS AND BENEFITS

Provision description	Total costs	Transfers
Modifying the agent/broker requirements, specifically agent/broker compensation.	N/A	N/A
Improving Payment Accuracy	N/A	N/A
Eligibility of Enrollment for Incarcerated Individuals.		We estimate that this change could save the MA program up to $27 million in 2015, increasing to $103 million in 2024 (total of $650 million over this period), and could save the Part D program (includes the Part D portion of MA PD plans) up to $46 million in 2015, increasing to $153 million in 2024 (total of $965 million over this period).

II. Background

A. General Overview and Regulatory History

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) created a new ''Part C'' in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which established what is now known as the Medicare Advantage (MA) program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), enacted on December 8, 2003, added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 42 of the Act) entitled the Medicare Prescription Drug Benefit Program (PDP), and made significant changes to the existing Part C program, which it named the Medicare Advantage (MA) Program. The MMA directed that important aspects of the Part D program be similar to, and coordinated with, regulations for the MA program. Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules implementing the MMA for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively).

Since the inception of both Parts C and D, we have periodically revised our regulations either to implement statutory directives or to incorporate knowledge obtained through experience with both programs. For instance, in the September 18, 2008 and January 12, 2009 **Federal Register** (73 FR 54226 and 74 FR 1494, respectively), we issued Part C and D regulations to implement provisions in the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275). We promulgated a separate interim final rule in January 16, 2009 (74 FR 2881) to address MIPPA provisions related to Part D plan formularies. In the final rule that appeared in the April 15, 2010 **Federal Register** (75 FR 19678), we made changes to the Part C and D regulations which strengthened various program participation and exit requirements; strengthened beneficiary protections; ensured that plan offerings to beneficiaries included meaningful differences; improved plan payment rules and processes; improved data collection for oversight and quality assessment; implemented new policies; and clarified existing program policy.

In a final rule that appeared in the April 15, 2011 **Federal Register** (76 FR 21432), we continued our process of implementing improvements in policy consistent with those included in the April 2010 final rule, and also implemented changes to the Part C and Part D programs made by recent legislative changes. The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010, as passed by the Senate on December 24, 2009, and the House on March 21, 2010. The Health Care and Education Reconciliation Act (Pub. L. 111–152), which was enacted on March 30, 2010, modified a number of Medicare provisions in Pub. L. 111–148 and added several new provisions. The Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act (Pub. L. 111–152) are collectively referred to as the Affordable Care Act. The Affordable Care Act included significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the Affordable Care Act concerning the Part C and D programs largely focused on beneficiary protections, MA payments, and simplification of MA and Part D program processes. These provisions affected implementation of our policies regarding beneficiary cost-sharing, assessing bids for meaningful differences, and ensuring that cost-sharing structures in a plan are transparent to beneficiaries and not excessive. In the April 2011 final rule, we revised regulations on a variety of issues based on the Affordable Care Act and our experience in administering the MA and Part D programs. The rule covered areas such as marketing, including agent/broker training; payments to MA organizations based on quality ratings; standards for determining if organizations are fiscally sound; low income subsidy policy under the Part D program; payment rules for non-contract health care providers; extending current network adequacy standards to Medicare medical savings account (MSA) plans that employ a network of providers; establishing limits on out-of-pocket expenses for MA enrollees; and several revisions to the special needs plan requirements, including changes concerning SNP approvals.

In a final rule that appeared in the April 12, 2012 **Federal Register** (77 FR 22072 through 22175), we made several changes to the Part C and Part D

programs required by statute, including the Affordable Care Act, as well as made improvements to both programs through modifications reflecting experience we have obtained administering the Part C and Part D programs. Key provisions of that final rule implemented changes closing the Part D coverage gap, or ''donut hole,'' for Medicare beneficiaries who do not already receive low-income subsidies from us by establishing the Medicare Coverage Gap Discount Program. We also included provisions providing new benefit flexibility for fully-integrated dual eligible special needs plans, clarifying coverage of durable medical equipment, and combatting possible fraudulent activity by requiring Part D sponsors to include an active and valid prescriber National Provider Identifier on prescription drug event records.

B. Issuance of a Notice of Proposed Rulemaking

In the proposed rule titled ''Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,'' which appeared in the January 10, 2014 **Federal Register** (79 FR 1918), we proposed to revise the Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement statutory requirements; strengthen beneficiary protections; exclude plans that perform poorly; improve program efficiencies; and clarify program requirements. The proposed rule also included several provisions designed to improve payment accuracy.

C. Public Comments Received in Response to the CY 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule

We received approximately 7,600 timely pieces of correspondence containing multiple comments on the CY 2014 proposed rule. While we are finalizing several of the provisions from the proposed rule, there are a number of provisions from the proposed rule (for example, enrollment eligibility criteria for individuals not lawfully present in the United States) that we intend to address later and a few which we do not intend to finalize. We also note that some of the public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading. However, we note that in this final rule we are not addressing comments received with respect to the provisions of the proposed rule that we are not finalizing at this time. Rather, we will address them at a later time, in a subsequent rulemaking document, as appropriate.

D. Provisions Not Finalized in This Final Rule

As noted previously, some of the provisions of the proposed rule will be addressed later and, therefore, are not being finalized in this rule. Table 3 lists the provisions that were proposed but are not addressed at this time. We note that several provisions that were proposed are not being finalized in this rule and are effectively being withdrawn; those provisions are not listed in Table 3.

TABLE 3—PROVISIONS NOT FINALIZED AT THIS TIME

Proposed rule section	Topic
	Clarifying Various Program Participation Requirements
III.A.2	Two-year Limitation on Submitting a New Bid in an Area Where an MA has been Required to Terminate a Low-enrollment MA Plan (§ 422.504(a)(19)).
III.A.6	Changes to Audit and Inspection Authority (§ 422.503(d)(2) and § 423.504(d)(2)).
III.A.9	Collections of Premiums and Cost Sharing (§ 423.294).
III.A.10	Enrollment Eligibility for Individuals Not Lawfully Present in the United States (§§ 417.2, 417.420, 417.422, 417.460, 422.1, 422.50, 422.74, 423.1, 423.30, and 423.44).
III.A.11	Part D Notice of Changes (§ 423.128(g)).
III.A.12	Separating the Annual Notice of Change (ANOC) from the Evidence of Coverage (EOC) (§ 422.111(a)(3) and § 423.128(a)(3)).
III.A.14	Exceptions to Drug Categories or Classes of Clinical Concern (§ 423.120(b)(2)(vi)).
III.A.15	Medication Therapy Management Program (MTMP) under Part D (§ 423.153(d)(1)(v)(A))—outreach strategies.
III.A.16	Business Continuity for MA Organizations and PDP Sponsors (§ 422.504(o) and § 423.505(p)).
III.A.21	Efficient Dispensing in Long Term Care Facilities and Other Changes (§ 423.154).
III.A.23	Medicare Coverage Gap Discount Program and Employer Group Waiver Plans (§ 423.2325).
III.A.26	Payments to PDP Plan Sponsors For Qualified Prescription Drug Coverage (§ 423.308) and Payments to Sponsors of Retiree Prescription Drug Plans (§ 423.882).
III.A.32	Transfer of TrOOP Between PDP Sponsors Due to Enrollment Changes during the Coverage Year (§ 423.464).
III.A.37	Expand Quality Improvement Program Regulations (§ 422.152).
III.A.38	Authorization of Expansion of Automatic or Passive Enrollment Non-Renewing Dual Eligible SNPs (D-SNPs) to another D-SNP to Support Alignment Procedures (§ 422.60).
	Improving Payment Accuracy
III.B.2	Determination of Payments (§ 423.329).
III.B.3	Reopening (§ 423.346).
III.B.4	Payment Appeals (§ 423.350).
III.B.5	Payment Processes for Part D Sponsors (§ 423.2320).
III.B.6	Risk adjustment data requirements—proposal regarding annual deadline for MAO submission of final risk adjustment data (§ 422.310(g)(2)(ii)).
	Strengthening Beneficiary Protections
III.C.1	Providing High Quality Health Care (§ 422.504(a)(3) and § 423.505(b)(27)).
III.C.2	MA-PD Coordination Requirements for Drugs Covered Under Parts A, B, and D (§ 422.112).

TABLE 3—PROVISIONS NOT FINALIZED AT THIS TIME—Continued

Proposed rule section	Topic
III.C.3	Good Cause Processes (§ 417.460, § 422.74 and § 423.44).
III.C.4	Definition of Organization Determination (§ 422.566).
III.C.5	MA Organizations May Extend Adjudication Timeframes for Organization Determinations and Reconsiderations (§ 422.568, § 422.572, § 422.590, § 422.618, and § 422.619).
Strengthening Our Ability to Distinguish Stronger Applicants for Part C and D Program Participation and to Remove Consistently Poor Performers	
III.D.1	Two-Year Prohibition When Organizations Terminate Their Contracts (§§ 422.502, 422.503, 422.506, 422.508, and 422.512).
III.D.2	Withdrawal of Stand-Alone Prescription Drug Plan Bid Prior to Contract Execution (§ 423.503).
III.D.3	Essential Operations Test Requirement for Part D (§§ 423.503(a) and (c), 423.504(b)(10), 423.505(b)(28), and 423.509).
III.D.4.	Termination of the Contracts of Medicare Advantage Organizations Offering PDP for Failure for 3 Consecutive Years to Achieve 3 Stars on Both Part C and Part D Summary Star Ratings in the Same Contract Year (§ 422.510).
Implementing Other Technical Changes	
III.E.1	Requirements for Urgently Needed Services (§ 422.113).
III.E.2	Skilled Nursing Facility Stays (§§ 422.101 and 422.102).
III.E.3	Agent and Broker Training and Testing Requirements (§§ 422.2274 and 423.2274).
III.E.4	Deemed Approval of Marketing Materials (§ 422.2266 and § 423.2266).
III.E.5	Cross-Reference Change in the Part C Disclosure Requirements (§ 422.111).
III.E.6	Managing Disclosure and Recusal in P&T Conflicts of Interest: [Formulary] Development and Revision by a Pharmacy and Therapeutics Committee under PDP (§ 423.120(b)(1)).
III.E.8	Thirty-Six-Month Coordination of Benefits (COB) Limit (§ 423.466(b)).
III.E.9	Application and Calculation of Daily Cost-Sharing Rates (§ 423.153).
III.E.10	Technical Change to Align Regulatory Requirements for Delivery of the Standardized Pharmacy Notice (§ 423.562).
III.E.12	MA Organization Responsibilities in Disasters and Emergencies (§ 422.100).
III.E.14	Technical Changes to Align Part C and Part D Contract Determination Appeal Provisions (§§ 422.641 and 422.644).
III.E.15	Technical Changes to Align Parts C and D Appeal Provisions (§§ 422.660 and 423.650).
III.E.17	Technical Change to the Restrictions on use of Information under Part D (§ 423.322).

III. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

A. Clarifying Various Program Participation Requirements

1. Closing Cost Contract Plans to New Enrollment (§ 422.503(b)(4))

To ensure that our original intent is realized and to eliminate the potential for organizations to move enrollees from one of their plans to another based on financial or some other interest, we proposed to revise paragraph § 422.503(b)(4)(vi)(G)(5) so that an ''entity seeking to contract as an MA organization must [n]ot accept, or share, a corporate parent organization with an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.''

In making the proposed revision to paragraph § 422.503(b), we also proposed to add the definition of ''parent organization'' to § 422.2 of the MA program definitions, specifying that, ''Parent organization means a legal entity that owns one or more other subsidiary legal entities.'' Although the MA program regulations do not currently define the term ''parent organization,'' our proposed definition is consistent with the way the term is currently used in the context of the MA program, for example, when assessing an organization's business structure. We requested comments on whether a parent organization with less than a 100 percent interest in a subsidiary legal entity should trigger the prohibition we proposed with the amendment at § 422.503(b)(4).

During the public notice and comment process, a handful of commenters provided their input on our proposal. Some of the respondents included multiple comments. The comments and our responses follow.

Comment: A commenter supported the proposal, stating that it would prevent possible shifting of sicker enrollees to cost plans and should result in Medicare savings.

Response: We thank the commenter for the support.

Comment: A commenter stated that there is no evidence of complaints about the current situation and thus no change in current policy is necessary.

Response: The intention of our initial rule was to ensure that situations not arise in which an entity was able to move an enrollee from one of its plans to another plan in the same area based on financial or other reasons that may not be in the enrollee's best interest. The current regulations limit this possibility to some extent, but, without the proposed changes, would leave open the possibility that legal entities controlled by a shared parent organization could move enrollees from one plan to another, based on something other than the enrollee's best interest.

Comment: A commenter stated that risk-adjusted payments for MA plans eliminate any incentive for an entity to move sicker enrollees from an MA plan to a cost plan.

Response: While risk adjusted payments do help to account for costs associated with sicker enrollees, it may still be advantageous for an organization to move an enrollee from an MA plan to a cost plan. Even with risk adjustment, there are other reasons an organization might want to move enrollees from one plan to another to include enrollment and other interests based on the organization's business model.

Comment: A commenter stated that, because cost plan cost-sharing and premiums must be equal to the actuarial value of Medicare fee-for-service cost-sharing, cost plan enrollees with high health care needs would have high relative costs resulting in higher premiums for the cost plan, thus removing any incentive for moving sicker enrollees from an entity's MA plan to the cost plan.

Response: MA plans also have constraints with respect to cost-sharing that affect premiums, and out-of-pocket payments by enrollees. We believe, as a result, that any difference in cost plan and MA premiums or cost-sharing is negligible and does little to remove the incentives for organizations to move enrollees from one of their plans to another.

Comment: A couple of commenters requested that, at minimum, the provision not be applied to entities that have both a cost plan and dual eligible special needs plan (D–SNP). One of the commenters states that: (1) cost plans would likely have a premium and cost sharing that would make it unattractive for dual eligibles; and (2) the regulation could eliminate D–SNPs that ''participate in longstanding dual eligible integrated plans,'' and thus the proposal ''could have the effect of hurting a major initiative of the Administration.''

Response: As we have addressed elsewhere in the comments on this issue, we do not believe that any premium and cost-sharing differences in cost plans and MA plans necessarily reduce the incentives an organization may have for moving an individual from one of its plans to another. We believe this is also the case for D–SNPs and, that in the case of D–SNPs, which are frequently made up of enrollees that are sicker and frailer than the general Medicare population, there may be even greater incentive to move these enrollees to a cost contract plan.

Comment: A commenter requested that we not finalize the proposal because cost plan enrollees will already be subject to dwindling cost plan enrollment options as a result of the cost plan competition statute. The commenter stated that if we do finalize the proposal, we should grant an exception and not require cost plans affected by the cost plan competition requirements to close to new enrollment.

Response: It isn't clear at this point what kind of overlap there might be between cost plans affected by the cost plan competition requirements and those cost plans that would have to stop accepting enrollment because of sharing a parent organization with an MA plan. However, we do not believe that a significant number of cost plans will be affected by expanding the requirement to include a shared parent organization, as the requirement is largely prospective and designed to prevent a situation that we did not originally account for, but which we believe could lead to potential harm for enrollees.

Comment: A commenter stated that ''the test should not only be whether entities have the same parent but also whether the two entities are affiliated, including if one entity is the parent of the other (rather than shares a parent).''

Response: We agree with the commenter with respect to the specific example cited and have included language in the final rule that will also trigger a prohibition on new enrollment in a cost plan in situations in which a parent organization and its subsidiary have a cost contract and MA plan in the same service area. In addition to the proposed language that MA organizations ''Not accept, or share a corporate parent organization with an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan,'' we are adding to § 422.503 (b)(4)(vi)(G)(5)(ii) that MA organizations ''Not accept, as either the parent organization owning a controlling interest of or subsidiary of an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.'' The language from the initial proposal along with the additional language will now be contained in § 422.503 (b)(4)(vi)(G)(5)(i) and (ii).

Comment: A few commenters stated that CMS should define a parent organization as an entity that ''exercises a controlling interest in the applicant.'' Other commenters stated that we should limit the definition of ''parent organization'' to the context of this provision only as our proposed definition could create inconsistencies in the Part C and D polices and guidance or have ''unanticipated implications that are difficult to identify at this time.'' One of the commenters, who asked us to limit the application of the ''parent organization'' definition to this provision only, stated that it would support our proposal if we clarified that the parent organization must have a ''controlling interest'' in the subsidiary legal entities in question.

Response: In the proposed rule, we specifically solicited comments on whether the requirement should be applied to a parent organization with less than 100 percent interest in the affected cost contract and MA plan. We agree that a controlling interest is a reasonable standard that is consistent with our intention to prevent an organization from having control over both a cost contract and MA plan in the same service area. We also agree that the threshold for determining when the prohibition should be applied is best established in the context of this provision and thus are not finalizing the definition of ''parent organization'' in § 422.2 . Instead, we are including the threshold for the prohibition in modifications in § 422.503(b)(4)(vi)(G)(5)(i) and (ii). These sections will now state that any entity seeking to contract as an MA organization—

- Not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.
- Not accept, as either the parent organization owning a controlling interest of, or subsidiary of, an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

We are finalizing the provisions of the proposed rule with the revisions and additions discussed in this section III.A.1 of this final rule.

2. Authority To Impose Intermediate Sanctions and Civil Money Penalties (§§ 422.752, 423.752, 422.760 and 423.760)

Sections 1857(a) and 1860D–12(b)(1) of the Act provided the Secretary with the authority to enter into contracts with MA organizations, and Part D sponsors (respectively). Section 1857(g)(1) of the Act provided a list of contract violations and the corresponding enforcement responses (intermediate sanctions (sanctions) and/or civil money penalties (CMPs)) are listed under section 1857(g)(2) of the Act (section 1860D–12(b)(3)(E) applied these provisions to Part D contracts).

We proposed two changes to our existing authority to impose sanctions and CMPs based on section 6408 of the Affordable Care Act (Pub. L. 111–148). The provisions of section 6408 provided CMS with the authority to impose intermediate sanctions or CMPs for violations of the Part C and D marketing and enrollment requirements. As well as, an organization that enrolls an individual without prior consent (except in certain limited circumstances) or transfers an individual to a new plan without prior consent. Additionally, we proposed to revise the language of these provisions to clarify that either CMS or the OIG may impose CMPs for the violations listed at §§ 422.752(a) and 423.752(a), except 422.752(a)(5) and 423.752(a)(5).

Comment: A commenter expressed concern and stated that MA organizations and Part D sponsors should be given the opportunity to refute marketing or other allegations of

non-compliance prior to sanctions and/or CMPs being imposed.

Response: Enforcement actions are only typically taken based on substantiated, well documented instances of non-compliance and in the case of both a sanction and a CMP, even after they are issued, MA organizations and Part D sponsors are given an opportunity to rebut or appeal CMS' determination through a formal appeals process.

Comment: A few commenters requested clarification regarding the new sanction authority, specifically the language that would allow CMS to impose intermediate sanctions on an organization that enrolls an individual without prior consent (except in certain limited circumstances) or transfers an individual to a new plan without prior consent. The commenters requested that CMS clarify that this would not apply to organizations that perform facilitated or auto-enrollment, passive enrollment, seamless enrollment or requests from Employer Group Waiver Plans (EGWPs).

Response: In the proposed rule, we proposed to amend the regulation text at §§ 422.752 and 423.752 by adding (a)(9), and (a)(7), respectively, which read: ''. . . Except as provided under § 423.34 of this chapter, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual.'' Section 423.34 specifically refers to enrollment of individuals who receive the low income subsidy (LIS) and are therefore subject to facilitated or auto-enrollment. Therefore, we believe that the proposed regulation text already makes clear that this provision would not apply to those organizations that are performing facilitated enrollment of LIS beneficiaries. Additionally, passive enrollment and use of the seamless enrollment option are initiated or approved by CMS, respectively. Therefore, an organization who is contacted by CMS to receive passive enrollment would not be considered to have performed enrollment without prior consent. As for the seamless enrollment option, as these proposals must be submitted to and approved by CMS, as long as organizations are following CMS' enrollment guidance in Chapter 2, § 40.1.4, an organization, again, would not be considered as enrolling without prior consent and would, therefore, not be considered for a possible sanction. Finally, an organization who is accepting group or individual enrollment requests from EGWPs must follow CMS' enrollment guidance in Chapter 2, § 40.1.6. As long as CMS enrollment guidance is being followed with respect to processing these enrollments, CMS would not consider MA and Part D organizations in violation of the new requirement.

Comment: One commenter stated that only one organization, either CMS or OIG should have CMP authority and that there should be no overlapping authority. They went on to state that if CMS proposed to allow overlapping CMP authority that CMS agree that the total amount of the CMPs issued not exceed what either CMS or OIG could impose separately.

Response: It is not CMS' intent to create overlapping CMP authority, simply to clarify our existing CMP authority. However, to the extent CMS or OIG were planning on pursuing a CMP, we have internal mechanisms in place to ensure that the other entity within the department is not simultaneously pursuing a CMP for the same or similar conduct. If we were to determine that OIG was pursuing a CMP for similar conduct, we would coordinate with the OIG so that only one CMP action would move forward.

Comment: One commenter requested that CMS not finalize this provision because they believe the current division of authority to impose CMPs should remain unchanged, with the authority to CMP for certain violations remaining with OIG, instead of adding to CMS' existing CMP authority, as this approach ensures a natural division of power and oversight expected from government agencies.

Response: CMS has always had the statutory authority to impose CMPs for the violations currently designated as belonging solely to the OIG in the regulation. However, CMS agrees that there are certain violations that should be retained solely by OIG for purposes of imposing CMPs, which is why the proposed rule states that the authority to impose CMPs for violations listed at §§ 422.752(a)(5) and 423.752(a)(5), involving misrepresentation or falsification of information furnished to CMS, an individual, or other entity, will continue to reside solely with the OIG.

Comment: One commenter, in addition to expressing support for our proposal, stated that CMS should authorize use of monies collected from CMPs to allow states to contract with, or grant funds to entities, provided that the funds are used for CMS approved projects to protect or improve SNF services for residents.

Response: We thank the commenter for their support and we will explore in the future if such arrangements are allowed within our current statutory authority.

Comment: We received several comments that supported the new proposed sanction authority for marketing and enrollment violations.

Response: We thank the commenters for their support.

After careful consideration of all of the comments we received, we are finalizing these proposals without modification.

3. Contract Termination Notification Requirements and Contract Termination Basis (§§ 422.510 and 423.509)

Sections 1857(c) and 1860D–12(b)(3)(B) of the Act provided us with the authority to terminate a Part C or D sponsoring organization's contract. Sections 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act provided us with the procedures necessary to facilitate the termination of those contracts. We proposed three revisions to our existing regulations that relate to contract termination.

First, we proposed to clarify the scope of our authority to terminate Part C and D contracts under §§ 422.510(a) and 423.509(a) by modifying the language at §§ 422.510(a) and 423.509(a) to separate the statutory bases for termination from our examples of specific violations which meet the standard for termination established by the statute. We proposed to effectuate this change by renumbering the list of bases contained in §§ 422.510(a) and 423.509(a).

Second, we proposed revisions to our contract termination notification procedures contained at §§ 422.510(b)(1) and 423.509(b)(1). Current regulations state that if CMS decides to terminate a Part C or Part D sponsoring organization's contract, we must notify the organization in writing 90 days before the intended date of termination. We proposed to shorten the notification timeframe from 90 days to 45 days. Additionally, in an effort to respond to changes in the media and information technology landscape, we proposed a slight modification to the termination notification provision for the general public at §§ 422.510(b)(1)(iii) and 423.509(b)(1)(iii) which includes the contracting organizations releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site instead of publishing the notice in applicable newspapers.

Finally, we proposed minor revisions to the wording of our regulations at §§ 422.510 and 423.509 to reflect the authorizing language contained in sections 1857(c)(2) and 1860D–12 of the Act. Specifically, we proposed to replace the word ''fails'' with ''failed'' so that it reads consistently throughout §§ 422.510 and 423.509.

Comment: Several commenters opposed our proposal to shorten the notification period for contract termination from 90 days to 45 days. Commenters made several arguments supporting their opposition to the shortened notification timeframe, but most stated that it is not enough time to ensure members' needs are adequately addressed, specifically noting the difficulty in effectively communicating the change with their members and ensuring their members were effectively transitioned to a new plan. Other commenters stated that the timeframe was too short to provide adequate notice to affected providers and vendors. Yet another commenter stated that the shortened timeframe did not allow enough time for a plan to appeal the termination. A final commenter noted that the shortened timeframe would increase costs to the contracting organization if the termination period is reduced.

Response: After carefully considering the commenters' concerns, we respectfully disagree that these concerns outweigh the need to protect beneficiaries and have them moved from a plan that is in such substantial non-compliance with our regulations that CMS would proceed with termination. Plans that receive a notice of termination from CMS are instructed that they must provide notice to their affected beneficiaries at least 30 days prior to the effective date of the termination. If CMS provides their notice of termination to contracting organizations 45 days before the effective date of the termination, this affords plans 15 days to issue their notice to enrollees while still complying with the existing 30-day beneficiary notification requirements. While we do request that terminated plans work with the receiving plan to transition enrollee data and records, it is not expected that these tasks would be completed by the effective date of the termination, but would instead begin upon transfer of the enrollees once the termination was actually effective.

As for adequate notification to affected vendors and providers, it is the responsibility of the contracting organization to design their contracts with their providers and vendors in a manner that recognizes possible contract actions, such as termination, that could be taken by CMS. For example, all plans that have a contract with CMS could ultimately be subject to immediate termination if they are found in such substantial non-compliance by CMS that it poses an imminent and serious risk to Medicare enrollees. Therefore, most, if not all plans, likely have clauses in their provider and vendor contracts that allow them to terminate these contracts expeditiously with the affected entities in the event of a contract termination by CMS.

We also do not agree that the shortened timeframe in any way affects a contracting organization's ability to appeal. Contracting organizations who are subject to a contract termination in §§ 422.510(b) or 423.509(b) must file their request for a hearing within 15 days from the date of receipt of the notice of termination. A timely filed request for hearing effectively stays the termination proceeding until a hearing decision is reached. Consequently, shortening the notice of termination from 90 to 45 days should have no impact on a contracting organization's ability to file an appeal of the contract termination.

Finally, we do not agree that the shortened notice timeframe to effectuate a termination would result in increased costs to an organization. We already have the ability to prorate its payment to an organization for terminations that are effective in the middle of a month; consequently we do not agree that shortening the notification timeframe would in any way change the CMS's current approach to payment or recoupment of capitated payments in these circumstances.

Comment: One commenter suggested that CMS should have different notification timeframes for termination. They recommended that 90 day notice be provided to all post-acute care (PAC) providers as well as to beneficiaries in PAC. They stated that 45 days for notice may be sufficient for non-post-acute care beneficiaries, but not for people in a short stay setting. They also suggested that MA plans that are serving full dual eligible beneficiaries should be required to provide 180 day notice to individuals and providers.

Response: CMS' proposal to shorten the notification of termination from 90 days to 45 days affects the amount of notice that CMS must give to an MA or Part D organization prior to moving forward with a termination action. The timeframe in which that organization must then notify their beneficiaries, which is currently 30 days, is not being changed in this proposal. While we appreciate the commenter's suggestion, we believe that it would be incredibly burdensome to organizations and confusing to our beneficiaries to implement such a striated notification process for our beneficiaries during a termination. Additionally, if we were to adopt the commenter's suggestion of a 90 day notice period for beneficiaries in a PAC setting or 180 day notice for dual eligible beneficiaries, this would require that we give organizations even more advance notice of our intent to terminate than we do currently, which is contrary to the ultimate goal of our proposal, which is to remove beneficiaries as quickly as possible from a plan with such significant noncompliance issues that CMS is pursuing termination. Consequently, we plan to proceed with our proposed change.

Comment: Several commenters supported CMS' proposed revisions to the contract termination authority (§§ 422.510 and 423.509) and stated that these measures will help enforce consumer protections and enhance plan accountability.

Response: We thank the commenters for their support.

After consideration of the public comment(s) received, we are finalizing these proposals without modification. We note that the amendatory instruction to the regulation text in this final rule more precisely describes the redesignation of subparagraph (a)(4) of § 423.509 than that found in the proposed rule.

4. Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C))

Section 1857(a) and section 1860D–12(b)(1) of the Act provided the Secretary with the authority to enter into contracts with MA organizations and Part D sponsors (respectively). Sections 1860D–12(b)(3)(D)(i) and 1857(e)(1) of the Act, specify that these contracts shall contain other terms and conditions that the Secretary may find necessary and appropriate. We first established that all Part C and Part D contracting organizations have the necessary administrative and management arrangements to have an effective compliance program, as reflected in §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi). We later established that compliance plans for sponsoring organizations must include training and education and effective lines of communication between the compliance officer and the sponsoring organization's employees, managers, and directors, as well as their first-tier, downstream and related entities (FDRs). We reiterated the importance of this requirement in the October 22, 2009 proposed rule entitled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (74 FR 53634). We were concerned that these FDRs would potentially have to participate in

(largely duplicative) training for each organization with whom they contract. We requested public comments on how best to ensure that the training requirement continued to be met while not overly burdening the contracting organization or its FDRs. In response, we received numerous comments suggesting that CMS develop its own web-based trainings to lessen this burden on sponsors and FDRs (75 FR 19688).

Consequently, we proposed in this rule to require that all contracting organizations accept a certificate of completion of the CMS developed training as satisfaction of this general compliance program training requirement. We proposed to modify the regulation text by adding a new §§ 422.503(b)(vi)(C)(3) and 423.504(b)(vi)(C)(4) to permit only this CMS training for satisfaction of the requirement to train first–tier, downstream and related entities.

Comment: One commenter questioned if there would be a fee associated with the CMS mandated training.

Response: There is no fee to take the CMS Standardized General Compliance Program Training; it is provided free of charge.

Comment: Multiple commenters stated that Part C and Part D contracting organizations should have the option of using the CMS Standardized General Compliance Program Training and Education Module. The commenters wrote that there should be flexibility in meeting the proposed training requirement, and that CMS should consider allowing plan sponsors to utilize their own training or the training developed by established training companies to meet the requirement.

Response: The CMS Standardized General Compliance Program Training and Education Module was created to reduce the burden on sponsors and FDRs. If we continue to allow sponsors to modify or utilize their own training in lieu of using the CMS Compliance training, it will no longer ensure the elimination of the prior duplication of effort that so many FDRs stated was creating a huge burden on their operation. This is why CMS proposed that only our training can be used, as it is the only means to ensure that duplication of effort is avoided for FDRs who hold contracts with multiple Part C and Part D contracting organizations.

Comment: One commenter raised concerns over the significant amount of time required to complete the current CMS Compliance training and stated that it may take time away from other areas of training the organization has deemed necessary through their own internal risk assessments. They suggested CMS consider modifying the requirement to allow the longer training initially and developing a shorter ''refresher'' version that could be taken annually thereafter.

Response: We will not modify the existing CMS Standardized General Compliance Program Training at this time. However, we recognize the commenter's concern and will take under consideration the development of a refresher training module for future use.

Comment: A few commenters recommended that CMS establish a single centralized electronic location where FDRs could obtain this training, and that the centralized location would also serve as a repository to hold attestations of training completion accessible to Part C and Part D contracting organizations for compliance oversight purposes. Commenters suggested it be searchable or that CMS provide updates, one suggesting daily reports be pushed to each MA organization and Part D sponsor so that they could track compliance with the training requirement. One other commenter suggested that the training be provided in a Sharable Content Object Reference Model (SCORM) format for downloading into various organizations' systems.

Response: The training is in a centralized location on the Medicare Learning Network. All who take the training will be able to print out a certificate of completion to prove they have completed the training. It is the responsibility of Part C and Part D contracting organizations to determine how to best retrieve and catalog this information from their FDRs. CMS is unable, at this time, to provide the capacity for a publicly searchable database of users who have completed that training or a system that would allow reports to be sent to the various contracting organizations regarding the training status of various FDR organizations. We will consider and determine if our training module could be available for download into the format suggested by commenters, but we would need to ensure that the content could not be modified to ensure the integrity and completeness of the training module.

Comment: One commenter suggested CMS leverage the existing Compliance Training, Education & Outreach (CTEO) site to support this initiative and to interactively execute the training and collect and track the required attestations.

Response: When we developed the Standardized General Compliance Program Training, the CTEO Web site was not yet in existence. We will take the commenter's suggestion under consideration and further explore that Web site's capability to determine if it actually exceeds the current capability of the Medicare Learning Network, where the training is currently housed.

Comment: A few commenters recommended maintaining the current policy of allowing flexibility in how the training requirement is met. These commenters stated the current training requirements meet their needs because it allows options and reduces the burden on various sectors of the industry. They stated that various organizations had already invested resources to become compliant and to develop efficient means of both delivering and tracking the training. The flexibility in the current regulations allows plan sponsors to work in concert with FDRs to develop effective training for those specific entities and their existing learning models.

Response: We recognize that the current compliance program training requirement does meet the needs of some contracting organizations. However, based on public feedback received previously, as well as in response to this proposed change, we continue to believe that the proposed approach is most efficient and effective for the majority of FDRs and contracting organizations.

Comment: Many commenters requested clarification regarding who is required to take the training: Providers, brokers, FDRs, and/or internal employees.

Response: The compliance and fraud, waste, and abuse (FWA) training and education requirement applies to all delegated entities (which may include agents/brokers) whom the Part C or Part D contracting organization qualifies as an FDR using the definition at 42 CFR §§ 422.500(b) and 423.500. Whether a Part C or Part D contracting organization identifies a certain entity or individual provider as an FDR depends on the contractual relationship and/or written agreement between the entity/individual and the contracting organization. The compliance and FWA training is not intended to be mandatory for the employees of those contracting organizations.

Comment: Several commenters wanted to know if this training would satisfy the FWA and Compliance training requirements.

Response: There is both a FWA and a Compliance training module available on the Medicare Learning Network,

FDRs must take both modules in order to satisfy the entire training requirement.

Comment: A few comments requested clarification regarding who was deemed for purposes of the FWA training requirement (for example, is it just the provider participating in Medicare FFS or also all of the employees that work in his office, similarly with a hospital participating in Medicare, does it extend to their employees). Commenters also requested if CMS was exploring deeming status for providers in the Part D program.

Response: This question is outside of the scope of this regulation. We did not propose any changes to the FWA training module or the associated deeming requirements. Therefore, we are unable to address your question at this time.

Comment: Several commenters had questions regarding the one-pager that contracting organizations can provide with organization specific information, and requested whether this meets the requirements for distributing their codes of conduct (COC) or standards of conduct (SOC) located in Chapter 9 of Pub. 100–18, Medicare Prescription Drug Manual, and Chapter 21 of Pub. 100–16 of the Medicare Advantage Manual. Some commenters inquired if this new proposal could be construed to forbid them from distributing their COC/SOC to their FDRs.

Response: We intend that the standardized FWA and Compliance Training modules will cover the basic training requirements. We recognize that each contracting organization has specific information that must be shared with their FDRs regarding the organization's specific operations. The one-pager was suggested for organizations to communicate unique information that is usually shared in FWA/Compliance such as relevant organization contact information (for example, Web site address, hotline/ethics phone numbers) the Compliance Officer's contact information, the Compliance Department staff, and possibly even online access to the COC/SOC or disciplinary policies. Our experience has shown that many contracting organizations issue their COC/SOC electronically (internally and externally) and/or create Web sites designated for their FDRs to locate the information mentioned previously. Contracting organizations must continue to distribute their COC/SOC to all of their employees, FDRs, board members, etc. Nothing is this regulation should be interpreted to preclude organizations from satisfying the seven elements of the compliance program requirements.

Comment: The commenters suggested that feedback should be solicited from the plans to assist with improving the content of the training, specifically including more examples that are relevant to FDRs, as commenters mentioned the modules examples are often organization-centric.

Response: We always welcome feedback from contracting organizations and FDRs with respect to improving our training products. Organizations, entities or individuals who have suggestions should submit them to the following mailbox: *Parts_C_and _D_CP_Guidelines@cms.hhs.gov.*

Comment: Some commenters stated that CMS should consider how it can implement this proposal in a way that reduces administrative burdens on contracting organizations and FDRs, as new processes to collect and track attestations may be difficult and time consuming. Many suggested that a January 1, 2015 effective date was an insufficient amount of time to set up such elaborate processes and recommended that these provisions be effective no earlier than January 1, 2016.

Response: CMS recognizes the administrative burden imposed on the contracting organizations and their FDRs. The primary goal of this proposal is to reduce that administrative burden by instituting a uniform compliance training module and we believe that contracting organizations are in the best position to determine the most effective way to collect and track compliance amongst their FDRs. However, we recognize that setting up these new processes may take time, along with potentially updating contracts to reflect the new requirements. Therefore, we will delay the implementation of this provision to January 1, 2016.

Comment: The largest number of commenters represented FDRs that wrote in support of the proposed compliance training program requirements and use of the CMS Standardized General Compliance Program Training, agreeing that it would greatly reduce burden on FDRs.

Response: We thank the commenters for their support.

After careful consideration of all of the comments received, we are finalizing this proposal with the one modification discussed previously, with a delayed applicability date of January 1, 2016.

5. Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Parts C and D (§§ 422.756 and 423.756)

Sections 1857(g) and 1860D–12(b)(3)(E) of the Act provide the Secretary the ability to impose intermediate sanctions on MA organizations and PDP sponsors. Intermediate sanctions consist of suspension of enrollment, suspension of marketing and suspension of payment. Current regulations governing intermediate sanctions are contained in subparts O of part 422 and part 423. Sections 422.756 and 423.756 provide specific procedures for imposing intermediate sanctions and include provisions which address: The duration of the sanction; and the standard that we apply when determining if a sanction should be lifted.

We proposed to expand the potential applicability of the test period requirement to three types of intermediate sanctions by modifying the existing rules to clarify that CMS may require a test period for a sponsoring organization that has had any of the three types of intermediate sanctions imposed: Marketing, enrollment and/or payment. Second, we proposed to clarify the enrollment parameters for sanctioned sponsoring organizations offering Part D plans to include language specifying that a sanctioned plan is not available to receive automatically assigned beneficiaries for the entire duration or a portion of the testing period. We proposed to modify the regulation text at §§ 422.756 and 423.756 to reflect these changes.

Comment: One commenter questioned clarification on what CMS considers a contract violation of marketing requirements and requested if violations would be based solely on allegations of misconduct.

Response: Marketing standards for MA organizations and Part D sponsors are codified in subpart V of parts 422 and 423. The current Medicare Marketing guidelines are located in Chapter 3 of *Pub. 100–16, Medicare Managed Care Manual, and Chapter 3 of Pub.100–18, The Medicare Prescription Drug Manual,* which should provide sponsors with guidance regarding current marketing requirements. With respect to contract violations being based on unsubstantiated allegations of wrong-doing, enforcement actions are only taken based on substantiated, well documented instances of non-compliance. Additionally, MA organizations and Part D sponsors that are sanctioned are given an opportunity to rebut or appeal our determination through a formal appeals process.

Comment: One commenter suggested the prohibition on auto-enrollment into plans under a test period should also apply to passive enrollment. Specifically, the commenter stated that

Medicare-Medicaid eligible individuals should not be passively enrolled into an MA or an MA Special Needs Plan (SNP) that is under sanction or under sanction and in a test period as part of a demonstration or a state developed integrated plan product.

Response: Plans that are under a sanction are not eligible to receive enrollments. However, we have the discretion to require a sanctioned plan to market or accept enrollments for a limited period to assist in making a determination as to whether the bases for imposing the sanction have been fully corrected and are not likely to recur. As stated previously, sanctioned sponsoring organizations offering a Part D benefit would not be eligible to receive automatically assigned beneficiaries during the test period. During a ''test period'' the sanction(s) remain in effect.

Comment: One commenter requested that we extend the proposal to also not allow passive enrollment into plans that are coming off of sanction or are currently in a test period until we have determined they are ready.

Response: CMS has determined that it is legally permissible to provide for enrollment in an MA or Part D plan under a passive enrollment request process in specific, limited circumstances generally associated with either immediate plan terminations or in other situation where CMS determines that remaining enrolled in the plan would pose potential harm to members. We determine when passive enrollment is appropriate. In evaluating whether such CMS-directed enrollee movements are appropriate, a key factor is the determination as to whether the receiving plan is essentially equivalent to (or better than) the current plan from an overall perspective.

Therefore, in situations where passive enrollment is determined permissible, like an immediate plan termination, CMS would factor in a number of criteria, including the receiving plan's current premium, benefit and formulary structure, as well as plan past performance. In any event, our goal would be to ensure that those affected members suffered as little disruption as possible during their transition. Plans that were under sanction at the time of a passive enrollment would not be considered a viable option for affected enrollees and it is unlikely that sponsors under a test period would either. However, if a sponsor who was removed from sanction and was under a test period met several other criteria for receiving passive enrollment (that is, plan's benefit and formulary structure was largely the same and their premium was not significantly higher), we may consider them among the group of available plans to receive passive enrollment.

Comment: A few commenters requested clarification regarding the new sanction authority, specifically the language that would allow CMS to impose intermediate sanctions on an organization that enrolls an individual without prior consent (except in certain limited circumstances) or transfers an individual to a new plan without prior consent. The commenters asked that CMS clarify that this would not apply to organizations that perform facilitated or auto-enrollment, passive enrollment, seamless enrollment or group or individual enrollment requests from EGWPs.

Response: In the proposed rule, we proposed to amend the regulation text at §§ 422.752 and 423.752 by adding subparagraph (a)(9), which reads: ''. . .Except as provided under § 423.34 of this chapter, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual.'' Section 423.34 specifically refers to enrollment of individuals who receive the low income subsidy (LIS) and are therefore subject to facilitated or auto-enrollment. Therefore, we believe that the proposed regulation text already makes clear that this provision would not apply to those organizations that are performing facilitated enrollment of LIS beneficiaries. Additionally, passive enrollment and use of the seamless enrollment option are initiated or approved by CMS, respectively. Therefore, an organization who is contacted by CMS to receive passive enrollment would not be considered to have performed enrollment without prior consent. As for the seamless enrollment option, as these proposals must be submitted to and approved by CMS, as long as organizations are following CMS' enrollment guidance in Chapter 2, § 40.1.4, and have received CMS' approval, an organization again would not be considered as enrolling without prior consent and would therefore not be considered for a possible sanction. Finally an organization who is accepting enrollment requests for an employer or union sponsored plan using the group enrollment mechanism must follow CMS' enrollment guidance in Chapter 2, § 40.1.6.1. As long as CMS enrollment guidance is being followed with respect to processing these enrollments, CMS would not consider MA and Part D organizations in violation of the new requirement. However, we expect that requests for enrollment into an employer or union sponsored plan outside of the group enrollment process (that is, beneficiary initiated enrollment requests) follow all requirements, including prior consent, applicable to any other individual enrollment request.

Comment: Several commenters expressed support for our proposal to expand the use of the ''test period'' requirement to all intermediate sanctions, and support the proposal that previously sanctioned below-the-benchmark Part D plans not be allowed to receive or process auto-enrollments or reassignments until they are determined to be ready by CMS.

Response: We thank the commenters for their support.

After careful consideration of the comments received, we are finalizing these proposals without modification. We inadvertently failed to include proposed regulation text for § 423.756 that corresponds to this proposal. In this final rule, we finalize amendments to §§ 422.756 and 423.756 that are virtually identical to implement this proposal.

6. Timely Access to Mail Order Services (§ 423.120)

Section 1860D–12(b)(3) of the Act authorizes the Secretary to include contract terms for Part D sponsors, not inconsistent with the Part C and D statutes, as necessary and appropriate. Section 423.120(a)(3) specifies that a Part D sponsor's contracted network may include non-retail pharmacies, including mail order pharmacies, so long as the network access requirements are met. Part D plans are increasingly entering into contracts with mail order pharmacies to offer beneficiaries an alternative way to fill prescriptions under the Part D benefit, often at much lower cost sharing than is available at network retail pharmacies. While mail order pharmacies make up a relatively small percentage of total prescriptions filled under the Part D program, we are committed to ensuring consistent and reliable beneficiary access to medications, regardless of what type of pharmacy fills the prescriptions.

Section 1860D–4 of the Act describes the various beneficiary protections in place in the Part D program. For mail order pharmacies, the industry standard for delivery times appears to range from 7 to 10 business days from the date the prescription was received, and Part D sponsors' marketing materials often specify this time frame to beneficiaries. Beneficiaries generally choose to fill prescriptions through a mail order pharmacy, for lower cost sharing, when it is feasible to wait 7 to 10 days to receive their medications. However, if

this time frame is disrupted, beneficiaries may experience gaps in therapy.

When issues with filling a prescription arise in a retail setting, the beneficiary often is notified of the problem in real time, or within hours of discovery. When issues arise in a mail order setting, the delays in finding, communicating, and making the appropriate contacts to resolve the problem may add days onto the ultimate delivery date, resulting in a potentially more significant concern for mail order beneficiaries if these delays result in gaps in therapy. For this reason, we proposed to establish fulfillment requirements for mail order pharmacies as well as home delivery services offered by retail pharmacies, to set consistent expectations for beneficiary access to drugs in this growing segment. Many beneficiaries may be very well served by this type of pharmacy access, but only if they can rely upon efficient processing and turnaround times. Mail order pharmacies contracted by Part D sponsors can reasonably be expected to meet minimum performance standards for order fulfillment, including convenient order turnaround times, as a beneficiary protection and as a component of providing good customer service. Clearly stating in beneficiary materials the expected turnaround time for delivery allows the beneficiary to better control when they need to reorder to ensure no gaps in medication supply. Clarity in expected turnaround times also can prevent needing to address customer inquiries into the status of a pending order, setting parameters for when an order is or is not delayed and what options become available at that point. We believe that established companies that have been providing these services for years have generally been meeting these standards in practice already, and that the proposed turnaround times are in line with current practices followed by mail order pharmacies today.

Therefore, we proposed to amend § 423.120(a)(3) to specify mail order fulfillment requirements in line with what we have observed in other markets: 5 business days (from when the pharmacy receives the prescription order to when it is shipped) for those prescriptions requiring intervention beyond filling (such as clarifying illegible orders, resolving third party rejections, and coordinating with multiple providers as part of drug utilization management); and 3 business days (from when the pharmacy receives the prescription order to when it is shipped) for those prescriptions not requiring intervention. We recognize that some prescription orders may require clarification or additional steps to be taken by the provider or beneficiary that would extend beyond the proposed period of 5 days. We believe that such cases represent a minority of mail order prescriptions, and as such we would anticipate that more than 99 percent of all mail order prescriptions processed are filled in compliance with either the 3- or 5-day standard. We believed our proposed standards are in alignment with fulfillment requirements already in place in the market and as such do not create a new burden or new standard for mail order pharmacies to meet. We solicited comments not only on the proposed time frames, but also on whether there are instances (in addition to those discussed previously) in which the proposed 5-day time frame should apply. We received the following comments and our response follows:

Comment: A few commenters questioned why we proposed turnaround times of 3 and 5 days if we list in preamble that standard turnaround times are 7 to 10 days for delivery.

Response: The preamble discussion surrounding delivery of prescriptions within 7 to 10 days is from the perspective of the beneficiary; listing the total time from when a medication is ordered to the time it is delivered. Importantly, this includes shipping time. The proposed fulfillment standards were specific to mail order pharmacy processing times and did not include actual time in shipping. In other words, the 3 to 5-day turnaround time only refers to the timeframe from when the pharmacy receives the order until the pharmacy ships the order.

Comment: Many commenters expressed concerns that 5 business days is too short of a time frame to require mail order pharmacies to resolve some issues when they arise (such as manufacturer drug shortages), many of which are outside the control of the pharmacy. Many commenters noted unique timeline concerns specific to specialty medications, such as cold chain shipping and needing to contact the beneficiary to coordinate delivery. Multiple commenters suggested that additional leeway is also needed to accommodate issues such as natural disasters. Multiple commenters suggested that mail order pharmacies should contact beneficiaries as a good customer service practice when any delay in filling will prevent an order from shipping within 5 days. Many commenters noted that they currently would be able to meet a 3-day turnaround standard for filling orders not requiring follow up contact with the beneficiary or prescriber.

Response: We recognize that some interventions may require more than 5 business days to resolve. In those cases, we agree with the suggestion from multiple commenters that mail order pharmacies should contact beneficiaries as a good customer service practice when any delay in filling will prevent an order from shipping within 5 days. However, in light of the comments received regarding a variety of situations that we had not considered, including some outside of the pharmacy's control that could create delays longer than 5 days, we are not finalizing the proposal to establish fulfillment standards for mail order. Instead, we will continue analysis on mail order fulfillment time frames, including evaluating the impact of the implementation of the auto-ship beneficiary consent policy finalized in the 2014 Call Letter. In addition, Part D sponsors are expected to follow best practices by making clear their expected delivery turnaround times in their beneficiary materials, consistently meeting such delivery time frames, and having contingency plans for when they cannot, such as allowing retail access at mail order cost sharing levels if necessary. The volume of complaints that we receive related to mail order delivery suggests that beneficiary expectations are not consistently being met. We will increase our monitoring of mail order pharmacies, and will consider the need to establish standards and requirements in the future. Based on the comments submitted, additional consideration may be necessary surrounding specialty medications and their delivery, especially when there are cold chain or other shipping considerations. We reviewed the information provided on how specialty pharmacy differs from other mail order deliveries, and agree that additional consideration should be given to these pharmacies and medications in any future guidance. Additionally, we will clarify existing guidance about exception processes and coverage denials to ensure that mail order pharmacies provide beneficiaries notice of non-fulfillment of a prescription as expeditiously as possible. Current guidance on disaster responses and drug shortages still apply, and we encourage sponsors to communicate with their enrollees when unique situations like these arise.

Comment: A few commenters suggested that mail order turnaround times are best left to state Boards of Pharmacy to monitor, instead of being set in regulation.

Response: We proposed specifying parameters for timely mail order fulfillment, consistent with the authority given to the Secretary to specify additional contract terms not inconsistent with the Part D statute. However, we had not considered the potential conflict or duplication with state-based requirements and appreciate the comments. We will take this under consideration as we consider establishing requirements for Part D sponsors offering a mail order benefit in the future.

Comment: Some commenters wrote that turnaround times would be better defined in guidance or incorporated in star ratings or other quality metrics.

Response: We appreciate the suggestion. As we will not be finalizing the proposed fulfillment standards in this final rule, we are exploring alternatives for ensuring consistent and predictable access to medications for beneficiaries in a plan offering a mail order benefit. As part of this effort, we are currently developing a study of how mail order benefits are used within the Part D benefit. The comments received on the proposed rule and the results of this study will be considered when determining whether fulfilment standards should be included in future star ratings measures, as well as used to inform the need for future guidance or rulemaking. Additionally, we will increase our monitoring and analysis of mail order-related complaints in the CTM and explore setting a threshold for the volume or severity of complaints triggering a review by CMS. We remain very concerned by the high level of complaints received relating to mail order, and take seriously the issues raised by beneficiaries. We are also exploring how fulfillment of plan-designated turnaround times listed in marketing or other beneficiary materials could be included within the audit framework.

Comment: One commenter wrote in with concerns that the methodology used in two CMS studies cited in another provision were problematic and stated that no regulation proposals relating to mail order should be finalized until corrected and reexamined.

Response: The studies noted by the commenter were not used when designing the proposal specific to timely delivery of mail order prescriptions.

Comment: Some commenters suggested that the policy announced in the CMS 2014 Call Letter that pharmacies obtain beneficiary consent prior to shipping any medications that the beneficiary did not affirmatively order directly affects the timeline for order fulfilment and any defined turnaround times for delivery should be adjusted accordingly.

Response: We recognize that the CMS 2014 Call Letter auto-ship policy necessitates an increased level of coordination with the beneficiary for some pharmacies, when filling prescriptions that the beneficiary did not directly request (such as new orders submitted directly by the provider or refills prompted by an automatic delivery program). We will not be finalizing the proposed fulfillment standards in this final rule, but encourage all plan sponsors to consider the need for coordination with the beneficiary when establishing and marketing average turnaround time estimates for their members.

Comment: A few commenters suggested that beneficiaries should be allowed to fill their medications at the retail pharmacy of their choice, at the same cost sharing level as mail order, if a mail order pharmacy encounters any delays, or delays extending beyond 5 days.

Response: While this was not a part of our proposal, and we will not be finalizing any new requirements at this time, we do agree with commenters that this would be an important beneficiary protection. We believe that best practices for addressing a lost or delayed order would include plan sponsors providing clear and timely guidance to the beneficiary in the event of a lost or delayed order, including a list of options for obtaining a medication. Part D sponsors should have contingencies in place when issues are encountered that lead to a delay and potentially a gap in therapy. This could include offering beneficiaries the ability to fill a delayed mail order prescription at a retail pharmacy and pay no more than what they would have been charged by a mail order pharmacy. The need to prevent gaps in therapy for beneficiaries relying on mail order pharmacies remains a significant concern to us.

In summary, we are not finalizing any fulfillment standards for mail order prescriptions, in light of the concerns raised. We will use the information gained from our mail order study and from the public comments submitted to explore the need for additional guidance or rulemaking in the future. The need to ensure consistent access to and prevent gaps in therapy for enrollees relying on mail order for their medications continues to be a significant concern.

We additionally solicited comments on whether we should establish additional requirements for beneficiary materials relating to mail order services, such as: Clear definitions of processing time and delivery time; how to access customer support; how to submit a complaint via 1 800 MEDICARE; and beneficiary options for accessing medications when a delivery is lost or delayed. We received the following comments and our response follows:

Comment: Many commenters stated that additional requirements for beneficiary materials would enhance mail order services and that this would be a positive change for beneficiaries. These commenters noted that clear definitions of requirements are needed to resolve issues, ensure consistent access, and ensure no gaps in therapy.

Response: We appreciate the comments. We intend to conduct a study of mail order benefits offered by Part D sponsors and will use this, and the information received from public comments, to inform changes to beneficiary materials relating to mail order. At a minimum, we expect sponsors offering mail order services to follow best practices by clearly listing estimated delivery times in their marketing and beneficiary materials. In the event of a failure to meet plan-designated timeframes for delivery, as a best practice sponsors should be prepared to take the steps necessary to provide their enrollee the medication in a timely manner in order to avoid gaps in therapy. This could include offering enrollees the option to obtain delayed medications at a retail pharmacy at the same cost sharing level as mail order.

We also welcomed comments on any other requirements we should consider for mail order or other home delivery options. For example, also potentially affecting consistent access to medication is the use of mail order to fill initial prescriptions of new drugs or to fill 30-day supplies of chronically used medications. The need to order a refill early, allowing sufficient time for processing and delivery, can result in refill-too-soon edits based upon retail 30 day standards. Resolving inappropriate or inapplicable edits increases burden on the beneficiary and the mail order pharmacy and essentially creates a disincentive for beneficiaries who are planning ahead and attempting to order early enough to ensure uninterrupted supplies of chronic medications. In general, we believe that filling initial prescriptions or routine 30-day supplies at mail order is not good practice. We recognize that there may be a small minority of beneficiaries who successfully depend solely upon mail order or other home delivery options for access to prescription drugs due to particular circumstances of geography or mobility. We have no reason to

discourage their continued use of these services. However, due to the difficulties reported to CMS with consistently and effectively filling short time frame supplies through mail order, we do not believe that Medicare beneficiaries in general should be incentivized through lower cost sharing to utilize mail order pharmacies for initial prescriptions or 30-day supplies. We received the following comments and our response follows:

Comment: A few commenters agreed that mail order is not an appropriate venue for filling 30 day supplies of medications.

Response: We appreciate the comments and will explore how often mail order is used for short days' supplies of medications as a part of the current study on mail order benefits.

Comment: Some commenters noted that specialty pharmacies often dispense medications by mail order in an amount lasting 1 month or less.

Response: We agree with the comments that noted some specialty medications may be best supplied, when supplied by mail order, in quantities less than a 3 month supply, due to frequent dose titrations, financial concerns, or applicable controlled substance laws.

We did not propose any specific regulatory requirements to mail order for 30-day supplies or less. We are currently analyzing the types of prescriptions filled by mail order pharmacies and will use the information gained from this to explore the need for future guidance or rulemaking that could help ensure consistent timely access for Part D beneficiaries opting to use mail order for both short and extended days' supplies.

7. Agent/Broker Compensation Requirements (§§ 422.2274 and 423.2274)

Section 103(b)(1)(B) of MIPPA revised the Act to charge the Secretary with establishing guidelines to ''ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet their health care needs.'' Section 103(b)(2) of MIPPA revised the Act to apply these same guidelines to Part D sponsors. Our program experience indicates that some agents may encourage beneficiaries to enroll in plans that offer higher commissions without regard to whether plan benefits meet the beneficiaries' health needs. In recognition that agents and brokers play a significant role in providing guidance and advice to beneficiaries and are in a unique position to influence beneficiary choice, we had proposed, prior to the enactment of MIPPA, a rule to regulate agent and broker compensation. To implement the MIPAA provisions and relying in part on comments in response to our previously proposed rule, we adopted an interim final rule on September 18, 2008, entitled ''Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Final Marketing Provisions'' (73 FR 554226), which, among other things, established the current compensation structure for agents and brokers as it applies to Parts C and D. That rule remains significantly in place at §§ 422.2274 and 423.2274, and our experience since then indicates that revision of the compensation requirements is necessary to ensure that we continue to meet our statutory mandate.

The current compensation structure is comprised of a 6-year compensation cycle that began in Contract Year (CY) 2009. MA organizations and Part D sponsors were to provide an initial compensation payment to independent agents for new enrollees (Year 1) and pay a renewal rate (equal to 50 percent of the initial year compensation) to independent agents for Years 2 through 6. These rates were to be adjusted annually based on changes to the MA payment rates or Part D parameters as established by CMS. We later amended the regulations to allow MA organizations and Part D sponsors to compensate independent agents and brokers annually using an amount at or below the Fair Market Value (FMV). (See the final rule with comment period entitled, ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' (77 FR 22072) published in the April 12, 2012 **Federal Register**.)

The first 6-year cycle ended at the end of CY 2013, on December 31, 2013. The first year, CY 2009, was considered to be the first renewal year for those already enrolled, effectively making CY 2009 the second full year of compensation. Because our regulations were silent regarding compensation amounts for Year 7 and beyond, we stated in our Final Call Letter for Contract Year 2014, issued on April 1, 2013, that MA organizations and Part D sponsors could, at their discretion, pay agents and brokers the renewal amount for Year 7 and beyond. However, this subregulatory guidance was intended to be a temporary measure, pending final changes to our regulations.

Under the current structure, MA organizations and Part D sponsors pay an initial rate for the first year, and then a renewal payment of 50 percent of the initial compensation paid to the agent for years 2 through 6. This structure has proven to be complicated to implement and monitor as it requires the MA organization or Part D sponsor to track the compensation paid for every enrollee's initial enrollment, and calculate the renewal rate based on that initial payment. In our NPRM, dated January 10, 2014, we provided a detailed example of the complexities of the current compensation structure. Summarizing the current complexities, every MA organization or Part D sponsor has to know, at any given time, the amount of the initial compensation for each plan year—going back as far as 2009—in which the member enrolled in order to pay the correct compensation amount to the agent for the current contract year. For new members, MA organizations and Part D sponsors must first review CMS' reports to determine whether an initial or renewal payment should be made, and then combine that information with the FMV, or, if applicable, the plan's compensation set at less than the FMV, for each plan year to ensure the correct payments are made to agents.

In addition to its complexity, we remain concerned that the current structure creates an incentive for agents and brokers to move enrollees from a plan of one parent organization to a plan of another parent organization, even for like plan-type changes. In our NPRM, we discussed and expanded upon our example of how the current system results in different payments when a beneficiary moves from one like plan to another like plan in different organizations. In these cases, the new parent organization would pay the agent 50 percent of the current initial rate of the new parent organization; not 50 percent of the original initial rate paid by the other parent organization. Thus, in cases where the FMV has increased, or the other parent organization pays a higher commission, an incentive exists for the agent to move beneficiaries from one parent organization to another. (See §§ 422.2274(a)(3) and 423.2274(a)(3)).

Since 2008, we have received inquiries from MA organizations and Part D sponsors regarding the correct calculation of agent/broker compensation, and found it necessary to take compliance actions against MA organizations and Part D sponsors for failure to comply with the compensation requirements. To the extent that there is confusion about the required levels of compensation or the timing of compensation, there could be an uneven playing field for MA organizations and Part D sponsors

operating in the same geographic area. In addition, CMS' audit findings and monitoring efforts have shown that MA organizations and Part D sponsors are having difficulty correctly administering the compensation requirements. Therefore, we proposed simpler agent/broker compensation regulations to better ensure that plan payments are correct and establish a level playing field that will further limit incentives for agents and brokers to move enrollees for financial gain.

We proposed to revise the existing compensation structure for agents and brokers so that, for new enrollments, MA organizations and Part D sponsors could make an initial payment that is no greater than the FMV amount for renewals in Year 2 and beyond, the MA organization or Part D sponsor could pay up to 35 percent of the FMV amount for the renewal year, resulting in renewal year payment changes each year if the MA organization or Part D sponsor chooses to pay 35 percent of the current FMV (that is, the renewal year FMV threshold). As is currently the case, we would interpret the FMV threshold in our annual guidance to MA organizations and Part D sponsors. This flexibility would enable MA organizations and Part D sponsors to better react to changes in the marketplace and adjust their compensation structures accordingly.

When we proposed the 35 percent renewal rate, we also discussed several different alternatives, including prohibiting compensation payments entirely beyond year 6, permitting MA organizations and Part D sponsors to pay a residual payment for year 7 and subsequent years, and permitting existing renewal payments to extend past year 7. We also evaluated different renewal amounts, including a 50 percent renewal payment for years 2 through 6 with a continuing 25 percent residual payment for years 7 and beyond. The evaluation took into account different beneficiary ages for an initial enrollment, as well as life expectancy. In the analysis, a renewal payment of 35 percent was similar in payout to the combination of a 50 percent payment for years 2 through 6 and a residual payment of 25 percent for year 7 and beyond.

In our NPRM, we stated that we believed that revising the existing compensation structure to allow MA organizations or Part D sponsors to pay up to 35 percent of the FMV for year 2 and beyond was appropriate based on several factors. First, we stated that a two-tiered (initial and renewal) payment system would be significantly less complicated than a three-tiered system (initial, 50 percent renewal for years 2 through 6, and 25 percent residual for years 7 and beyond), and would reduce administrative burden and confusion for plan sponsors. Second, our analysis determined that 35 percent is the renewal compensation level at which the present value of overall payments under a two-tiered system would be relatively equal to the present value of overall payments under a three-tiered system (taking into account the estimated mortality rates for several beneficiary age cohorts). This analysis was based on the existing commission structure basing renewal commissions on the starting year initial commission amount and not the current year FMV amount.

In order to implement the changes in the identical Part C and Part D regulations at §§ 422.2274 and 423.2274, our NPRM first proposed to revise the introductory language for each section and then define ''compensation'' in paragraph (a)(1) and to restate the fair market value limit on compensation for the initial year as paragraph (b)(1)(i). Second, we proposed to combine the current (a)(1)(i)(B), which addresses payments for renewals, and (a)(1)(iii), which addresses the length of time that renewals should be paid, and designate the revisions as a new (b)(1)(ii). Thus, the proposed new paragraph (b)(1)(ii) would state that plans may pay up to 35 percent of the current FMV and that renewal payments may be made for the second year of enrollment and beyond.

In addition, we proposed to modify paragraph (a)(3) to remove the 6-year cap on the compensation cycle. Currently, paragraph (a)(3) refers to policies that are replaced with a like plan during the first year or the subsequent 5 renewal years. Since we proposed to eliminate the 6-year cycle, our revised paragraph (b)(2) deletes the reference to the initial year and the 5 renewal years. By tying renewal compensation to the FMV for the renewal year, rather than to the initial year of enrollment, our proposal reduces the financial incentives for an agent or broker to encourage Medicare beneficiaries to change plans, especially from one parent organization to another parent organization. As with the current regulation, we proposed in paragraph (b)(2)(iii) that a change in enrollment to a new plan type be payable under the same rules that apply to an initial enrollment, regardless of whether the change is to an unlike plan type in the same parent organization or an unlike plan type in another parent organization. Note that, as with the current rule, our proposal only addresses compensation paid to independent agents and does not address compensation payable by an MA organization or Part D sponsor to its employees who perform services similar to agents and brokers.

We welcomed comments on both the amount of the renewal payment, as well as the proposed indefinite time frame, which are discussed in depth as follows. In summary, we received a number of comments supporting our efforts to simplify agent/broker compensation calculation. These comments were primarily from plans and industry trade groups. We will be finalizing the rule to implement a two-tiered (initial and renewal) payment system using the FMV in the current year for renewal calculations.

We received numerous comments from agents, brokers, plans and trade associations overwhelmingly opposing the 35 percent renewal rate. Based on the comments received, we will finalize the amendment to the regulations with a cap of 50 percent of the current FMV for renewals.

In response to the comments received, we also determined that some clarifications were necessary. For renewals, the payment is based on the current FMV and not the initial enrollment year FMV. For example, assume a beneficiary enrolls in an MA plan in CY 2013. The plan pays the initial FMV for CY 2013, which is $413. In CY 2015, assume the FMV is $420. The plan chooses to pay 50 percent of the FMV for renewals. The maximum renewal payment for this member for CY 2015 would be $210 ($420 * .50) instead of $207 ($413 * .50). For all enrollments, MA organizations and Part D Sponsors should calculate the renewal rate based on the FMV of the enrollment year. We are also clarifying that our proposed and final regulations do not require an indefinite payment of 50 percent of the FMV. The final rule would permit up to 50 percent of the current FMV to be paid by an MA organization or Part D sponsor. CMS currently requires that plans inform CMS as to whether they are using independent agents. Contracts between MA organizations and Part D Sponsors, on one hand, and their independent agents and/or downstream entities on the other hand, such as Field Marketing Organizations, are not exhaustively regulated by CMS. Therefore, MA organizations and Part D sponsors may decide the duration of their contract with agents, number of applicable renewals, and the actual rate for renewals for each year, subject to the limits in this final rule.

Current regulations at §§ 422.2274(a)(4) and 423.2274(a)(4),

which we proposed to redesignate as part of paragraph (b), address the timing of plan payments, as well as recoupment of payments when a beneficiary disenrolls from a plan. Specifically, current paragraph (a)(4) states that compensation may only be paid for the beneficiary's months of enrollment during the year (January through December). Under our proposal, the new subparagraph (a) would more clearly define a plan year for purposes of compensation. The annual compensation amount covers January 1 through December 31 of each year. Our proposal also clarified that the payment made to an agent must be for January 1 through December 31 of the year and may not span calendar years. For example, a renewal payment cannot be made for the period of November 1, 2013 through October 31, 2014. These proposed revisions represented clarifications rather than new proposals and were necessary based on our findings that some plans have been paying compensation based on a rolling year cycle, rather than a calendar year cycle. Therefore, we are implementing the provision defining ''plan year'' and, at subparagraph (b)(3)(i), limiting payments to the months of enrollment during the calendar year, as proposed. Comments concerning this provision are discussed later in this section.

Currently, regulations at § 422.2274(a)(4)(i) permit payments to be made at one time or in installments and at any time. In order to reduce the number of payments that need to be recouped based on changes made during the annual coordinated election period (AEP), which runs from October 15 through December 7, CMS proposed, in new subparagraph (b)(3)(ii), changing the timing of payments to require that payments may not be made until January 1 of the enrollment year and must be paid in full by December 31 of the enrollment year. We stated that this proposal was appropriate given that the beneficiary's final application during the AEP becomes the effective enrollment. This would reduce the number of recoupments required when an enrollee signed more than one application during the AEP. We received several comments opposing the requirement that MA organizations and Part D plans may not make AEP payments until January 1 of the following year, but do not find these arguments sufficiently compelling to outweigh the simplification that would be gained by establishing the January deadline. We also received comments regarding our proposed requirement that payments be completed by December 31. MA organizations and industry associations stated that accurate payments, especially for enrollments effective on December 1, would be difficult to operationalize by the end of the year. However, we would expect enrollment requests for a December 1 effective date to be relatively low, as only individuals newly eligible to Medicare Advantage and those with a special election period would be able to enroll for that date. Moreover, organizations and sponsors are already required to process most post-enrollment activities within two weeks. Therefore, we continue to believe that the December 31 deadline is in the best interest of the program and are finalizing subparagraph (b)(3)(ii) as proposed.

Current regulations at §§ 422.2274(4)(ii)(A) and 423.2274(4)(ii)(A) require MA organizations and Part D sponsors to recoup compensation paid to agents when a beneficiary disenrolls from a plan within the first 3 months of enrollment. However, in sub-regulatory guidance, we have recognized several circumstances (for example, death of the beneficiary, the beneficiary moves out of the service area, the beneficiary becomes eligible to receive LIS, or the beneficiary loses Medicaid benefits) in which plans should not recoup compensation, even though the beneficiary was enrolled in the plan for less than 3 months. In such circumstances, since the disenrollment decision could not be based on agent or broker behavior, we believe it to be appropriate and in the best interest of the Medicare program for the agent to receive the compensation based on the number of months that beneficiary was enrolled in the plan. While the plan would not recoup the compensation for those months, it would recoup any compensation paid for the months after the date of disenrollment.

CMS proposed to combine current paragraphs (a)(4)(ii)(A) and (a)(4)(ii)(B) into a revised paragraph (b)(3)(iii), which included new text to require plans to recover compensation for only the months that the beneficiary is not enrolled, unless the disenrollment took place within the first 3 months. In our proposed rule, paragraph (b)(3)(iii) would require recoupment of all compensation in cases where the disenrollment was the result of agent or broker behavior. We received few but compelling comments on this proposal, which stated that it would be extremely difficult for MA organizations and Part D Sponsors to determine whether the disenrollment was a result of agent behavior, potentially resulting in compensation either being inappropriately recouped or not recouped when necessary. Based on these comments, we are not finalizing our proposal for subparagraph (b)(3)(iii) but are finalizing regulation text to state that the entire compensation must recouped if a disenrollment occurs during the first 3 months unless CMS determines that recoupment is not in the best interest of the Medicare program. We intend for this standard to be applied as we have implemented this aspect of the current regulation in past, with certain circumstances (for example, death of the beneficiary, the beneficiary moves out of the service area, the beneficiary becomes eligible to receive LIS, or the beneficiary loses Medicaid benefits) not triggering the recoupment requirement. We will continue to provide exceptions to the requirement in sub-regulatory guidance by applying the standard we are finalizing today.

We also proposed, to be codified at §§ 422.2274(h) and 423.2274(h), to codify existing sub-regulatory guidance regarding referral (finder's) fees. We released a memorandum on October 19, 2011 addressing excessive referral fees, noting that referral fees should not exceed $100. We have long been concerned that some MA organizations or Part D sponsors can offer the entire amount of compensation an agent or broker receives through only a referral while referral fees paid to others are part of the total compensation. This creates an uneven playing field within the marketplace and a clear financial incentive for the referring agent to steer beneficiaries to MA organizations or Part D sponsors that offer the higher amount, without regard for whether plan benefits meet the beneficiaries' health care needs. Therefore, we proposed to limit the amount that can be paid as a referral fee to independent, captive, and employed agents and brokers, regardless of who completes the enrollment form, to a reasonable amount, as determined by CMS, which is currently $100, for CY 2013 and CY 2014. The entire proposal concerning agent and broker compensation was discussed in the context of our concern that agents and brokers not be influenced by payments from MA organizations and Part D sponsors to steer beneficiaries to plans that do not meet the beneficiaries' needs. We note that this proposal was clearly identified in the preamble, 79 FR 1936, but the proposed regulation text, 79 FR 2060 and 2071, mistakenly included language discussing enrollee behavior and the value of health-related activities.

Furthermore, under §§ 422.2274(h)(2) and 423.2274(h)(2), CMS proposed that that referral fees paid to independent agents and brokers must be part of total compensation not to exceed the FMV for that calendar year. Although a few comments were received concerning our proposals on referral fees, we are implementing this proposal substantively as described in the preamble. However, we believe that use of the phrase ''. . . while not exceeding the value of the health-related service or activity itself'' was an error in the proposed regulation text. Therefore, we are finalizing text at subparagraph (h)(1) by removing that error and more clearly providing that CMS will set an annual threshold for finder fees based on a determination about amounts that would improperly incentivize agents and brokers to steer beneficiaries. We are finalizing subparagraph (h)(2) as proposed. Comment details and our responses may be found as follows.

We are finalizing the regulations with additional regulation text for a technical correction. One entity commented that the proposal eliminated §§ 422.2274(a)(1)(iv) and 423.2274(a)(1)(iv). Our proposal was not to remove these provisions concerning the applicability of compensation to third party entities and the regulation text should have included the substance of current subparagraph (a)(1)(iv). We have inserted the text from the regulation prior to the proposal at §§ 422.2274(b)(1)(iii) and 423.2274(b)(1)(iii) of this final rule.

Finally, we are not finalizing the change to the introductory language to §§ 422.2274 and 423.2274 in favor of deleting the existing introductory language (which forms the substantive basis for the new paragraph (a) definitions); the introductory language we proposed seems unnecessary to establish the scope of each regulation.

Comment: We received more than 140 comments concerning the level of renewal payments, proposed at 35 percent. A few of the comments appreciated the simplification and briefly discussed the 35 percent but neither strongly supported the amount or strongly opposed the amount. A few commenters believed renewal compensation should increase. The vast majority (over 95 percent) of the comments did not support the proposed renewal rate of 35 percent for years two and beyond with a few clearly stating that the renewal rate should be 50 percent. Commenters included agents, brokers, plans, and industry trade associations. One major trade association representing 37 plans stated that 35 percent was overly restrictive and 50 percent is in line with industry standards, especially concerning PDPs where the 35 percent renewal would not cover the agent's costs to ensure members are in the best plans for them. The commenters provided various reasons why the 35 percent should not be implemented. The majority of commenters stated that agents play an important role in educating beneficiaries and the reduced level of compensation would result in a negative impact on beneficiaries, as it would reduce the level and quality of services provided to beneficiaries, resulting in less information and poor plan choices made by beneficiaries and would also result in agents leaving the MA marketplace. Many commenters stated that agents spend a significant amount of time in training, preparing, and testing in order to properly educate beneficiaries about plan choices. A number of commenters stated that their overhead costs (travel, postage, facility costs) were significant and a reduction in compensation would affect this aspect of their business. Commenters also stated that the lower compensation would discourage new agents from entering the MA market.

Response: Based on the comments received, we are modifying our proposed regulations to permit the renewal payment to be up to 50 percent of FMV. MA organizations and Part D sponsors may still determine how much will be paid, up to 50 percent of the current FMV, and retain the authority to specify the details of their contracts with agents, including how many years renewal payments will be made. We believe that this increased percentage meets the statutory standard of ''ensur[ing] that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet their health care needs.''

Comment: We received one comment from an individual who misunderstood our proposal. It appears that the commenter thought our proposal would allow two different payment options.

Response: We have reviewed this comment and are not taking action based on an incorrect understanding of the proposal. Our proposal actually discussed two options that we considered for the renewal compensation.

Comment: We received two comments from individuals who suggested alternative agent payment strategies. One commenter suggested modifying Medicare.gov to track agents for enrollments processed through the Web site for payment by plans. The commenter also proposed paying agents on a monthly basis, coinciding with the months the beneficiary is in a plan, eliminating the need to commission reversals. Another commenter proposed that plans submit compensation schedules to CMS for review and approval.

Response: These recommendations entail significant changes with numerous operational implications. Therefore, we are not implementing the suggestions from these comments at this time. With respect to the comment regarding the frequency of payments, we did not propose to modify the existing regulatory permission for MA organizations and Part D sponsors to determine whether payments would be made at one time or in installments; therefore the comment is outside the scope of this proposed rule.

Comment: We received a few comments regarding the requirement that payments be made between January 1 and December 31 of the enrollment year. One commenter supported the proposal. A few commenters did not support the January 1 date because agents would have to wait 3 to 4 months for compensation for those enrolling during the AEP. One of these commenters also noted that getting the commission assures agents that the beneficiary was enrolled. A few plans were concerned about timely payment of December 1 effective enrollees.

Response: Our proposal is aimed at simplifying compensation while ensuring an even playing field. As explained previously, using a January 1 through December 31 payment timeframe limits the recoupment of payments made when a beneficiary makes more than one election during the AEP. Therefore, we are implementing this provision as proposed.

Comment: We received one comment stating that regulating the payment of only independent agents was unfair and that employed agents should also be regulated.

Response: We have reviewed this comment and have determined that the regulation of only independent agents is still appropriate. Our initial regulations were promulgated to ensure that agents/brokers do not steer beneficiaries into plans due to the agent's/broker's financial or other interest; we continue to be concerned about such steerage on the part of independent agents, since they often sell multiple products, with varying levels of compensation. In contrast, employed agents work for only one company and therefore do not have an incentive to move a member into a plan offered by a different organization

or sponsor in exchange for a higher commission.

Comment: We received a comment from a trade association recommending that CMS consider changes from cost plans to MA plans as ''like'' plan changes, rather than ''unlike'' plan changes for compensation purposes. The commenter stated beneficiaries evaluate cost plans similar to MA plans and that treating these as unlike plan types encourages churning.

Response: We have received this comment and declined to implement such this change from our proposal; we believe that this is outside the scope of the proposed rule. Our proposal did not address what constitutes ''like'' and ''unlike'' plan types, but instead simply referenced ''like'' and ''unlike'' plan types, using the existing regulation standards on this point, because CMS re-designated and revised certain portions of the existing regulation for simplification.

Comment: We received a few comments regarding referral fees. One commenter recommended that the referral fee for enrollments be limited to FMV instead of $100. Other commenters requested that CMS not allow referral fees to be paid.

Response: We reviewed these comments and are finalizing our proposal as described in the preamble to the proposed rule, with the changes to the regulation text at subparagraph (h)(1) as explained previously. Referral fees are applicable to employed, captive, and independent agents, and permitting the referral fee to be as high as the Fair Market Value (FMV) would increase the potential for steerage among different types of agents and thus plans. The $100 cap, which is required to be part of the total compensation, is an added protection to ensure financial interests of agents do result in misleading beneficiaries. Our proposal did not address whether referral fees should be permitted, only whether such fees should be capped and, if so, at what level. We do not believe that it is appropriate to prohibit or eliminate referral fees without additional rule-making that is specific on that question.

Comment: One plan requested clarification as to whether the renewal rate of the ''current'' FMV meant the year in which the renewal commission is being paid.

Response: We intend, for purposes of renewal rates, that the ''current'' FMV be the FMV for the enrollment year. For example, an agent would be paid 50 percent of Contract Year (CY) 2015's FMV for a renewal member who is enrolled in CY 2015.

Comment: One plan requested clarification as to whether CMS would require payments to be retroactive or if the existing regulations would continue until member's current 6-year cycle ended. One trade organization wanted to know whether the requirements will be effective for January 1, 2015 enrollments and how the new regulations will affect members currently in the existing 6-year cycle.

Response: As part of this final rule, the new compensation requirements will be implemented for all members for CY2015. One of CMS' intentions was to simplify the regulations and create an even playing field. We would not be able to accomplish these goals if we were to wait to implement these new requirements until all members finish their current 6-year cycle. However, we note that the final provides flexibility to MA organizations and Part D sponsors so long as payments are within the thresholds established in the rule. To the extent that an MA organization or Part D sponsor wishes to continue payment using a cycle system, negotiates that payment structure with its agents and brokers, and that cycle system complies with the limits and requirements of this final rule, the MA organization or Part D sponsor may do so.

Comment: We received a few comments concerning recoupment of compensation when a member disenrolls within the first three months of enrollment. One plan requested a better definition of ''broker behavior.'' One trade association stated that there would be significant challenges in determining whether disenrollments were due to independent agent/broker conduct. The trade association is concerned that plans could face significant disputes with agents/brokers about these decisions.

Response: We have reviewed these comments and determined that the current situation should remain unchanged based on these concerns that our proposed revisions would hamper MA organizations' and Part D sponsors' ability to determine which enrollments should be fully recouped, with the result that compensation is either inappropriately recouped or not recouped when necessary. Therefore, we are finalizing the regulation to require full recoupment of compensation when a member disenrolls within the first three months unless CMS determines that the recoupment is not in the best interests of the Medicare program. CMS will apply this standard and specify exceptions in sub-regulatory guidance. Our current guidance is consistent with this standard and will remain applicable.

Comment: We received a few comments regarding the implementation date of the regulations. One trade association stated that it typically took nine months to make systems changes to accommodate new requirements.

Response: We understand that systems changes may take time to implement. Because of necessary industry systems changes, and because the rule provides for a payment structure applicable by calendar year, these compensation changes do not take effect until enrollments effective January 2015. Therefore, organizations and sponsors will have approximately seven months to make such changes. Other than simplifying how FMV applies to renewal rates, the new compensation structure is similar to industry practice and present guidance. Therefore, we did not make any changes to this section of the regulation.

Comment: One trade organization commented that many MA organizations and Part D sponsors currently operate on a ''rolling year'' basis, such that, if an enrollment is effective February 1, the compensation covers the period starting on February 1 and continuing through January 31 of the following year. The association said that these were well-established processes and a change could disrupt systems and require a significant re-design effort.

Response: Our position has always been that organizations and sponsors were required under the existing rules to pay compensation on a calendar year basis, not a ''rolling'' year basis. When we encountered situations where organizations and sponsors have not implemented these requirements correctly, we have required the organization to adjust its processes to comply and they have done so in a timely manner. We decided to clarify this requirement in our regulations to ensure that all plans fully understand the CMS definition of an enrollment year. Therefore, we will not be making any modification based on this comment.

Comment: One trade association stated that the NPRM appears to have eliminated the current provisions at §§ 422.2274(a)(1)(iv) and 423.2274(a)(1)(iv), which address compensation requirements for Third Party Entities.

Response: We thank the commenter for this observation. These provisions were inadvertently eliminated from the current provisions. We have revised the regulation text accordingly.

Comment: We received one comment from a trade association that was concerned about CMS' requirement to recover commissions if an enrollee disenrolls in the middle of the year. They suggested that CMS require MA organizations and Part D sponsors to take ''commercially reasonable efforts'' to recover funds.

Response: The requirement to recover funds when a member disenrolls mid-year remains the same; we did not propose to change this requirement. Organizations and sponsors have the ability to make payments yearly, quarterly, monthly, or in other frequencies. Therefore, they could pay monthly, rather than on a yearly or quarterly basis, and thereby limit the need to recoup funds for disenrollments that occur at mid-year. Therefore, we will not be making any changes to the regulation.

Comment: We received a few comments recommending that CMS provide a mandatory plan comparison form. Agents/Brokers would be required to fill this out and provide to the beneficiary for review.

Response: These comments are outside the scope of our proposed rule, but we will consider this suggestion for future changes.

Comment: We received a few comments from beneficiary advocacy groups stating that MA organizations and Part D sponsors slow down, artificially delay, or dispute the payment of compensation, which ultimately encourages agents and brokers to take their business to another plan.

Response: These comments are outside the scope of our proposed rule, but we believe that our new requirement that compensation be paid within the enrollment year will address some of these issues.

After consideration of the public comments received, we are finalizing our proposal at §§ 422.2274(a), (b) and (h) and 423.2274(a), (b), and (h) with the following modifications as previously discussed:

- Deleting the introductory text to the regulation section.
- Raising the renewal compensation rate from 35 percent to (up to) 50 percent of the current fair market value cut-off amounts published annually by CMS.
- Removing the proposed recoupment standard for rapid disenrollments by reverting to the status quo where subregulatory guidance describes activities not triggering recoupments (rather than requiring recoupment based on ''agent or broker behavior''; implementing a standard based on the best interests of the Medicare program to identify disenrollments that do not require recoupment.
- Incorporating existing regulation text about compensation to Field Marketing Organizations.
- Clarifying the CMS standard for applying the limit on referral fees.

8. Drug Categories or Classes of Clinical Concern (§ 423.120(b)(2)(v))

Section 3307 of the Affordable Care Act amended section 1860D–4(b)(3)(G) of the Act by replacing the specific criteria established under MIPPA in 2008 to identify categories or classes of Part D drugs for which all Part D drugs therein shall be included on Part D sponsor formularies. The specified criteria were replaced with the requirement that the Secretary establish criteria through notice and comment rulemaking to identify drug categories or classes of clinical concern. In addition, section 3307 of the Affordable Care Act requires the Secretary to engage in rulemaking to establish exceptions that permit a Part D sponsor to exclude from its formulary a particular Part D drug that is otherwise required to be included in the formulary in a drug category or class of clinical concern (or otherwise limit access to such a drug, including through prior authorization or utilization management). The Affordable Care Act amendments to section 1860D–4(b)(3)(G) of the Act specified that until such time as the Secretary establishes through rulemaking the criteria to identify drug categories or classes of clinical concern through rulemaking, the following categories or classes shall be identified as categories or classes of clinical concern: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. We proposed to implement the Affordable Care Act requirements set forth in section 1860D–4(b)(3)(G) of the Act by revising § 423.120(b)(2)(v) and (vi) to specify: (1) the criteria the Secretary will use to identify drug categories or classes of clinical concern; and (2) exceptions that permit Part D sponsors to exclude a particular Part D drug from within a category or class of clinical concern that is otherwise required to be included in the formulary (or to otherwise limit access to such a drug, including through utilization management or prior authorization restrictions). We also proposed to specify which drug categories or classes met the proposed criteria and explained the process we used for making these determinations.

We proposed to modify § 423.120(b)(2)(v) to require that, unless an exception applies, all Part D drugs within a drug category or class be included on the formulary if the drug category or class of drugs for a typical individual with a disease or condition treated by the drugs in the category or class meets both of the following criteria, as determined by CMS—

- Hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled; and
- More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

We were concerned that requiring essentially open coverage of certain categories and classes of drugs presents both patient welfare concerns and financial disadvantages for the Part D program as a result of increased drug prices and overutilization. We also believed that criteria for identifying drug categories and classes of clinical concern should identify only those drug categories or classes for which access cannot be adequately ensured by beneficiary protections that otherwise apply. Consequently, as we took the opportunity to propose to codify criteria for identifying categories or classes of drugs that are of clinical concern, we believed that the requirements of section 3307 of the Affordable Care Act should be implemented taking into consideration the other protections available to beneficiaries. Otherwise, we believed section 3307 of the Affordable Care Act would establish duplicative, and thus unnecessary, protections that would serve only to increase Part D costs—without any added benefit and with the possibility of added harm from misuse. Therefore, in considering whether additional protections continue to be needed under this section, we needed to take the other beneficiary access protections into account. We detailed five such protections: formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the coverage determination and appeals processes. Taken together, we believed these requirements were comprehensive

enough that additional access safeguards would be needed only in those situations where a Part D beneficiary's clinical needs cannot be more efficiently met.

We received the following comments, and our response follows:

Comment: We received strong support for our entire proposal from some commenters who agreed, as they stated, with ''all of the reasons'' underlying the proposal, but we received no supportive comments explicitly directed toward our proposed criteria for identifying categories and classes of clinical concern. However, we did receive significant opposition to our proposed criteria. Several commenters generally stated that the criteria themselves were flawed, much less their application to the drug categories and classes in our analysis. Although the statute did not provide individual criteria, some commenters stated that the criteria were more restrictive than statutory intent and insufficiently accounted for patient complexity. Other commenters stated that application of overly restrictive criteria set a dangerous precedent, and other commenters raised related concerns that other categories and classes of clinical concern could be eliminated in the future or that they could be incorrectly applied to other disease states whose guidelines indicate the use of these drugs. For example, many commenters expressed concern that if immunosuppressants for transplant rejection no longer received the additional protections under section 3307, patients with multiple sclerosis who use immunosuppressants may face access issues. Additionally, although it was mentioned as a source of savings in our RIA, some commenters opposed the idea that future drugs in a particular category or class, representing advances in therapy, may not be covered, believing this jeopardized beneficiary health. Indeed, many commenters stated that the application of these criteria would be life-threatening.

Response: We thank the commenters for bringing their concerns to our attention. We attempted to embrace the principle of balancing access and cost through optimal formulary management inherent in the design of the Part D benefit in proposing to establish criteria pursuant to section 3307 of the Affordable Care Act. However, based on the comments received, we have concluded that our proposed criteria did not strike the balance among beneficiary access, quality assurance, cost-containment, and patient welfare that we were striving to achieve. Thus, we are not finalizing our proposal to establish new criteria for the categories and classes of clinical concern. Accordingly, we are maintaining the existing six categories and classes of clinical concern listed in the statute and are amending the regulation at § 423.120(b)(2)(v) to reflect that the categories and classes of clinical concern will be as specified in section 1860D–4(b)(3)(G)(iv) of the Act until we undertake rulemaking to specify criteria to identify the categories and classes of clinical concern.

During our annual formulary review and approval process, regardless of a drug's placement in a category or class of clinical concern, to the extent that a treatment guideline speaks to a specific category or class of drugs, we look for representation from that category or class of drugs on the formulary. Moreover, if the treatment guidelines address specific drugs, we would review formularies to ensure inclusion of those specific drugs. Thus, although a category or class of clinical concern is immunosuppressants for transplant rejection, to the extent that the treatment guidelines for multiple sclerosis indicate the use of immunosuppressants, we still would look for representation of these drugs on the formulary during our treatment guidelines review for multiple sclerosis.

After consideration of the public comments we received, we are finalizing a technical change to § 423.120(b)(2)(v) to reflect the existing categories and classes of clinical concern. Because the existing regulation at § 423.120(b)(2)(v) is obsolete in light of the Affordable Care Act, we are making a technical change to specify that until such time as we undertake rulemaking to establish criteria to identify, as appropriate, categories and classes of drugs for which we determine are of clinical concern, the categories and classes of clinical concern shall be as specified in section 1860D–4(b)(3)(G)(iv) of the Act.

9. Medication Therapy Management Program (MTM) Under Part D (§ 423.153(d))

Section 1860D–4(c)(2) of the Act provides that Part D sponsors, in offering Medication Therapy Management (MTM) programs, must target individuals who: (1) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure); (2) are taking multiple covered Part D drugs; and (3) are identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary. At the start of the Part D program, we believed that 25 percent of enrollees would qualify for MTM services. However, analysis revealed that MTM program enrollment was well below that level. In the 2010 Call Letter and subsequent regulation, we modified the criteria to reduce the variability in eligibility and level of service and to improve access to MTM services, again targeting 25 percent of enrollees. Despite these changes, MTM program participation remains very low. Moreover, additional evidence that the program improves quality and generates medical savings supports the belief that more than 25 percent of enrollees will benefit from MTM services.

We continue to see restrictive criteria, such as plan sponsors specifying a narrow list of chronic diseases or Part D drugs coupled with requiring a higher minimum number of covered drugs (for example, eight drugs versus two) for eligibility. As a result, access to MTM services remains very low with MTM program eligibility rates at less than 8 percent in 2011. In the proposed rule, we cited a number of studies which discussed the following: there may be racial disparities in meeting the eligibility criteria, the current eligibility criteria and variability are restricting access to MTM services, and MTM enrollees with certain chronic diseases, particularly those who received annual comprehensive medication reviews (CMRs), experienced significant improvements in drug therapy outcomes when compared to beneficiaries who did not receive any MTM services, and cost savings.

We believe the studies support the necessity to reduce variability and racial disparity in eligibility criteria among plans and improve access to beneficial MTM services. We proposed changes to the eligibility requirements regarding multiple chronic diseases, multiple Part D drugs, and the annual cost threshold.

a. Multiple Chronic Diseases

Under the statute, one of the three criteria that are used to target beneficiaries for MTM services is whether a Part D beneficiary has multiple chronic diseases such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure. We previously interpreted this language to allow sponsors to define ''multiple chronic diseases'' with three chronic diseases being the maximum number a plan sponsor may require for targeted enrollment. Further, sponsors are allowed to target beneficiaries with select chronic diseases, but must include at least five of the nine core chronic diseases in their criteria. This list of core chronic diseases, as updated in the 2013 Call Letter (available at *http://www.cms.gov/Medicare/Health-*

Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2013.pdf), includes hypertension, congestive heart failure, diabetes, dyslipidemia, respiratory disease, bone disease—arthritis, mental health, Alzheimer's disease, and end stage renal disease. We proposed to revise our interpretation of ''multiple chronic diseases'' to require that sponsors must target enrollees having two or more chronic diseases for MTM services. We also proposed to require that at least one of the chronic diseases that a beneficiary has in order to satisfy the eligibility criteria must be one of the list of core chronic diseases. In addition, we proposed to redefine the core diseases by combining hypertension and congestive heart failure under the umbrella of ''cardiovascular disease,'' which would also encompass congestive heart failure, acute myocardial infarction, cerebral hemorrhage and effects of stroke, vascular disease, specified heart arrhythmias, and hypertensive heart disease. The proposed list of core chronic diseases became cardiovascular disease, diabetes, dyslipidemia, respiratory disease, bone disease—arthritis, mental health, Alzheimer's disease, and end stage renal disease.

b. Multiple Part D Drugs

The second of the three statutory criteria for identifying targeted beneficiaries is whether a Part D beneficiary is taking multiple covered Part D drugs. We proposed to revise our interpretation of ''multiple Part D drugs'' to require that sponsors must target enrollees taking two or more Part D covered drugs for MTM services. We also proposed to restrict the flexibility previously available to sponsors by requiring that they consider any Part D covered drug. In the proposed rule, we cited literature that supported the idea that patients with multiple diseases and taking at least two drugs are more likely to have drug therapy problems and need MTM.

c. Annual Cost Threshold

The final statutory requirement for targeting Part D beneficiaries for MTM services is that the beneficiary be identified as likely to incur costs for covered Part D drugs that exceed a level specified by the Secretary. The Congress did not impose any specific requirements with respect to the cost threshold at the time the MTM criteria were passed in to law, nor has it addressed this threshold in any of the subsequent amendments to section 1860D–4(c)(2) of the Act. We previously codified a $3,000 threshold, as updated annually by the annual percentage increase in the average per capita aggregate expenditures for Part D drugs for Part D eligible individuals under § 423.104(d)(5)(iv) in the April 2010 final rule entitled, ''Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs'' (75 FR 19818). The threshold is currently $3,017 in 2014. However, we are concerned that there are a number of beneficiaries who need MTM, but are not currently eligible because they do not meet the current cost threshold of $3,017, despite the increased likelihood of having drug therapy problems as a result of having multiple chronic diseases and taking multiple medications. Moreover, the current cost threshold may have the unintended consequence of causing beneficiaries to no longer qualify for MTM services in the next plan year (whether remaining in the same plan or enrolling into a new plan) if they fall below the cost threshold as a result of their enrollment in plans that employ cost avoidant strategies, such as aggressive use of generics, or in MTM programs that center on therapeutic interchange. Consistent with our proposal that sponsors must target enrollees taking two or more Part D covered drugs for MTM services and taking into account that one or more of these Part D drugs are likely to be generics, we proposed setting the annual amount in Part D drug costs at an amount that represents the intersection of multiple conditions and multiple drugs. Specifically, we proposed setting the threshold at $620 which is the estimated annual total drug cost for a beneficiary filling two generic prescriptions, based on an analysis of prescription drug event (PDE) data.

We are not finalizing these proposals. We will engage in new notice and comment rulemaking on this issue as warranted in the future.

We received a large number of comments related to our proposal to revise § 423.153(d)(2)(i) through (iii) to expand MTM program eligibility and our response follows.

Comment: Many commenters were supportive of MTM in general and CMS' goals. These commenters were supportive of the proposed changes to expand access to MTM services, shared CMS' concerns regarding restrictive and variable eligibility criteria established by some sponsors, and endorsed the proposals to revise the eligibility criteria to increase uniformity. This included support for and clarifying questions regarding the revised definitions for ''multiple chronic diseases,'' with the addition of ''cardiovascular disease'' to the list of core diseases, and ''multiple Part D drugs.'' Some commenters stated that CMS should post MTM eligibility rates on the CMS Web site or make plan-reported data more available for research. Other commenters, who supported the proposed changes to expand access to MTM, provided information on return on investment, outcomes, or individual experiences in improving quality and lowering costs through MTM provided by community pharmacists who have close relationships with the beneficiaries and local prescribers. A large number of commenters also stated that, to date, variability in plan offerings and limited compensation has made the provision of MTM in the community setting difficult in a consistent, scalable and timely manner.

A significant number of commenters also were strongly opposed to the broad expansion of eligibility. They questioned the effectiveness of expansion under the current infrastructure as delivered by drug plans with limited incentives and a lack of care coordination, and they commented that the clinical evidence did not support the proposed changes. We received many comments that the proposed changes would significantly increase costs (both administrative and beneficiary premiums), reduce the quality of programs delivered to beneficiaries who most need MTM, and could overwhelm limited resources. Many commenters requested that the proposed changes be withdrawn, and some commenters offered alternative eligibility criteria for CMS to consider in the future. These included: delay the proposed changes or implement the changes incrementally, alternative criteria for the minimum thresholds for eligibility, alternative eligibility criteria based on risk factors, and requiring MTM at transition of care.

Response: We thank these commenters for their thoughtful and supportive comments. MTM has been shown to improve drug therapy outcomes and lower costs, and we agree that the use of community-based resources for providing MTM services shows promise in improving access and quality. We still have concerns that many sponsors are applying restrictive criteria to narrow the pool of targeted beneficiaries for MTM rather than optimizing the eligibility criteria to offer MTM to beneficiaries who will most benefit from these services. These programs are not living up to our expectations. As we discussed in the regulatory impact analysis for the proposed rule (79 FR 2036), we estimate that only 2.5 million beneficiaries (8 percent) are eligible for MTM services,

13 percent opt-out of the MTM program, and 10 percent of participating beneficiaries receive an annual CMR. That means that less than 220,000 Part D enrollees receive CMRs, which studies have shown is a crucial element of MTM to improve drug therapy outcomes and lower costs. Not enough is being done by sponsors to provide sufficient access to MTM services and engage beneficiaries and providers in this process. We will consider publicly posting the MTM program eligibility rates for each Part D contract, similar to how we display MTM program CMR rates, and explore ways to make the plan-reported data available for public use.

Despite the persuasive comments from those who support the proposed changes in eligibility criteria, we also take into account the comments that the timeline for implementing the proposed changes may be too aggressive and could negatively affect existing MTM programs. While our goal was to increase eligibility and access to MTM, we do not want to do it at the expense of sacrificing any quality with existing programs. Therefore, we are not finalizing our proposed changes to the eligibility criteria. But, we will continue to evaluate information on MTM programs and monitor sponsors' compliance in accordance with the MTM requirements established by § 423.153, with the goal of proposing other revisions to criteria in future rulemaking that will help expand the program. We believe that Part D sponsors can target more beneficiaries for MTM under the existing criteria. We plan to closely scrutinize sponsors that may be abusing the flexibility provided to them in establishing the eligibility criteria, which may have contributed to the racial disparity, variability, and beneficiary confusion with respect to MTM eligibility that we identified in the proposed rule. We will consider the commenters' suggestions for alternative criteria and may consider revisions to MTM eligibility criteria for future rulemaking. We may also consider changes to the definitions for ''multiple chronic diseases,'' including the core chronic diseases, and ''multiple Part D drugs'' in the future.

10. Requirement for Applicants or Their Contracted First Tier, Downstream, or Related Entities To Have Experience in the Part D Program Providing Key Part D Functions (§ 423.504(b))

Since its establishment in 2006, the Medicare Part D program has matured into a generally stable, well-functioning program, and the Part D sponsors (as well as their first tier, downstream, and related entities (FDRs)) with which CMS contracts have developed vast expertise in the operational complexities of the program. While we will continue to fine tune the program through rulemaking, guidance, and additional oversight procedures, we believe the program has largely entered a mature stage. Despite this progress, we still find ourselves spending a disproportionate amount of resources and attention on the operations of new Part D sponsors where neither the new sponsor nor its supporting FDRs have experience with Part D.

To address this problem, pursuant to our authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, not inconsistent with the Part C and D statutes, that are necessary and appropriate to administer the Part D program, we proposed to adopt provisions that would require any entity seeking to contract as a Part D plan sponsor (as a stand-alone prescription drug plan sponsor or as a MA organization offering Part D benefits) to have arrangements in place such that either the applicant or one of its contracted FDRs has one full benefit year serving as a Part D plan sponsor, or at least one full benefit year of experience performing key Part D functions for another Part D plan sponsor. The applicant or a contracted FDR will be required to have obtained that experience within the 2 years preceding the Part D sponsor qualification application submission. Under this proposal, the experience requirement would be met by an entity seeking to contract as a Part D plan sponsor if its parent or another subsidiary of that parent already holds a Part D sponsor contract that has been in effect for at least one year at the time of the application submission.

Given the wealth of available Part D expertise that now exists, it is justifiable for us to require that new applicants to the program bring with them Part D experience so that we can better protect Part D enrollees and minimize unnecessary expenditures of resources by us in correcting avoidable problems. When neither a Part D sponsor, nor its FDRs providing key Part D functions, has any experience delivering Part D benefits, the consequences can be disastrous for beneficiaries and highly disruptive for the program and CMS.

While there are many operational functions that must run smoothly for a Part D plan to be successful (for example, pharmacy network development/maintenance, enrollment processing, prescription drug discount negotiation, and provision of customer service), we proposed to require Part D experience in only three critical areas in which beneficiaries are particularly vulnerable should the sponsor demonstrate significant non-compliance. The three areas for which we proposed to require prior experience in Part D at the time of application to become a new Part D sponsor are—

- (1) Authorization, adjudication and processing of pharmacy claims at the point of sale;
- (2) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers; and
- (3) Operation of an enrollee appeals and grievance process.

It is in these three areas where—in our view, based on our experience with Part D—enrollee health is placed at the most significant risk by Part D sponsor compliance failures.

Under our proposal, multiple separate organizations could together combine their experience to meet the prior qualification requirements for the three key Part D functions. That is, no one single entity would need to have prior experience in all three areas. Rather, the requirement would be for the Part D applicant in combination with its FDRs, if any, to have Part D experience covering the three key functions.

Our proposal also does not prohibit additional organizations from gaining Part D experience in the selected key functional areas. Should an organization wish to become a new Part D FDR for one or more of the key functions, this ''novice'' entity could provide the service for just one of the hundreds of existing Part D sponsors. After a period of one year, the novice entity would then be qualified to provide its services to existing Part D sponsors as well as partner with new Part D applicants. In somewhat the opposite scenario, a new Part D sponsor contracting with experienced FDRs will have the opportunity to gain its experience in the key Part D functions by working closely with its FDRs, developing in house expertise, and providing oversight. After a period of one or more years, if desired, the Part D sponsor itself could conceivably take responsibility for carrying out one or more of the key Part D functions.

While our proposal did not require the Part D experience to be current at the time of an application to become a Part D sponsor, we proposed that the experience be recent (that is, within the past 2 years) and have lasted for at least one full benefit year. We believe that any experience older than 2 years would be out of date and would not represent experience with the current state of the

Part D program. As for our proposed requirement that the experience be for at least a term of one full benefit year, this approach is appropriate because operating the benefit involves cyclical activities, some of which take place only one time per year, and thus an organization can only gain full experience by operating its Part D functional area for an entire benefit year.

We intend to implement this proposal through our existing Part D contract qualification application process, and we proposed to amend § 423.504(b) accordingly. Applicants with existing Part D contracts or whose parents or other subsidiaries of the same parent hold Part D contracts will not be required to submit evidence of their Part D experience.

We received the following comments and our response follows:

Comment: We received strong statements of support from many commenters. We received only one suggestion of not finalizing the policy, but the commenter did not provide any details or rationale to support its comment.

Response: We appreciate the widespread support for this proposal.

Comment: We received one recommendation to consider a less stringent standard for employer groups seeking to act as Employer Group Waiver Plan (EGWP) sponsors.

Response: We expect all sponsors, including EGWP sponsors, to meet our experience and capability requirements. We have an obligation to ensure that all beneficiaries receive their benefits from experienced Part D sponsors.

Comment: One commenter that supported the policy suggested that CMS should also address the problem of applicants not having the skills or capacity to even oversee their experienced FDRs.

Response: We share the concern that applicants may not have experience overseeing FDRs, which is why, in addition to the current requirements and standards in place for administration and management, we are finalizing at section A.III.11. of this final rule our proposed requirement that new PDP sponsor applicants have immediately prior to the date of the application submission 2 years' experience administering health insurance benefits directly or 5 years' experience providing certain prescription drug benefit management services to a health insurer . We also have procedures and mechanisms in place to monitor a Part D sponsor's administration and management of its contract, including the option of conducting an audit of a sponsor's operations prior to the start of the contract year to confirm that it is prepared to oversee the delivery of Part D benefits to its members.

Given the near universal support for this proposal we are finalizing this provision without modification.

11. Requirement for Applicants for Stand-Alone Part D Plan Sponsor Contracts to Be Actively Engaged in the Business of the Administration of Health Insurance Benefits (§ 423.504(b)(9))

The Medicare prescription drug benefit program has matured into a generally stable, well-functioning program, and the Part D sponsors with which CMS contracts have developed vast expertise in the operational complexities of the program. The market for stand-alone Part D Prescription Drug Plans (PDPs) has also matured significantly since the program's inception and what was once a novel product is now available to residents of every state from multiple sponsors who offer several plan options. Over the same period, we have noticed that the Part D program has in some cases attracted sponsors wishing to offer stand-alone PDPs who have no prior experience in the delivery of health or prescription drug insurance benefits, often to the detriment of the Part D program and the Medicare beneficiaries who elect plans offered by these sponsors.

To address this problem, we proposed, pursuant to our authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms that are necessary and appropriate to administer the Part D program, regulatory provisions that would require any entity seeking to contract as a stand-alone PDP sponsor, to have either actively provided health insurance or health benefits coverage for 2 continuous years immediately prior to submitting a contract qualification application, or provided certain prescription drug benefit management services to a company providing health insurance or health benefits coverage for 5 continuous years immediately prior to submitting an application. This requirement would not apply to an entity seeking to contract as the sponsor of a stand-alone PDP if its parent or another subsidiary of itself or its parent possesses the requisite experience.

This proposal may appear similar to the immediately-preceding proposal (section III.A.10. of this final rule) requiring, at § 423.504(b)(8), that new Part D sponsors engage first tier, downstream, and related entities with prior Part D experience. However, the proposed change we are discussing in this section, which we proposed to codify at § 423.504(b)(9), would apply only to entities seeking to contract as a Part D sponsor of a stand-alone PDP, whereas the proposed requirement at § 423.504(b)(8) would apply to all new Part D sponsors, including those seeking to contract as MA organizations offering Part D through an MA–PD plan. We proposed both requirements because the problems encountered by new PDP sponsors with no experience in the health insurance market are distinct from those encountered by new PDP sponsors and MA organizations that use PBMs with no experience in the Part D market. New PDPs with no prior health insurance or health benefits experience have demonstrated significant problems even when using experienced PBMs.

While relatively few sponsors fit this profile each year, they have caused disproportionate problems for beneficiaries and CMS. Time and again, these sponsors fail our past Medicare contract performance and audit tests or receive low quality scores (that is, star ratings) because they lack the ability to administer even the most basic elements of a health or drug benefit program, let alone one as complex as Medicare Part D.

When the sponsor is a novice not only to Medicare Part D, but also to virtually every aspect of health benefits administration, there is no assurance that the entity will be able to administer or oversee the most basic elements of health benefits coverage, such as processing claims, administering a coverage determination and appeals process, enrolling beneficiaries, or administering the benefit as approved. To entrust inexperienced applicants with responsibility for correctly operating a program for which even experienced health insurers have had to develop new expertise has proven to be unacceptably risky. We proposed that new applicants have 2-years of experience providing health insurance or health benefits coverage (that is, operating as risk-bearing entities licensed in the states where they offer benefits) prior to applying as stand-alone Part D Sponsors because we believe that this provides sufficient time to demonstrate the applicant's ability to operate a health plan. We believe that requiring 2-years of experience as a risk bearing entity offering health insurance or health benefits coverage ensures that new sponsors of stand-alone PDPs have minimal experience operating a health benefits program without unduly limiting new entrants to the marketplace.

We recognize that a number of PBMs and Third Party Administrators with experience administering prescription drug benefits have entered the stand-alone PDP market and have adapted to providing the Part D benefit despite their lack of previous experience as health insurers. Therefore, we proposed that organizations applying to contract as stand-alone PDP sponsors that do not have experience as a risk-bearing entity providing health insurance or health benefits coverage would, in the alternative, be eligible to hold a PDP contract if they had 5-continuous years of experience performing services on behalf of an insurer in the delivery of benefits in any health insurance market in the three key areas indicated in this section III.A.10. of this final rule. The three areas that we proposed as meeting the experience requirements are: (1) Adjudication and processing of pharmacy claims at the point of sale; (2) administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers; and (3) operation of an enrollee appeals and grievance process. Our reasons for selecting these three areas as meeting the experience requirements are described in more detail in the section of this rulemaking notice relating to the proposed requirement at § 423.504(b)(8) that new Part D sponsors employ experienced FDRs for these functions. We proposed a longer experience requirement for these entities because entities offering these services face fewer barriers to entry in the marketplace and are not as tightly regulated as risk bearing entities. Therefore, we believe that entities that seek to qualify on the basis of their experience as PBMs or Third Party Administrators should be required to have provided services in these key areas for 5-continuous years, rather than merely 2.

We intend to implement this proposal through our existing Part D contract qualification application process, and we proposed to amend § 423.504(b) accordingly.

We received the following comments and our response follows:

Comment: We received strong statements of support from several commenters.

Response: We appreciate the support for this proposal.

Comment: We received one recommendation to consider a less stringent standard for employer groups seeking to act as EGWP sponsors.

Response: We are not persuaded by this comment because, in general, we expect that all sponsors, including EGWP sponsors, meet all of our experience and capability requirements. EGWP sponsors perform the same core functions as sponsors of individual market PDPs, including claims processing, formulary administration, operation of an appeals and grievance process, and coordination of benefits. Therefore, the same concerns that led us to adopt the requirement that new PDP sponsors have experience in these areas applies to EGWP sponsors as well as sponsors of individual market plans.

Given the universal support for this proposal, we are finalizing this provision without modification.

12. Limit Parent Organizations to One Prescription Drug Plan (PDP) Sponsor Contract per PDP Region (§ 423.503)

Each year, we accept and review applications from organizations seeking to qualify to offer stand-alone prescription drug plans in one or more PDP regions. With limited exceptions (for example, poor past contract performance, limited Part D experience), we approve all applications submitted by organizations that demonstrate that they meet all Part D application requirements. We proposed, under our authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, not inconsistent with the Part C and D statutes, that are necessary and appropriate to administer the Part D program, to add as a basis upon which we may deny a PDP sponsor application the fact that the applicant is applying for qualification in a PDP Region where another subsidiary of the applicant's parent organization already holds a PDP sponsor contract. In our description of this proposal, the term ''parent organization'' refers to an entity that controls a subsidiary through ownership of more than 50 percent of the subsidiary's shares.

Section 1860D–12(b)(1) of the Act provides that PDP sponsors may offer multiple plan benefit packages (referred to as PBPs or plans) under one PDP sponsor contract. Therefore, parent organizations need only one PDP sponsor contract to offer the full range of the possible plan options in a particular PDP Region. Additionally, informal communications made by past requestors of duplicate contracts indicated that the purpose has been to either a) segregate low income beneficiaries into their own contract, or b) corral the experience of a particular low-performing plan into its own CMS contract so as not to taint the performance rating of the better performing plan offering, as performance ratings are calculated at the contract level. We oppose the inefficiencies of duplicate contracts and the gaming duplicate contracts can support. That said, we welcomed comments from industry, advocates, and others as to circumstances for our consideration under which duplicate contracts may be beneficial.

One of the fundamental principles of the Part D program is that the selection of plans made available to beneficiaries is the product of true competition among PDP sponsors. Two subsidiaries of the same parent organizations offering plans in the same PDP region are not truly competitors, as decisions concerning their operations are ultimately controlled by a single entity, or parent organization. Also, we only approve those PDP offerings that meet the meaningful differences test stated at § 423.265(b)(2), and we apply that test at the parent organization level. A parent organization would not gain an opportunity to offer more plan benefit packages under two or more contracts it controlled through its subsidiaries than it would under one contract because we would, as part of our bid review, evaluate whether all the plans proposed by the same parent organization met the meaningful differences test.

The proposed limitation on the number of PDP sponsor contracts a parent may control in a PDP Region is also necessary to preserve the integrity of CMS' star ratings. CMS assigns star ratings at the contract level, and they are intended to reflect all aspects of the PDP operations controlled by a unique contracting entity. However, that principle is compromised when a parent organization to one of the contracting entities is permitted to control, through other subsidiaries, more than one PDP contract. Allowing a parent organization to effectively administer two or more PDP sponsor contracts would allow it potentially to artificially inflate the star ratings on one contract by excluding the poor performance under its other contract from the rating calculation. In that instance, some beneficiaries could make a plan election without complete information about the performance of the organization ultimately responsible for the quality of services they would receive by enrolling in that plan.

Based on our experience in administering the Part D prescription drug benefit program we do not believe that there is a compelling justification for parent organizations to administer two PDP sponsor contracts in the same PDP region. Moreover, such arrangements impede our ability to efficiently administer the Part D program and provide a means by which the integrity and reliability of our star ratings system can be compromised. Therefore, we proposed to amend

§ 423.503(a) by adding a paragraph (3) stating that CMS will not approve an application when it would result in the applicant's parent organization holding more than one PDP sponsor contract in the PDP region for which the applicant is seeking qualification as a PDP sponsor. We anticipate that we would most frequently use this authority to deny an application in instances where the applicant's parent organization already controls a PDP sponsor contract, either directly by acting as a PDP sponsor itself (in instances when the parent is licensed as a risk-bearing entity) or through its ownership of a subsidiary that qualifies as a PDP sponsor and is a party to a stand-alone PDP sponsor contract. In the less likely situation where two or more subsidiaries of the same parent organization each submit applications in the same year for PDP regions where the parent organization controls no PDP sponsor contracts, we would request that the parent withdraw all but one of the applications. In the absence of a withdrawal election, we will deny all of the parent organization's applications.

We received the following comments and the response follows:

Comment: The comments of several beneficiary advocacy organizations contained expressions of support for our proposal, citing in particular the role it will play in preserving the integrity of CMS' star ratings system.

Response: We appreciate the expressions of support for our proposal.

Comment: Several commenters stated their opposition to our proposal on the basis that it would limit their business opportunities and reduce competition in the Part D market by reducing the number of plan sponsors participating in a given PDP region.

Response: We note that the commenters did not describe or provide examples of the nature of the business opportunities that Part D sponsors and their parent organizations would be denied should this provision go into effect. Also, we believe that to properly assess the level of competition in the Part D market, it is important to consider not just the number of plan sponsors offering benefits, but also whether all of those sponsors truly have incentives to compete against one another. As we noted in our preamble discussion to the proposed rule, additional plan sponsors controlled by entities that already participate in the Part D market do not promote improved plan options since subsidiaries of the same parent cannot be said to be truly in competition with each other. In a truly competitive market, multiple entities develop and promote products to capture as large a share of that market as possible at the expense of other market participants. It is our experience that two or more subsidiaries of the same parent organization are ultimately accountable to the same set of shareholders and are administered by the same senior management team. In such an arrangement, we believe there is little incentive for the parent organization to manage one PDP contract in a way that would attempt to take enrollees away from, or prevent beneficiaries from electing, plans offered by the related entity operating a second contract. We also note that none of the commenters provided an explanation as to how related entities would truly compete in the same PDP region.

Comment: Several plan sponsors that have recently acquired other plan sponsor contracts expressed their concern that the new policy would jeopardize their right to maintain two or more contracts during a transition period following the acquisition.

Response: We assure the commenters that our proposal has no effect on our application of the regulatory provision at § 423.272(b)(3), which provides acquiring organizations an exemption from the meaningful differences standard normally applied to a sponsor's (or its parent organization's) bids for a 2-year period following the acquisition of or merger with another Part D sponsor. We have allowed acquiring sponsors to maintain the separate acquired contract during the authorized 2-year period, and we will continue to apply that policy after the adoption of this provision.

Comment: Some plan sponsors that currently hold more than one PDP sponsor contract in a PDP region commented that they were concerned that the proposed provision would require them to consolidate their operations into one contract.

Response: We note that the proposal only addressed our intention to deny applications for new contracts submitted by entities related to organizations that already hold a PDP sponsor contract in a particular region. As we discussed in the preamble to the proposed regulation, we will continue to encourage such organizations to consolidate their contracts, but we are not requiring organizations to take such action at this time.

Comment: One commenter requested that CMS revise the proposal to allow a parent organization to hold two contracts in the same PDP region if one of those contracts is maintained solely for the purpose of offering employer group waiver plans (EGWPs). The commenter explained that because EGWPs operate differently than individual market plans (for example, different enrollment processes, the need to coordinate with non-Part D supplemental coverage), it may reduce the complexity of a parent organization's Part D operations if it is permitted to keep its EGWP business under a separate contract. Moreover, since EGWP plans are not offered to individual beneficiaries, these contracts would not be subject to the same incentives that might encourage sponsors to game their star rating performance to attract enrollments.

Response: We do not believe the commenter's arguments support special treatment under our proposal for organizations offering EGWPs. While it is true that CMS affords EGWPs, through the application of our statutory waiver authority, flexibility in meeting Part D requirements, the resulting differences in requirements are not so significant that a separate EGWP-only contract is necessary for an organization to administer such plans successfully. In fact, the resulting differences do not represent conflicting requirements that might create the need for a separate contract held by a different legal entity to administer EGWPs. Rather, the EGWP requirements are a result of our completely waiving certain requirements (for example, pharmacy access standards, prior approval of marketing materials) or modifying other requirements (for example, enrollment limited to employer group members), and a single plan sponsor can meet these if it is already offering individual market PDPs. In fact, it is common for a PDP sponsor to sign a stand-alone PDP contract with CMS that includes an EGWP addendum through which the single entity offers both individual market plans and EGWPs (that is, ''800 series'' plans). Our experience in administering the Part D program indicates that a properly managed single legal entity is capable of complying with multiple sets of Part D requirements. Also, while sponsors may not have the same incentives to game the star rating system to attract EGWP enrollments as they do to attract individual beneficiaries, that fact alone would not support allowing sponsors to maintain separate EGWP contracts. We believe the single contract rule is necessary to maintain the integrity of the star ratings that are reported to the public. As we stated earlier in the preamble discussion of our proposal, star ratings are intended to reflect all aspects of the PDP operations controlled by a unique contracting entity, including the

administration of EGWP products. Allowing a parent organization to maintain a separate EGWP contract would mean that the star ratings associated with each of its PDP contracts contract would provide an incomplete picture of the organization's performance. We believe that all members of the public, including those who make plan elections on behalf of employer group members as well as individual beneficiaries, benefit from star ratings information that clearly indicates the quality of all Part D operations under one organization's control.

After consideration of the public comments we received, we are finalizing our proposal without modification, with the exception of a technical edit which changes the proposed phrase ''may not approve'' to ''does not approve'' to clarify that CMS will deny all applications that meet the criteria stated in the provision.

13. Limit Stand-Alone Prescription Drug Plan Sponsors To Offering No More Than Two Plans per PDP Region (§ 423.265)

Under our authority at section 1860D–11(d) of the Act, we conduct negotiations with stand-alone prescription drug plan (PDP) sponsors concerning our approval of the bids they submit each year. As the Part D program has evolved, we have adopted regulations designed to authorize us to use that negotiating authority to ensure that the number of plans offered in a given PDP region reflects a balance between sponsors' interest in providing options tailored to meet the needs of a diverse Medicare population and the need to avoid creating undue confusion for beneficiaries as they consider various plan offerings. We continued with this proposal our process of updating our bid review authority to reflect the evolution of the Part D program by proposing to limit to two the number of plans stand-alone PDP sponsors may offer in each PDP region.

PDP sponsors must offer throughout a PDP region at least one basic plan that consists of: standard deductible and cost sharing amounts (or actuarial equivalents); an initial coverage limit based on a set dollar amount of claims paid on the beneficiary's behalf during the plan year; a coverage gap during which a beneficiary pays more of his drug costs; and finally, catastrophic coverage that applies once a beneficiary's out-of-pocket expenditures for the year have reached a certain threshold. Prior to our adopting regulations requiring meaningful differences among each PDP sponsor's plan offerings in a PDP Region, CMS guidance allowed sponsors that offered a basic plan to offer in the same region additional basic plans, as long as they were actuarially equivalent to the basic plan structure described in the statute. These sponsors could also offer enhanced alternative plans that provide additional value to beneficiaries in the form of reduced deductibles, reduced copays, coverage of some or all drugs while the beneficiary is in the gap portion of the benefit, or some combination of those features.

As we have gained experience with the Part D program, we have made consistent efforts to ensure that the number and type of plan benefit packages PDP sponsors may market to beneficiaries are no more numerous than necessary to afford beneficiaries choices from among meaningfully different plan options. In addition to setting differential out-of-pocket-cost (OOPC) targets each year to ensure contracting organizations submit bids that clearly offer differences in value to beneficiaries, we issued regulations in 2010 that established at § 423.265(b)(2) our authority to deny bids that are not meaningfully different from other bids submitted by the same organization in the same service area. Our application of this authority has effectively eliminated PDP sponsors' ability to offer more than one basic plan in a PDP region since all basic plan benefit packages must be actuarially equivalent to the standard benefit structure discussed in the statute. That regulation also effectively limited to two the number of enhanced alternative plans that we can approve for a single PDP sponsor in a PDP region. As part of the same 2010 rulemaking, we also established at § 423.507(b)(1)(iii) our authority to terminate existing plan benefit packages that do not attract a number of enrollees sufficient to demonstrate their value in the Medicare marketplace. Both of these authorities have been effective tools in encouraging the development of a variety of plan offerings that provide meaningful choices to beneficiaries without creating undue confusion for beneficiaries.

We believe that the progressive closure of the coverage gap provided for in the Affordable Care Act affords us another opportunity to promote even greater clarity in the set of stand-alone PDP plan options from which beneficiaries may make an election. Under the statute, beginning in 2011, applicable beneficiaries enjoy discounts of 50 percent off negotiated prices on covered brand name drugs when purchased while in the coverage gap portion of the benefit. Also, since 2011, the required coverage in the gap has increased and will continue to do so gradually until 2020, when the combination of required coverage and manufacturer discounts covers 75 percent on average for both brand-name and generic drugs. This ''closing'' of the coverage gap effectively will leave the beneficiary with only a 25 percent cost share on average across the entire benefit (or its actuarial equivalent) before the catastrophic threshold.

Our experience in applying the meaningful differences standard indicates that, as the Part D coverage gap is closed, it will become increasingly difficult for a PDP sponsor to qualify to offer more than two plans in the same service area and still meet the meaningful differences test. Since we began applying the meaningful differences standard to our bid reviews, we have generally approved two types of enhanced alternative plans. The first type of plan offers beneficiaries, in exchange for a higher premium than that charged for basic plan coverage, significant reductions in the cost sharing and deductible amounts associated with the basic Part D benefit. The second type offers even greater cost sharing and deductible reductions as well as coverage for many drugs in the gap. Since coverage of Part D drugs in the gap is the distinguishing feature between the two types of enhanced alternative plans currently available, closing the coverage gap also means that sponsors can no longer rely on it to establish that their proposed second enhanced alternative plan is meaningfully different than their first.

Despite these developments, many sponsors continue to submit three bids per region each year. We believe that plan sponsors and beneficiaries, as well as the taxpayers, would be better served by a more streamlined bid submission process that limited sponsors to submitting two PDP bids (one basic and one enhanced) per PDP region each year. This limitation would provide a consistent bidding framework for all sponsors, allowing them to focus on quality, rather than quantity, in development of their bids. It would also reduce some of the sponsors' administrative costs associated with preparing, marketing, and administering a third benefit package. It may also help ensure that beneficiaries can choose from a less confusing number of plans that represent the best value each sponsor can offer.

While the incremental closure of the coverage gap continues until 2020, we believe that the observed enrollment trends in these plans demonstrate the reduction in beneficiaries' coverage gap

costs that has occurred already has moved the stand alone PDP plan market in a way that warrants the imposition of the two plan limit as soon as possible. In addition, in many cases one of the two enhanced plans offers the minimum level of supplemental coverage required to meet our meaningful differences tests. We refer to these as ''low value enhanced plans'' to distinguish them from second enhanced plans with substantially more supplemental coverage. In some cases, the premiums for these low value enhanced plans have been less than the premiums for the sponsors' basic plans due to favorable risk selection. This occurs because many of the beneficiaries with more serious health issues and higher utilization of prescription drugs are in the low-income subsidy (LIS) eligible population, which will not receive the full LIS subsidies in plans with supplemental coverage. For this reason we neither auto-assign the LIS eligible population into such plans, nor will this population generally affirmatively enroll in such plans. Thus, continuing to permit multiple enhanced plans, particularly low value enhanced plans, facilitates risk segmentation. This can increase costs for the Part D program and the taxpayers overall. During the most recently completed CY 2014 bid review cycle, we continued to encounter bids submitted by sponsors for low value enhanced plans with premiums lower than the premiums for their basic plans. We believed it was urgent that we adopt the proposed policy as soon as possible so that we could bring an end to this bidding practice. We solicited comments on whether there is any real need for more than two standalone plan options per PDP sponsor.

Therefore, we proposed to amend the Part D regulations at § 423.265 to add a revised subsection (b)(3), which would state that ''CMS shall not accept more than one basic bid and one enhanced bid for a coverage year from a single PDP sponsor in the same PDP region.'' We would adopt this provision under our authority at section 1860D–11(d) of the Act. In instances where a parent organization owns a controlling interest in more than one subsidiary that operates as a PDP sponsor in a single PDP region, we would apply subsection (b)(3) at the parent organization level. That is, in the same way that we currently apply the meaningful differences test, a parent organization with two subsidiary PDP sponsors could offer no more than one plan under each sponsors' contract.

In addition to proposing to limit PDP sponsors to submitting one basic and one enhanced bid per coverage year, we also stated that we were considering several regulatory proposals for limiting the type of coverage offered in those two plans to reduce or eliminate the risk segmentation described previously. We believe that risk segmentation is not consistent with the policy goal, based on our interpretation of current law, of obtaining the best value for the government and the taxpayer. We believe the Congress intended sponsors to compete in the Part D market by offering their best bids for basic plans, in order to attract the greatest enrollment through the lowest premiums, and that this competition would maintain downward pressure on Part D bids and government subsidies. We do not believe that the Congress intended that instead sponsors would offer their best bids for a segment of the market that represents individuals who are low utilizers of prescription drugs due to better health and who can afford unsubsidized supplemental premiums due to better socioeconomic status. When many healthy individuals are not included in the basic plans, the cost of the basic plans is increased, and this in turn increases low-income premium subsidies. Therefore, permitting risk segmentation does not generate the best value for the Part D program as a whole. To reduce or eliminate risk segmentation, we stated that we were considering three options, including a proposal, based on a reinterpretation of section 1860D–11(b) and (c) of the Act, that enhanced alternative coverage be redefined to consist of supplemental coverage added to the sponsor's one basic benefits offering (for an additional premium). This could be thought of as basic benefits plus a supplemental benefit rider. We solicited comments on this approach and on our belief that this approach would be the most effective strategy for eliminating risk segmentation and providing the best value for the government and the taxpayer. We received the following comments and our response follows:

Comment: Several commenters expressed support for our proposal to limit sponsors to offering no more than two plans per PDP region. They agree that beneficiaries can be overwhelmed by the number of plan choices, which can cause them to avoid even considering exploring during the annual election period plan options that might better meet their needs.

Response: We appreciate the expressions of support for our proposal.

Comment: A number of commenters stated their opposition to the proposal to limit sponsors to offer no more than two plans per PDP region. Among the assertions made by the commenters was that the regulatory authority already in place will produce shortly the improvements in bid submissions that CMS seeks and that no further authority is required. The commenters stated that CMS' application of the meaningful differences standard to its review of bids and its authority to non-renew plans that do not meet minimum enrollment standards already place effective limits on a given sponsor's number of plan offerings. They stated that the continued application of those authorities, combined with the upcoming closure of the coverage gap, will eventually reduce the room for plan variation to the point of effectively creating the two-plan limit that CMS sought with its proposal. Commenters also expressed opposition to our three options for preventing risk segmentation in plan bidding, with the option requiring enhanced benefits to be offered as a supplement to a sponsor's basic plan benefit package being particularly disfavored. Commenters that addressed the ''supplement'' option stated that such a bidding structure would result in less generous enhanced benefits because there would be less opportunity to spread the costs associated with such benefits. They also stated that such a bidding structure would limit formulary options available to beneficiaries because sponsors would have to offer the same formulary for both the sponsor's basic benefit plan and its enhanced/supplemental option.

Response: We appreciate the comments. We believe that the commenters overstate the effectiveness of the tools already at our disposal to prevent risk segmentation and to make further strides in ensuring that beneficiaries have access to an array of plan options that represent real choice. We have been conservative in our use of the low enrollment non-renewal authority as demonstrated by our adoption of enrollment thresholds that ensure that only the plans that attract negligible interest from the market are non-renewed, so few additional non-renewals are likely to occur under this authority in the coming years. Also, we measure meaningful differences on a relative basis, generally using a 95 percentile threshold to arrive at the annual limits. As plan sponsors reduce the additional value offered in their benefit packages, the 95 percentile threshold will be expected to converge toward the value of basic plans. Consequently, we will need to explore alternative methodologies to ensure meaningful differences remain among a plan sponsor's PDP offerings.

Nevertheless, the comments have given us reason to conduct further analysis of this issue and continue our

close observation of the developments in the Part D market. Therefore, we are not finalizing this proposal. It may be, as the commenters suggest, that as the coverage gap closes, the problems of risk segmentation and large numbers of plan options may solve themselves. Should that not turn out to be the case, we may revisit the issues of plan number limits and changes to basic and enhanced bid structures, keeping in mind the comments we received in response to this proposal. In the event that we make this or a similar proposal again, we would only do it as part of a new rulemaking process, during which we would solicit public comment once more before deciding whether to publish final regulations.

After consideration of the public comments we received, we are not finalizing our proposal to limit PDP sponsors to offering no more than two bids per PDP region.

14. Applicable Cost-Sharing for Transition Supplies. Transition Process Under Part D § 423.120(b)(3)

We established transition requirements under § 423.120(b)(3) for Part D sponsors to address the needs of new Part D plan enrollees who are transitioning from other prescription drug coverage (Part D or otherwise), and whose current drug therapies may not be included on their Part D plan's formulary (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under the plan's utilization management requirements). While § 423.120(b)(3)(iii) specifies that PDP plans must provide a temporary fill when an enrollee requests a fill of a non-formulary drug during the transition time period (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules), it does not currently specify the cost sharing that should apply to such fills. Current guidance (at § 30.4.9 of Chapter 6 of the Medicare Drug Benefit Manual, found at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf*) states that a Part D sponsor may charge cost sharing for a temporary supply of drugs provided under its transition process. Further, cost sharing for transition supplies for low-income subsidy (LIS) eligible beneficiaries cannot exceed the statutory maximum copayment amounts. However, for non-LIS enrollees, we stated that a sponsor must charge cost sharing based on one of its approved drug cost sharing tiers (if the sponsor has a tiered benefit design), and this cost sharing must be consistent with cost sharing that the sponsor would charge for non-formulary drugs approved under a coverage exception. This guidance created a great deal of confusion on the part of sponsors and beneficiaries because it can result in beneficiaries paying different cost sharing for formulary drugs subject to utilization management edits (such as prior authorization or step therapy) during transition than specified in their tiered benefit design. It is possible that beneficiaries may pay more during transition than for his or her drug's normal designated formulary tier. Conversely, it is also possible that the beneficiary may pay more once the utilization management edit had been satisfied than he or she did under the transition fill.

We believe that more consistent treatment of formulary and non-formulary drugs, respectively, will simplify the benefit and reduce sponsor and beneficiary confusion. Consequently, we proposed to add a paragraph at § 423.120(b)(3)(vi) clarifying that when providing a transition supply, the cost sharing is determined as follows: A Part D sponsor must charge cost sharing for a temporary supply of drugs provided under its transition process such that the following conditions are met:

- For low-income subsidy (LIS) enrollees, a sponsor must not charge higher cost sharing for transition supplies than the statutory maximum copayment amounts.
- For non-LIS enrollees, a sponsor must charge—

++ The same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with § 423.578(b); and

++ The same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met.

Comment: We received numerous comments that this clarification in regulation will simplify the rules for transition policy and reduce beneficiary confusion.

Response: We agree with these commenters that this provision will simplify the rules for transition cost sharing and reduce beneficiary confusion. We believe this requirement will help ensure more consistent treatment of transition cost sharing for formulary and non-formulary drugs across all Part D plans and removes any ambiguity that Part D sponsors may have had with respect to transition cost sharing for formulary drugs that would otherwise be subject to utilization management edits.

Comment: One commenter wrote that this requirement will further complicate an already complex policy surrounding transition fills.

Response: We disagree with this commenter. This provision removes the ambiguity surrounding the allowable cost sharing when utilization management edits are overridden during transition for formulary drugs, and ensures that beneficiaries will pay the same cost sharing for such formulary drugs during transition and after transition if the utilization management criteria are met. There has been a great deal of confusion from both sponsors and beneficiaries with respect to the proper cost sharing that should apply in these situations during transition and both we and many commenters believe this provision provides the necessary clarification.

In light of the overwhelmingly positive comments on this proposal, we are finalizing this provision without modification.

15. Interpreting the Non-Interference Provision (§ 423.10)

Since the MMA created the Part D benefit in 2003, we have never formally interpreted section 1860D–11(i) of the Act, which is known as the noninterference provision. In practice we have generally invoked the spirit of this provision in declining to intervene in negotiations or disputes involving payment-related contractual terms between participants in the drug distribution channel. However, it is increasingly clear from the many questions that continue to arise when working with stakeholders on matters ranging from lawsuits to policy clearance to complaint resolution that the agency and all Part D stakeholders would benefit from a clear, formal interpretation of these limits on our authority. Some stakeholders appear to believe the prohibition on interference in negotiations extends far beyond the boundaries that we consider relevant, while others insist our authority extends into arbitrating matters that seem to us to clearly fall within the intended prohibition. Therefore, we proposed an interpretation through rulemaking in order to clarify and codify the extent of these limits on our authority.

The noninterference provision at section 1860D–11(i) of the Act provides that, ''In order to promote competition under this part and in carrying out this part, the Secretary: (1) May not interfere with the negotiations between drug manufacturers and pharmacies and PDP

sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs.'' In beginning with the words ''In order to promote competition under this part and in carrying out this part. . .'' we believe that the Congress intended that the activities addressed in the rest of the provision should take place through private market competition. We interpret this to mean two separate but related goals. The first goal is that the Secretary through CMS should promote private market competition in the selection of Part D drugs for Part D sponsor formularies. The second goal is that CMS should not create any policies that would be expected to interfere with competitive market negotiations leading to the selection of drug products to be covered under Part D formularies. Therefore, in light of these two goals we believe there is both a duty to act—to promote competition in the private market for Part D drugs—and a duty to refrain from acting—to avoid intervention in private market negotiations that take place in the context of that competitive market. Consequently, as an initial matter, in light of our interpretation of the general purpose of section 1860D–11(i) of the Act, we proposed a general rule at § 423.10(a) that CMS promotes fair private market competition in the market for Part D drugs.

There is also a duty to avoid intervention in private market negotiations that take place in the context of that competitive market. We believe the intent of 1860D–11(i) is to ensure that we do not create any policies or become a participant in any discussions that could be expected to interfere with negotiations leading to the selection of drug products to be covered under Part D formularies. By this we mean selection by Part D sponsors (or other intermediary contracting organizations) of specific manufacturers' products for inclusion on formularies, formulary tier placement, and negotiations of acquisition costs, rebates, and any other price concessions. We believe this interpretation is consistent with a textual reading of 1860D–11(i) and with how private market transactions determine which prescription drug products are covered under Part D plans. We outlined aspects of the complex process of private market competition for prescription drugs described in detail elsewhere (such as in the 2007 CBO report entitled ''Prescription Drug Pricing in the Private Sector'' at: *http://www.cbo.gov/publication/18275*) to support our reading of the distinctly different types of negotiations between the three parties in ''between drug manufacturers and pharmacies and PDP sponsors''. These distinct sets of negotiations in the private market between manufacturers and pharmacies on the one hand, and between manufacturers and plan sponsors on the other hand, support our textual reading of section 1860D–11(i)(1) of the Act to prohibit CMS involvement in negotiations between manufacturers and pharmacies, and between manufacturers and plan sponsors. There are also separate price negotiations between plan sponsors (or their intermediary contracting organizations) and pharmacies around the negotiated prices required for network participation. However, since the statute establishes numerous requirements that CMS must regulate concerning access to network pharmacies and negotiated prices, we believe that a CMS role in negotiations between plan sponsors and pharmacies is not prohibited under section 1860D–11(i)(1) of the Act, but rather under section1860D–11(i)(2), as discussed in this section.

Section 1860D–11(i)(1) of the Act states that we ''may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors''. We believe that the term ''interference'' in this context should be interpreted as prohibiting our involvement in discussions between manufacturers and their distribution channel customers (such as wholesalers and pharmacies) or the ultimate purchasers of prescription drugs (such as plan sponsors and PBMs) leading to signed contracts. We also believe section 1860D–11(i)(1) of the Act should be interpreted as prohibiting our involvement in arbitration of agreements already executed between any of these parties. Therefore, we interpret the prohibition in section 1860D–11(i)(1) of the Act on interference in negotiations to pertain to discussions either between prescription drug manufacturers and pharmacies, or between prescription drug manufacturers and Part D sponsors (or their intermediary contracting organizations, hereafter included by association whenever we refer to Part D sponsors). Our interpretation is based on the sequential phrasing of the clause ''negotiations between drug manufacturers and pharmacies and PDP sponsors.'' Because in general these negotiations are not among all three parties at once, and because manufacturers separately contract with pharmacies for the purchase of inventory and with sponsors for formulary placement, we believe the quoted phrase can be interpreted as recognizing these distinct types of negotiations. Therefore, in our proposed rule we stated that under such a reading, the prohibition on interference in negotiations, as described in section 1860D–11(i)(1) of the Act, would not pertain to negotiations between Part D sponsors and pharmacies. In hindsight, given the strong reaction of most commenters a better way to have articulated CMS' long-standing position would have been to focus on what ''interfere'' means and to interpret it to mean a sort of hindering or influence beyond the implementation and enforcement of statutory requirements.

This is the case because there are numerous statutory provisions that require us to directly intervene in the contractual relationship between Part D sponsors and network pharmacies, and these provisions clearly signal that the Congress expected CMS involvement in at least some of these negotiations. The Congress has provided many contractual requirements for CMS to enforce between sponsors and pharmacies; just the drug-cost-related of these include: interpretation of what ''access to negotiated prices'' means, any-willing-pharmacy standard terms and conditions, prohibition on any requirement to accept insurance risk, prompt payment, and payment standard update requirements. Consequently, we believe that Part D sponsors and pharmacies do not have sole discretion to interpret these specific matters. We would be obligated to intervene in disputes over whether proposed or finalized contractual arrangements violated our rules in any area where our oversight is directed under the statute. So we believe it is clear that such involvement could not be what the Congress intended to prohibit. Therefore, we proposed at § 423.10(b) that CMS may not be a party to discussions between prescription drug manufacturers and pharmacies, or between drug manufacturers and Part D sponsors, and may not arbitrate the meaning of or compliance with the terms and conditions of agreements reached between these parties, except as necessary to enforce CMS requirements applicable to those agreements. Thus, we could only be involved in such discussions in order to explain CMS requirements and to ensure compliance with Part D rules and regulations. We also add that nothing in this prohibition limits our authority to require documentation of and access to all such

agreements, or to require the inclusion of terms and conditions in agreements when necessary to implement requirements under the Act.

The first part of the section 1860D–11(i)(2) of the Act states that CMS ''may not require a particular formulary''. The noninterference clause must be read in context of the other provisions that give CMS authority with respect to formularies, so we proposed to interpret the term ''particular formulary'' to mean the selection of specific manufacturer licensed drug products to be on formulary, or on any particular tier of a formulary, assuming the product meets the definition of a Part D drug. We believe the first part of section 1860D–11(i)(2) of the Act would prohibit us from developing formulary guidelines that prefer one manufacturer's product over another's in Part D formularies, leading to more limited formularies such as provided by the Department of Defense and the Veteran's Administration. The most efficient formularies will make formulary selections and then exclude all or most competing multi-source and therapeutically equivalent brand products in order to concentrate volume and maximize rebates. Given the size of the Part D market, if CMS were able to similarly limit access to Part D formularies to certain products, this would bestow significant competitive advantage on the manufacturers of selected products and significant competitive disadvantage on manufacturers of competing products. Such limits would be expected to fundamentally alter supply and demand in the marketplace. This prohibited sort of formulary drug product selection would be distinguished from CMS formulary requirements that may require particular types of drug entities to be on all formularies, or on preferred tiers, in order to provide non-discriminatory access to drugs necessary to treat conditions in all Medicare beneficiaries, or to address drug classes of clinical concern. Therefore, we proposed a provision prohibiting establishment of formulary drug product selection at § 423.10(c) that would specify that CMS does not determine the specific drug products to be included on Part D sponsor formularies or any tier placement of such products, except as required to comply with §§ 423.120(b)(1)(v) or 423.272(b)(2).

The second part of section 1860D–11(i)(2) of the Act states that CMS ''may not institute a price structure for the reimbursement of covered Part D drugs''. Again, the noninterference clause must be read in context of the other provisions that give CMS responsibilities in a number of areas that pertain to pricing, so we stated our view that the phrase ''price structure'' refers to establishing either absolute or relative indices of price for Part D drugs. Specifically, we believe the intent of this provision is to prohibit two types of intervention by CMS. The first prohibited activity is that CMS may not require Part D drug acquisition costs or sales prices to be a function of (be defined relative to) any particular published or unpublished pricing standard, either existing or future. Thus, we could not require that Part D prices be based on, or be any particular mathematical function (such as a percentage or multiple) of established pricing standards such as Average Wholesale Price, Wholesale Average Cost, Average Manufacturer Price, Average Sales Price, Federal Supply Schedule, 340b pricing, etc. The second prohibited activity is that CMS cannot require price concessions (on any standard or basis) to be at any specific (absolute) dollar amount or equal to a level specified in other legislative requirements for other federal programs. Thus, we could not, for example, set minimum or maximum dollar prices for a drug product or require that Part D prices be offered at acquisition cost, or at the 'best price' applicable under the Medicaid program. However, since the statute requires us to regulate many aspects of how drug costs are made available and displayed to beneficiaries and treated in Part D bidding and payment processes, it is clear that we have an important role to play in establishing rules for consistent treatment of drug costs in the program. Consequently, we may establish definitions of what constitutes a pricing standard, a price concession, a cost, etc. We may also establish rules concerning how drug costs are treated under Part D, including, but not limited to, how such amounts are disclosed in the marketplace, projected in Part D bids, made available to beneficiaries at point of sale, reported in Explanation of Benefits (EOBs), submitted to CMS, and treated in CMS payments to Part D sponsors. Therefore, we proposed a provision prohibiting establishment of drug price reimbursement methodologies at § 423.10(d) that specifies that CMS does not establish drug product pricing standards or the dollar level of price concessions at any stage in the drug distribution channel for Part D drugs. Nothing in our proposed regulation would have limited our authority to require full disclosure or uniform treatment and reporting of drug costs and prices.

We received numerous comments on this proposed interpretation, both supportive and strongly critical. Different commenters asserted different ''plain readings'' of the statute. The wide variation in interpretations of the statutory prohibition evidenced in these comments, in our view, confirms our belief that this provision is not consistently understood by all stakeholders. Although the interpretation we proposed to codify is the same interpretation we have been operating under in managing the Part D program since before the beginning of the Part D program, many commenters perceived our proposal as a change in interpretation. And as noted previously, in hindsight we could have better articulated our policy rationale than by stating that the prohibition in section 1860D–1(i)(1) did not apply to negotiations between sponsors and pharmacies. These widely differing reactions to our proposal to codify our current interpretation lead us to understand that additional work needs to be done to better explain our policy, as well as to address the concerns and arguments advanced by numerous commenters. Consequently, we will not finalize the proposed regulatory provision at § 423.10 in this final rule, and do not intend to codify this provision without issuing an additional future notice of proposed rulemaking.

Comment: Some commenters supported our interpretation and regulatory proposal; others supported the interpretation but did not believe there was any need to codify our interpretation in regulation. One commenter supported our intent to clarify and specify the limits of our authority, but was very concerned about the proposed exceptions to the limitations on our authority and requested greater specificity around the particular CMS requirements that would invoke the exceptions.

Response: We appreciate the supportive comments, and can understand the desire for greater specificity in some areas.

Comment: Several commenters stated that our interpretation violated the plain reading of the statute, and then offered differing interpretations of the plan meaning of the statute. In particular, many commenters asserted that the phrase ''between drug manufacturers and pharmacies and PDP sponsors'' essentially had the plain meaning of prohibiting any and all negotiations between any two of the parties. Other commenters agreed with our interpretation and that it represented the plain meaning.

Response: These differing interpretations of the statute confirm our belief that the statutory language is not universally understood in the same way by all parties and would ultimately benefit from formal interpretation and codification in regulation.

Comment: Numerous commenters understood us to be proposing that we could now interfere in negotiations between Part D sponsors and pharmacies that we had previously avoided.

Response: We intended to explain how we could reconcile the distinct sets of negotiations in the private market between manufacturers and pharmacies, between manufacturers and plan sponsors, and between plan sponsors and pharmacies with both the non-interference provision and within the context of the rest of the statute. Since the statute establishes numerous requirements that CMS must implement concerning access to network pharmacies and negotiated prices, we sought to make that distinction in the proposed rule by proposing that a CMS role in negotiations between plan sponsors and pharmacies is not prohibited under section 1860D–11(i)(1) of the Act, but rather under section 1860D–11(i)(2) of the Act. The strong reaction of many commenters to this interpretation has persuaded us that a better way to have articulated this distinction would have been to focus on what ''interfere'' means and to interpret it to mean a sort of hindering or influence beyond the implementation and enforcement of statutory requirements. The Congress has provided many contractual requirements for CMS to enforce between sponsors and pharmacies, and we would be obligated to intervene in disputes over whether proposed or finalized contractual arrangements violated our rules in any area where our oversight is directed under the statute. In other words, we sought to explain that we could not involve ourselves in negotiations between plan sponsors and pharmacies except as necessary to fulfill our requirements established under the statute. From the many comments we received on this issue, we conclude that our explanation on this point in the proposed rule conveyed the wrong impression.

Comment: Numerous commenters characterized our proposal as a change in policy. These commenters frequently cited examples of our previous invocation of the prohibition on interference in private market negotiations as evidence of this alleged change. For instance, commenters cited a CMS response to a 2008 OIG report in which CMS did not concur with several OIG recommendations on the basis that to do so would violate the non-interference clause. This report, ''Review of Medicare Part D Contracting for Contract Year 2006'' (A–06–07–00082) is available at: *http://oig.hhs.gov/reports-and-publications/archives/oas/cms_archive.asp*.

Response: The interpretation put forth in our proposed rule was intended to represent the interpretation that the Part D program has been operating under since before the beginning of the Part D program. We believe the examples cited by commenters can all be traced back to specific situations and topics that are consistent with our proposal. For instance, in the case of the 2008 OIG report, the specific recommendations with which CMS did not concur on the basis of interference were recommendations that violated that provision in exactly the way we proposed to prohibit in our proposed rule. Specifically, we disagreed with requiring Part D sponsors to disclose to pharmacies the data source, basis, and methodology used to develop reimbursement rates, or to reveal to pharmacies criteria for receiving higher reimbursement rates available to certain categories of pharmacies, and with CMS determining whether reimbursement rates for extended days' supplies are adequate. In other words, we disagreed with CMS becoming a party to discussions between Part D sponsors and pharmacies on price structures or the arbiter of the adequacy of reimbursement methodologies. Thus, in our view, our responses to the OIG report were entirely consistent with our proposed regulation. (We note that section III.A.17 of this final rule addresses changes to the prescription drug pricing standard requirements established under MIPPA, but still does not require disclosure of data source, basis, and methodology used to develop reimbursement rates.) We believe that the perception of a change in interpretation arises from both the lack of a common understanding of the statutory prohibition, and from the absence of any discussion of how our previous statements on the record on this topic do or do not conform to our proposals. The numerous examples provided by commenters will be very helpful in developing such an explanation in any future rulemaking on this policy.

16. Pharmacy Price Concessions in Negotiated Prices (§ 423.100)

We have learned that some Part D sponsors have been reporting costs and price concessions to CMS in different ways. This reporting differential matters because this variation in the treatment of costs and price concessions affects beneficiary cost sharing, CMS payments to plans, federal reinsurance and low-income cost-sharing (LICS) subsidies, and manufacturer coverage gap discount payments. Differential treatment of costs would also be expected to affect plan bids. If the projected net costs a sponsor is liable for in its bid are understated because the sponsor has been reporting certain types of price concessions as direct or indirect remuneration (DIR) rather than as price concessions that affect the negotiated price, it follows that the sponsor may be able to offer a lower bid than its competitors and may achieve a competitive advantage stemming not from greater efficiency, but rather from a technical difference in how costs are reported to CMS. When this happens, such differential reporting could result in bids that are no longer comparable, and in premiums that are no longer valid indicators of relative plan efficiency. Therefore, we proposed changes to rectify this concern.

Negotiated prices are the payment amounts pharmacies receive from plans for covered Part D drugs dispensed to plan enrollees. CMS payments to plans are based on the reporting of negotiated prices (through PDE reporting) that are actually paid and are then offset by any other price concessions (submitted in aggregate through the separate annual DIR reporting process). CMS establishes rules for cost and price concession reporting through both PDE and DIR guidance and other payment reconciliation rules, and has regulated the definition of negotiated price and how it is to be treated in Part D benefit administration and in payment reconciliation. Since 2010, the regulatory definition at § 423.100 has been: ''Negotiated prices means prices for covered Part D drugs that: (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; (2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and DIR that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) Include any dispensing fees.''

We intended clause 2 to primarily refer to price concessions from parties other than pharmacies, since these would be price concessions that were not based on the sale of the drug by the pharmacy and calculated when the claim adjudicated and, in fact, could not

be calculated until a later date. In particular, we expected these other non-claim-based price concessions to be in the form of rebates offered by prescription drug manufacturers. Since prescription drugs are dispensed by pharmacies and purchased through transactions between Part D sponsors (or their intermediary contracting organizations) and pharmacies, manufacturers are never in a position to apply price concessions to negotiated prices at point of sale. We now understand that clause 2 is ambiguous and permits sponsors and their intermediaries to elect to take some price concessions from pharmacies in forms other than the negotiated price and report them outside the PDE. When this occurs, the increased negotiated prices generally shift costs to the beneficiary, the government and taxpayer, and when applicable to certain brand name drugs, to prescription drug manufacturers. (The mechanism of this sort of cost shift was discussed at length in the analogous context of lock-in pricing in our 2008 proposed rule entitled ''Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs'' which was published on May 16, 2008 in the **Federal Register**, 73 FR 28563 through 28566.)

In addition, when price concessions from pharmacies are reflected in forms other than the negotiated price, the degree of price concession that the pharmacy has agreed to is no longer reflected in the negotiated prices available at point of sale or reflected on the Medicare Prescription Drug Plan Finder (Plan Finder) tool. Thus, the true price of drugs at individual pharmacies is no longer transparent to the market. Consequently, consumers cannot efficiently minimize both their costs (cost sharing) and costs to the taxpayers by seeking and finding the lowest-cost drug/pharmacy combination. Moreover, as the coverage gap closes, there are fewer and fewer beneficiaries who are exposed to the full cost of drug products, either at the point of sale or as reflected in Plan Finder estimates. When this occurs, the basis of competition shifts from prices to cost sharing, and the pricing signals available to the market can be distorted when lower cost sharing is not aligned with lower prices. Thus, we believe the exclusion of pharmacy price concessions from the negotiated price thwarts the very price competition that the Congress intended with respect to how private plans would compete with other plans on both premiums and negotiated prices.

We are aware that certain pharmacy price concessions are being excluded from the determination of the negotiated price because they are being characterized as ''network access fees'', ''administrative fees,'' ''technical fees'' or ''service fees'' that are frequently imposed through PBM-issued manuals rather than explicit contractual terms. Pharmacies and pharmacy organizations report that they do not receive anything of value for those fees other than the ability to participate in the Part D network. The itemized types of services for which their payments are offset reportedly include things such as transaction fees for submission of claims, help desk support, information technology and telecommunication systems connectivity, electronic funds transfers, and other expenses associated with credentialing, maintaining, and auditing pharmacy networks. These fees take the form of deductions from payments to pharmacies for drugs dispensed, but in our view clearly represent charges that offset sponsor/PBM operating costs. We believe that if the sponsor or its intermediary contracting organization wishes to be compensated for these services and have those costs treated as administrative costs, such costs should be accounted for in the administrative costs of the Part D bid. If instead these costs are deducted from payments made to pharmacies for purchases of Part D drugs, such costs are price concessions and must be treated as such in Part D cost reporting. This is the case regardless of whether the deductions are calculated on a per-claim basis or not.

In our view, the decision on how such network management costs are funded between the PBM and the sponsor is not governed by our rules, but our rules do require that price concessions be fully disclosed and net against drug costs in reconciliation. We have also heard from pharmacies that some sponsors apply dispensing fees to claims when they are adjudicated at point of sale, but require that these fees later be rebated back to the sponsor and deducted from payment remittances. Such practices again misstate the negotiated price. Our proposal would require that dispensing fees could only be applied at point of sale if they are received and retained by the pharmacy in the negotiated price.

Some stakeholders have recommended that certain incentive payments to pharmacies, such as generic dispensing incentive fees, should not be included in negotiated prices. If these payments are included, they explain, the negotiated prices appear higher at the more efficient pharmacy as the result of the additional incentive payment. This higher price then proportionally increases costs borne by beneficiaries, the government, and manufacturers. These incentives really represent amounts that the sponsor is willing to bear in order to encourage the most efficient drug choices, which will drive down total costs overall, and thus the sponsor is willing to bear a disproportionate share of such expense. We agree with this argument and we believe that this sort of arrangement would not conflict with our proposed requirement that all price concessions be reflected in the negotiated price since such additional payments are the opposite of price concessions. Instead such incentive fees represent contingent price increases that cannot be predicted in advance. Therefore, they cannot be programmed to be applied at point of sale or reflected in the price posted on Plan Finder. We believe it would be appropriate to treat this particular sort of price increase differently than price decreases because including such amounts in the negotiated price (incentive fee component) at point of sale could disguise the relative competitiveness of the underlying pharmacy prices. Incentive fees also primarily benefit the plan sponsor who benefits from the lower costs associated with the incentivized behavior, rather than the beneficiary. Therefore, in this case, we agree that it would be more appropriate for such incentive payments to be excluded from the negotiated price, and reported later in reconciliation as negative DIR. When reported as negative DIR, these amounts disproportionately affect (increase) the amounts the sponsor is liable for in risk sharing, which is appropriate given the intent of the incentives to promote least-cost drug product selection at point of sale. Least-cost drug product selection will directly reduce the sponsor's allowable risk corridor costs, so any incentive paid to encourage this behavior would be expected to be more than offset by the ingredient costs savings achieved through avoidance of higher-cost drug selection. This is so because, as we learned from numerous commenters to the 2014 draft Call Letter, the incentive payments are generally in the range of a dollar or two and the difference between preferred and non-preferred drug products is generally much greater.

Therefore, we proposed to revise the definition of negotiated prices at § 423.100 to require that all price concessions from pharmacies are reflected in these prices. Specifically we proposed to redefine negotiated prices to mean prices for covered Part D drugs

that: (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; and (2) are inclusive of all price concessions and any other fees charged to network pharmacies; and (3) include any dispensing fees; but (4) exclude additional contingent amounts, such as incentive fees, only if these amounts increase prices and cannot be predicted in advance; and (5) may not be rebated back to the Part D sponsor (or other intermediary contracting organization) in whole or in part.

We received the following comments on our proposed revisions and our responses follow.

Comment: We received a significant number of comments in support of this provision based on the improved transparency of pharmacy price concessions. One commenter stated the belief that PDPs and their contracted PBMs are circumventing the Medicare Modernization Act by hiding pharmacy charge backs as overall administrative surcharges. These commenters stated that amounts charged to pharmacies in the form of ''administrative fees,'' ''network access fees'' or rebates of dispensing fees appeared to be vehicles for price concessions. Another commenter believed that the proposed provision would alleviate the complexity of tracking actual drug reimbursement and help ensure that reimbursement structures are not actually increasing Medicare costs. Several commenters stated that inclusion of accurate costs in the Plan Finder tool would be of benefit to consumers, and added that drug prices must be accurate and transparent to help seniors compare plan costs.

We also received some comments in opposition to the proposed provision. These commenters stated that some price concessions that benefit the Part D program do not lend themselves to inclusion in negotiated prices. A few commenters stated that savings from lower point-of-sale prices would be reflected in higher enrollee premiums and increased premium subsidies. Other commenters stated that payments received from pharmacies to PBMs were for services provided and should not be considered price concessions. One commenter stated that just because pharmacies pay for and benefit from services from PBMs does not necessarily make the fees price concessions. A few commenters opposed the provision on the grounds that it would place new limitations on the terms sponsors will be able to negotiate with network pharmacies and stated that CMS is limiting the tools available to sponsors to offer varied incentive-based agreements such as providing additional compensation for increased dispensing of generic medicines or superior customer service. Other commenters thought that Part D sponsors and PBMs should be able to retain the flexibility to determine which concessions to pass through to beneficiaries through drug prices or lower premiums. To bolster this argument one commenter quoted from our 2009 rule in which we stated that the statute says prices will ''take into account'' price concessions not include them all, and that a ''plain reading of this demonstrates the Congress' intent to be permissive of Part D sponsors to choose how much of their negotiated price concessions to pass through to Part D beneficiaries at the point of sale''.

One of the commenters who opposed the provision suggested that, as an alternative, CMS use its existing authority to require plans to disclose both in the bid pricing tool (BPT) and through DIR, specific line-item reporting of performance-based DIR received from network pharmacies. Several commenters urged CMS to use its existing DIR reporting authority to capture price concessions attributable to risk-based performance measures, which often require retrospective performance review and therefore cannot be captured in negotiated prices. The commenters argued that the DIR process must be used to allow sponsors to maintain innovative payment arrangements that yield efficient and quality pharmacy networks. One of these commenters voiced support for ''a competitive and level playing field for all sponsors'' and urged CMS to create clear and comprehensive regulatory guidance with respect to pharmacy price concessions.

Response: We appreciate the detailed comments we received in response to our proposal. We continue to believe it is critical that negotiated prices reported on PDEs have a consistent meaning across the Part D program in order to preserve a level playing field in bidding and cost reporting. As we stated in the proposed rule, we intended clause 2 of the existing definition of negotiated price to primarily refer to price concessions from parties other than pharmacies, since these would be price concessions that were not based on the sale of the drug by the pharmacy and calculated when the claim adjudicated and, in fact, could not be calculated until a later date. Our proposal to require all pharmacy price concessions be included in the negotiated price would ensure that negotiated prices have a consistent meaning, provide for increased transparency in cost reporting to CMS, and allow for meaningful price comparisons between Part D sponsors.

While we recognize that some pharmacy price concessions are contingent upon risk or incentive based arrangements, we provided an illustration of how such price concessions could adjust future negotiated prices, rather than adjusting the current quarter's prices downward through DIR reporting. Consequently, we did not believe that our proposal would limit Part D sponsors' ability to enter into such contracting relationships with their network pharmacies. We did not propose placing additional restrictions around such arrangements, only that their resulting costs must be transparent to all concerned.

Nevertheless, we are persuaded by the comments that there may be some price concessions from pharmacies that are based upon contingencies that cannot be known at the point-of-sale and that these price concessions should be distinguished from all other pharmacy price concessions and continue to be reported as direct or indirect remuneration. This would be also be consistent with the commenter who pointed out the statutory language that negotiated prices will ''take into account'' price concessions. While we had proposed including all price concessions from pharmacies in the negotiated price to provide maximum price transparency, we believe that there is room for further discussion with industry to determine whether there are specific types of arrangements that do not lend themselves to accurate inclusion in the negotiated prices. As long as all types of price concessions are consistently ''taken into account'' in the same way by each sponsor in preparing bids and reporting costs, bids and point-of-sale negotiated prices can remain comparable. Therefore, in response to comments we are revising our proposed definition of negotiated price to allow a narrow exception to the requirement that all pharmacy price concession be included in the negotiated price for those contingent pharmacy price concessions that cannot reasonably be determined at the point-of-sale. We intend to identify in our DIR reporting guidance which types of price concessions from pharmacies would meet the standard for this exception, and we intend to consult with industry in developing our guidance in this area. Any contingent pharmacy price concessions or incentive payments that

can be determined at the point-of-sale must be included in negotiated prices.

We agree with the commenter who pointed out that not all fees that pharmacies pay to PBMs are price concessions. But as discussed in the NPRM, when such fees take the form of deductions from payments to pharmacies for Part D drugs dispensed, such costs are price concessions and must be treated as such in Part D cost reporting. This is the case regardless of whether the deductions are calculated on a per-claim basis or not. Standard treatment of all price concessions will bring improved transparency to pharmacy payments. We disagree that this change is inconsistent with the MMA because the MMA established Medicare Part D as a voluntary, private-market-based program what would rely on private plans to provide coverage and to bear some of the financial risk for drug costs. These private plans would determine premiums through a bid process and would compete with other plans based on premiums and negotiated prices. While Part D sponsors may lose some flexibility in deciding how much of the price concessions should be applied to beneficiaries at the point of sale or through reduced premium, consistency in how specific types of price concessions are ''taken into account'' in negotiated prices is necessary in order to preserve reliance on market competition between plans, which is a cornerstone of the Medicare Part D program.

Comment: A few commenters questioned CMS' authority to implement the proposed change and some asserted that the non-interference provision prohibits CMS from defining negotiated prices.

Response: We disagree with these comments. We have the authority to interpret the provisions of section 1860D–2(d)(1)(B) and believe our interpretation is appropriate. We also have a history of regulating on cost and price concession reporting. We established detailed guidance for accurate and consistent cost and price concession reporting through both PDE and DIR guidance and other payment reconciliation rules, and have twice before regulated the definition of negotiated price and how it is to be treated in Part D benefit administration and in payment reconciliation. In the original Part D rule, negotiated prices were mainly defined as ''prices for covered Part D drugs that were available to beneficiaries at the point of sale at network pharmacies''. This definition permitted sponsors or their intermediaries to include PBM spread in the price. Therefore, on January 12, 2009 we published in the **Federal Register** the final rule with comment entitled, '' Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions'' (74 FR 4131), to clarify that negotiated prices must be the amounts actually received by the pharmacy for the drug. We are now once again revising the definition.

Comment: Several commenters addressed the effective date of the proposed rule. Commenters advocated for a prospective implementation only, or expressed the hope that the rule could be delayed until 2016. They stated that time was needed to allow collaboration with the industry, enable CMS to capture the changes in detailed guidance, and give Part D sponsors time to revise their pharmacy network contracts.

Response: In response to these comments we are postponing implementation of this provision until the 2016 contract year and will use this time to work with the industry to develop guidance on when the exception previously described applies.

After considering comments received, we are finalizing the provision as proposed with modification to require that negotiated prices be inclusive of all price concessions from network pharmacies except contingent price concessions that cannot reasonably be determined at the point-of-sale. We also modified the language in paragraph (4) by clarifying that additional contingent amounts, such as incentive fees, that increase prices are always excluded from the negotiated price by removing the word ''may,'' and we also replaced ''cannot be predicted in advance'' with ''cannot reasonably be determined at the point-of-sale'' to parallel paragraph (2). Finally, we have modified the effective date of this provision to 2016 to avoid disruption of the existing regulation which will be applicable for the rest of 2014 and 2015.

17. Preferred Cost Sharing (§§ 423.100 and 423.120)

In our original rule implementing the Part D Program, we codified an interpretation of section 1860D–4(b)(1)(B) of the Act at § 423.120(a)(9) that permitted Part D sponsors to offer lower cost sharing at a subset of network pharmacies, dubbed ''preferred pharmacies,'' than at other in-network pharmacies. This lower cost sharing was subject to certain conditions that seemed straightforward to us at the time, but which have proven to need clarification. We have recently discussed this concern in the Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (2014 Call Letter) on pages 175 and 176 [at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf*].

Section 1860D–4(b)(1)(B) of the Act contemplates the possibility of sponsors offering lower cost sharing at some network pharmacies than is offered in conjunction with the any willing pharmacy terms and conditions mandated in the immediately preceding paragraph (A). However, a plan's ability to reduce cost sharing is contingent upon one condition: ''In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D–15 of the Act to a plan.'' In our original proposed rule entitled ''Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule,'' published on August 3, 2004 in the **Federal Register**, 69 FR 46658 through 46659, we did not offer an interpretation of this language but implied that any assessment of whether the condition was met would be a matter of actuarial equivalence analysis. We proposed to codify the requirements in regulation with the following two conditions: ''. . . the plan must still meet the requirements under § 423.104(e)(2) and (5); and [a]ny cost sharing reduction must not increase CMS payments under § 423.329.'' In the final regulation entitled ''Medicare Program; Medicare Prescription Drug Benefit; Final Rule'', published on January 28, 2005 in the **Federal Register**, 70 FR 4247 through 4255, we reiterated the language from the aforementioned proposed rule (69 FR 46658). ''However, we note that while these within-network distinctions are allowed, the statute also requires that such tiered cost-sharing arrangements in no way increase our payments to Part D sponsors. Therefore, tiered cost-sharing arrangements based on within-network distinctions could be included in Part D plans' benefits subject to the same actuarial tests that apply to formulary-based tiered cost-sharing structures. Thus, a reduction in cost sharing for preferred pharmacies in a Part D plan network could be offered through higher cost sharing for non-preferred pharmacies (or as alternative prescription drug coverage).'' (70 FR 4254, January 28, 2005.) This statement was immediately followed by an expression of our intent to ensure that such network benefit designs were non-discriminatory: ''We recognize the possibility that Part D plans could

effectively limit access in portions of their service areas by using the flexibility provided in § 423.120(a)(9) of our final rule to create a within-network subset of preferred pharmacies. In other words, in designing its network, a Part D plan could establish a differential between cost-sharing at preferred versus non-preferred pharmacies—while still meeting the access standards in § 423.120(a)(1) of our final rule—that is so significant as to discourage enrollees in certain areas (rural areas or inner cities, for example) from enrolling in that Part D plan. We emphasize that such a network design has the potential to substantially discourage enrollment by certain Part D enrollees, and that we have the authority under section 1860D–11(e)(2)(D) of the Act to disallow benefit designs that are discriminatory.''

However, what we failed to sufficiently explain in 2005 was that if cost sharing cannot rise beyond a certain level, then in return for lower cost sharing, preferred networks must reduce drug costs paid by the plan in order to prevent an increase in CMS payments to the plan. In part this omission may have been because we presumed that Part D sponsors would motivate enrollees to go to a subset of pharmacies through lower cost sharing only if those pharmacies offered significantly lower negotiated prices, and thus would provide a competitive advantage for the sponsor in lowering costs. As the concerns expressed in the 2014 Call Letter indicate, this does not seem to have been the case for some sponsors. However, if drug costs (negotiated prices) are not lower in return for lower cost sharing, and the lower cost sharing cannot be completely offset by higher cost sharing on other beneficiaries due to our cost-sharing-outlier limits, then the amount that must be subsidized by the government and the taxpayer will increase.

Therefore, we proposed to clarify that preferred cost sharing should signal consistently lower costs. When lower cost sharing correctly signals the best prices on drugs, then choosing pharmacies on the basis of that lower cost sharing lowers not only beneficiary out-of-pocket costs, but also Part D plan and other government subsidy costs. Lower plan and government subsidies translate into lower CMS payments to plans, consistent with the statutory requirements at section 1860D–4(b)(1)(B) of the Act. Therefore, we proposed to revise § 423.120(a)(9) to state: ''Preferred cost-sharing in network pharmacies. A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a subset of network pharmacies, as long as such preferred cost sharing is offered in accordance with the requirements of § 423.120(a)(8) and for Part D drugs with consistently lower negotiated prices than the same drugs when obtained in the rest of the pharmacy network.'' We proposed that by 'consistently lower' we mean that sponsors must offer beneficiaries and the Part D program better (lower) negotiated prices on all drugs in return for the lower cost sharing. In practice we believe this would mean that whatever pricing standard is used to reimburse drugs purchased from network pharmacies in general, a lower pricing standard must be applied to drugs offered at the preferred level of cost sharing. We welcomed comments on alternative approaches to ensuring that the offering of preferred cost sharing does not increase our payments. We proposed that any alternative methodology must be based solely on the level of negotiated prices and thus consistent with our proposal to amend that definition (section III.A.15. of this final rule). As discussed in that section, we proposed to revise the definition to specify that all price concessions from pharmacies must be reflected in the negotiated price in order to promote transparent price competition, as well as to eliminate differential cost reporting and cost shifting that interfere with a fair and transparent competitive bidding process. We requested that any alternative methodology suggestions be accompanied by specific proposals for how we could objectively validate compliance through data we already collect.

In addition, we solicited comments on whether we should also establish standards on how much lower drug costs should be in return for preferred cost sharing. We are aware that there is a wide range of savings projections associated with the use of limited networks. For instance, a January 2013 study prepared for the Pharmaceutical Care Management Association (PCMA) provides various estimates ranging from 5 percent to 18 percent [at *http://www.pcmanet.org/images/stories/uploads/2013/visante-pcma%20pharmacy%20networks%20study%201-24-13%20final.pdf*]. We solicited comment on whether Medicare should require a minimum level of savings, such as 10 percent or 15 percent, over the costs available at retail cost-sharing rates. We believe that substantial discounts in this range would be necessary to balance the extremely low preferred cost sharing rates offered by many sponsors in 2013. We also solicited comments on how broadly preferred cost sharing should be applied to drugs on a sponsor's formulary. For instance, is it reasonable to offer cost sharing as low as $0 for only the least expensive generics on formulary? Or should preferred cost sharing have to apply to a minimum percentage of formulary products to be a meaningful benefit instead? Or should preferred cost sharing have to apply to all drugs available at pharmacies offering preferred cost sharing? This would require that the prices of all drugs at those pharmacies could be no higher than the prices at the other network pharmacies. Such a policy would prevent sponsors from offering lower prices on drugs with preferred cost sharing while offering higher prices on other drugs not subject to preferred cost sharing. Our concern is that without such rules, it is possible that the beneficiary is motivated to change pharmacies in order to pay very low copays on some drugs, but the program may end up paying higher costs on other drugs the beneficiary purchases at the same pharmacy out of convenience.

We also proposed a clarification in terminology to better describe the application of the policy to a sponsor's approved Part D pharmacy network. Specifically, we proposed to delete the definitions of ''preferred pharmacy'' and ''non-preferred pharmacy'' from § 423.100 and to add a new definition of preferred cost sharing. ''Preferred cost sharing'' would mean lower cost sharing for certain covered Part D drugs at certain network pharmacies offered in accordance with the requirements of § 423.120(a)(9). We would then require that Part D sponsors would revise any marketing materials to reflect the revised nomenclature, and eliminate any references to preferred or non-preferred network pharmacies. We solicited comment on whether any further clarifications of terminology are needed for this policy proposal.

We received the following comments and our responses follow:

Comment: Many commenters strongly supported our proposal to require consistently lower negotiated prices at pharmacies offering preferred cost sharing. These commenters found it troubling that some Part D plans' negotiated prices were not lower for some drugs at pharmacies offering preferred cost sharing and stated that the alignment of preferred cost sharing with lower negotiated prices is necessary to ensure that arrangements with pharmacies to offer preferred cost sharing do not cost the government more and provide savings for

beneficiaries. The commenters assert that the current framework is not transparent and allows PBMs to maximize profits by moving as much volume as possible to their mail order pharmacies with little, if any, savings for the beneficiary, and even the possibility that the beneficiary could pay more than they would at a pharmacy without preferred cost sharing.

However, other commenters strongly opposed our proposal to require consistently lower negotiated prices at pharmacies offering preferred cost sharing. While no commenters dispute that benefit designs that provide preferred cost sharing at some network pharmacies must not increase payment to Part D plans, many dispute our proposal to make this determination based entirely upon negotiated prices. They assert that the reference in the statute to ''an increase in payments'' does not refer solely to negotiated prices but must also take into consideration the direct subsidy, reinsurance subsidies, end of year reconciliation, and beneficiary premiums. Several commenters said that we do not have the authority to implement this proposal because it violates the section 1860D–11(i) statutory non-interference provision that prohibits CMS from instituting a price structure for the reimbursement of Part D drugs. One commenter said that while they share our objectives for preferred cost sharing arrangements to lower costs for the Part D program and beneficiaries, they believe these arrangements can be beneficial if the price concessions are reflected in prices at the pharmacies and/or used to lower premiums. Commenters also stated that requiring lower negotiated prices for every drug will restrict the flexibility that Part D sponsors need to negotiate discounts with pharmacies, which will lead to increased prices and beneficiary disruption. Moreover, commenters argue that savings from preferred cost sharing cannot be determined at the individual drug level because that does not account for different drug mixes at different pharmacies that could better be determined by actuarially sound aggregate methods of comparison. One commenter recommended that we implement a ''fixed basket of drugs'' approach similar to our Out-of-Pocket (OOPC) tools used for determining meaningful differences between basic and enhanced plans. A number of commenters also contend that such a consistently-lower-price requirement is unworkable because their contracts frequently have a ''lesser of'' provision to ensure they only pay the pharmacies' usual & customary prices when such prices are lower than the negotiated rate and they would have no way to ensure that pharmacy usual & customary prices are never lower at pharmacies that do not offer preferred cost sharing. Finally, most commenters opposed CMS establishing standards on how much lower drug costs should be in return for preferred cost sharing.

Response: We appreciate the significant support we received for the proposal and continue to believe that the proposal would provide a transparent mechanism for ensuring compliance with the statutory requirement that prohibits benefit designs with preferred cost sharing at certain network pharmacies from increasing payments to plans. While we agree that basing increased payments to plans entirely on negotiated prices is not the only possible interpretation of the statutory requirement, we believe it is a reasonable interpretation that would allow us to uniformly apply the statutory requirement while also providing price transparency to beneficiaries and maximizing price competition.

Nevertheless, we premised this proposal on our related proposal to change the definition of ''Part D Negotiated Price'' to include all pharmacy price concessions. If we are going to use negotiated prices as the sole basis for determining increased payments to plans for purposes of section1860D–4(b)(1)(B) of the Act, then all pharmacy price concessions must be in the negotiated price because the price would need to have the same meaning at every network pharmacy. Consequently, because we are finalizing a different definition of negotiated price than originally proposed, one that will allow for the exclusion of some pharmacy price concessions from the negotiated price, we will not be finalizing our proposal to require consistently lower negotiated prices at pharmacies offering preferred cost sharing. Clearly if some price concessions are not reflected in the negotiated price, a higher negotiated price may not result in increased payments to plans. We also are not finalizing an alternative requirement at this time, in light of the comments that suggested different approaches because we intend to consider them further as we determine how best to ensure, in a transparent manner, that preferred cost sharing does not increase payments to plans. While we are not finalizing the proposal, we disagree with the commenter who stated that CMS does not have the authority to implement such a requirement because it is consistent with our obligation to implement and enforce many statutory requirements under the Part D program that directly or indirectly affect negotiations between pharmacies and Part D sponsors, in particular section 1860D–4(b)(1)(B) of the Act, and including several other closely related statutory provisions contained in section 1860D–4(b)(1) of the Act. For example, we have previously established retail and non-retail pharmacy network adequacy requirements under this authority to ensure convenient pharmacy access as required under section 1860D–4(b)(1)(C) of the Act.

Comment: Some commenters asserted that our April 2013 study (''Negotiated Pricing between Preferred and Non-Preferred Pharmacy Networks'', posted at: *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/.*

Downloads/PharmacyNetwork.pdf) that we cited as showing some negotiated prices for drugs were higher at pharmacies offering preferred cost sharing than the rest of the network was flawed. Therefore, they contend that our rationale for the proposal was flawed. They point out that this study only looked at prescription drug event (PDE) data and did not take into consideration any direct or indirect remuneration. They claim that even if you accept the results of this study as stated, it shows only that drug prices were ''slightly higher'' and only in ''a few'' preferred networks in ''some plans''. In addition, commenters raised methodological concerns because the CMS study was not normalized for different drug mix and utilization between plans, which they said will bias the results and lead to incorrect conclusions that will contribute to higher costs for beneficiaries and the Part D program.

Response: We appreciate the detailed comments regarding the validity of our study and the conclusions that we drew. However, we disagree with the assertion that our study was flawed and believe some commenters misinterpreted our findings. Specifically, despite the comments, we did not conclude that our findings showed that some pharmacies with preferred cost sharing were more expensive than some other pharmacies that were not offering preferred cost sharing. We acknowledge that this study did not take into consideration price concessions reported as DIR or differences in drug mix, and therefore agree that one cannot make that conclusion given the current definition of negotiated price and variability among plans on what is included in the

price. Nevertheless, we believe the findings of some higher negotiated prices at some pharmacies offering preferred cost sharing demonstrates that we cannot assume point-of-sale negotiated prices are always lower at pharmacies offering preferred cost sharing and, therefore cannot assume that benefit designs with some pharmacies offering preferred cost sharing never increase payments to plans. Instead, we believe our study highlighted this vulnerability and the need for us to propose a transparent and consistent method for ensuring these benefit designs do not increase payments to plans.

Comment: Some commenters strongly supported our proposal to remove the definitions of preferred and non-preferred pharmacies and replace them with a definition of preferred cost sharing. These commenters agreed that the term ''preferred pharmacy'' is confusing for beneficiaries who sometimes interpret this to mean non-preferred pharmacies are out-of-network. Other commenters opposed the proposal because they believe the change in terminology will be confusing for beneficiaries. They note that under the current framework plans may already refer to non-preferred pharmacies as ''other network pharmacies'' and, therefore, there is no need for this change. Moreover, some commenters opposed removing the term ''preferred pharmacy'' because they believe it refers not only to lower cost sharing but also quality of services. Another commenter who was supportive of the proposed change also raised concerns about beneficiary confusion from the change in terminology and urged CMS to consider education and outreach efforts to help beneficiary understand the new terminology and add related language to Medicare & You.

Response: We appreciate the comments we received on this proposal. We agree with supporters that this change will help avoid confusion regarding pharmacy network status and more accurately reflect what is meant by preferred. While any change has the potential to initially create some confusion, we disagree that substantively this change will be more confusing to beneficiaries going forward. In addition, we are perplexed by the comments that said their identification of preferred pharmacies also takes into consideration the quality of pharmacy services because that was never part of the regulatory definition. Nevertheless, we are not finalizing this proposal because it is so closely tied to the other preferred cost sharing proposal to revise § 423.120(a)(9) that is not being finalized as a result of changes to the definition of negotiated price in this final rule (as described in section III.A.25 of this final rule).

After considering of the public comments received, we are not finalizing the proposed changes to §§ 423.120(a)(9) and 423.100. We will undertake notice and comment rulemaking if we are going to make changes to these provisions in the future.

18. Prescription Drug Pricing Standards and Maximum Allowable Cost (§ 423.505(b)(21)

We proposed a change to the regulations governing the disclosure and updating of prescription drug pricing standards used by Part D sponsors to reimburse network pharmacies to make clear that drug pricing based on maximum allowable cost is subject to these regulations. Section 173 of MIPPA amended sections 1860D–12(b) and 1857(f)(3) of the Act to add a provision requiring the regular updating of prescription drug pricing standards. Specifically, for plan years beginning on or after January 1, 2009, CMS's contracts with Part D sponsors must include a provision requiring sponsors to update any standard they use to reimburse network pharmacies based on the cost of the drug to accurately reflect the market price of acquiring the drug. These updates must occur not less frequently than once every 7 days, beginning with an initial update on January 1 of each year.

We codified this requirement in § 423.505(b)(21). We also amended § 423.505(i)(3) with respect to contracts or written arrangements between Part D sponsors and pharmacies or other providers, first tier, downstream and related entities. Specifically, § 423.505(i)(3)(viii)(A) requires that sponsors' pharmacy contracts include a provision establishing regular updates of any prescription drug pricing standard used by the Part D sponsor, consistent with § 423.505(b)(21), and § 423.505(i)(3)(viii)(B) requires that a Part D sponsor's pharmacy contract indicate the source used by the Part D sponsor for making any such pricing updates. We finalized these regulations in a final rule entitled, ''Medicare Program; Medicare Advantage Program and Prescription Drug Benefit Programs'' at 76 FR 54600 (September 1, 2011) (''September 2011 final rule'').

We stated in the preamble to the September 2011 final rule that a ''prescription drug pricing standard'' is an accepted methodology based on published drug pricing. In the preamble to the proposed rule, we explained that this was because we were unaware at the time that there is at least one standard based, at least in part, on costs of the drugs that is not based strictly on published drug pricing, which is maximum allowable cost prices. Now that we have become aware of these types of pricing standards, we wish to amend our regulatory requirement. We believe that the updating requirement should apply to pricing standards based on the cost of a drug, even when the standard is not based on published drug pricing, an approach consistent with the intent of the statute. The text of section 173 of MIPPA indicates the provision's purpose—Part D sponsors must update their prescription drug pricing standards regularly ''to accurately reflect the market price of acquiring the drug.'' We believe that this statement of purpose indicates that the Congress intended to provide pharmacies with a means of ensuring that they have current data on the amount of reimbursement that they can expect, including in cases when the reimbursement is based upon maximum allowable cost prices.

When the source of a prescription drug pricing standard is published publicly, such as with AWP or WAC, pharmacies can determine their reimbursement for all drugs at any given time and can monitor these sources to ensure they are being reimbursed correctly. However, when a prescription drug pricing standard is not published publicly, network pharmacies are unable to promptly determine whether their reimbursement is consistent with their contractual arrangements. This, in turn, presents risks to the Medicare Part D program in a number of ways. For example, disclosure of the source used to determine drug prices is necessary for pharmacies to ensure accurate payment of their claims, which is necessary for accuracy in the costs submitted to CMS by Part D sponsors on PDEs without unnecessary later adjustments that are disruptive to the operation of the Part D program.

In addition, when network pharmacies are unable to determine whether their reimbursement is consistent with their contractual arrangements, the accuracy of the prices displayed in the Medicare Prescription Drug Plan Finder (''MPDPF'') is questionable. While these prices only provide an estimate of Part D drugs costs at particular pharmacies, beneficiaries do use the MPDPF to make drug purchasing choices. If a pharmacy does not know what it will be paid for drugs on any given day, it cannot test the MPDPF and validate the prices.

Thus, there is no assurance that the posted prices are accurate, and pharmacies are deprived of the opportunity to compete based on more accurate prices, and beneficiaries may make choices based on erroneous estimated drug costs. This is contrary to the public policy goal of facilitating competition in the health care system and supporting consumers to be informed purchasers of health care. Also, when we compare posted prices to prices submitted on PDEs to evaluate the estimates provided in the MPDPF, there can be no assurance that those values correspond to the payments pharmacies actually receive.

For this and other reasons detailed in the preamble to the proposed regulation, as well as in response to comments received on the proposed regulation, we are defining ''prescription drug pricing standard'' in regulation. Specifically, in § 423.501 a ''prescription drug pricing standard'' is now defined as ''any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts that are based upon average wholesale price, wholesale acquisition cost, average manufacturer price, average sales price, maximum allowable cost, or other cost, whether publicly available or not.'' In addition, we are finalizing the following technical changes to make the regulations on prescription drug pricing standards easier to reference: (1) To combine the current requirements contained in § 423.505(b)(21) (i) and (ii) into (i) and eliminate the reference to the effective contract year 2009 as no longer necessary. These requirements generally state that Part D sponsors agree to update any prescription drug pricing standard (as would be defined in § 423.501) on January 1 of each contract year and not less frequently than once every 7 days thereafter. Also, we are moving the current requirement to indicate the source used for making any such updates to (b)(21)(ii) from § 423.505(i)(3)(viii)(B), so that it is clearer by its placement in the regulation that this requirement is on Part D sponsors.

For new paragraph § 423.505(b)(21)(iii), we are finalizing a new requirement and not a technical change, that Part D sponsors agree in their contracts with CMS to disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for any prescription drug pricing standard is not publicly available. This means, in conjunction with the proposed definition of a ''prescription drug pricing standard'' discussed previously, that Part D sponsors have to convey to network pharmacies the actual maximum allowable cost prices to be changed in advance. We are requiring that the actual maximum allowable cost prices be disclosed in advance because, if the pharmacies are not able to use the updates as a reference against which they can check their reimbursements, there would be no point to the statutory requirement.

As a final technical change, we are eliminating language in § 423.505(i)(3)(viii)(A) about establishing regular updates of any prescription drug pricing standard used by the Part D sponsor, which is duplicative to language in 423.505(b)(21). As a result of the changes described previously, there would be no paragraphs (A) and (B) of § 423.505(i)(3)(viii) (which we note will be redesignated as § 423.505(i)(3)(vii) due to other changes in this final rule), and this provision simply requires that, if applicable, each and every contract governing Part D sponsors and first tier, downstream, and related entities, must contain provisions addressing the prescription drug pricing standard requirements of § 423.505(b)(21). We believe these changes will make the regulation text easier to reference and understand.

Comment: We received a very significant number of supportive comments for our proposal. These commenters asserted that maximum allowable cost prices are a source of deep and ongoing concern for pharmacies. Specifically, these commenters assert that PBMs update maximum allowable cost prices of drugs for which the drug costs are declining in a timely manner, but do not do so when the drug costs are increasing. These commenters asserted in particular that there were significant spikes in the acquisition costs for certain generic drugs in Fall 2013, but that PBMs did not update their maximum allowable cost prices accordingly. These commenters also offered specific examples of maximum allowable cost prices of drugs that they asserted resulted in reimbursement that was below pharmacy acquisition costs for the drugs, yet the drugs were not available on the market at lower prices. These commenters stated that pharmacies were forced not to stock certain drugs due to inadequate reimbursement based on maximum allowable cost prices of drugs, sometimes creating access issues for patients. These commenters further stated that the pharmacies are even in danger of going out of business altogether due to the low maximum allowable cost prices for drugs, and that if pharmacies are forced to close their doors for this reason, there would be even greater health care access issues in many communities.

The supportive comments stated that greater transparency in maximum allowable cost prices of drugs would not only give pharmacies the ability to shop for more cost-effective versions of generic drugs, but would improve pharmacies' ability to evaluate Medicare Part D plan contract proposals, plan their business staffing levels and potential capital investments, and monitor claims reimbursements and appeal when it appears that there has been a reimbursement error.

Conversely, some other commenters opposed our proposal. One commenter asserted that our proposal was based upon anecdotal complaints from pharmacies. This commenter stated that PBMs make their most utilized maximum allowable cost list available upon request to any pharmacy that asks for it, and that pharmacies almost never make such a request.

Response: We thank the commenters for their supportive comments of our proposal. Given the voluminous number of supportive comments we received, we disagree with the commenter that stated that our proposal was based upon anecdotal pharmacy complaints. However, we were surprised to learn that pharmacies do not routinely request PBMs' most utilized maximum allowable cost lists, and wonder if pharmacies do not realize that they are available upon request. We agree with the supportive commenters that greater drug price transparency will further increase competition in the drug market which can lead to even lower drug prices. Therefore, we encourage pharmacies to make requests for the most utilized maximum allowable cost lists from the PBMs with which they do business, and thank the commenter for this suggestion.

Comment: Many commenters support our proposal out of concern that the uncertainties surrounding current maximum allowable cost prices for drugs fall more heavily on smaller rural and community pharmacies and may limit beneficiary access. Additionally, these commenters expressed support for greater drug price transparency for Medicare beneficiaries.

Response: We thank the commenters for their support of our proposal.

Comment: Some commenters opposed our proposal, asserting that it would increase costs by requiring a specific

time period (which many commenters interpreted to be 7 days advance notice) for advance notice, as generic drug costs generally decrease over time. It also appeared that some commenters asserted that requiring *any* advance notice of maximum allowable cost prices would increase costs, including one who made a general assertion that it would permit pharmacies and drug manufacturers to ''game the system'' by modifying the timing of their various transactions in a manner that capitalizes on the pricing changes. Other commenters stated that the proposal would interfere with a mechanism that incentivizes pharmacies to purchase the least expensive generic drug available. Finally, some commenters opposed the requirement, asserting that requiring price updates at least every 7 days is redundant of the frequent updates that are inherent in a maximum allowable cost pricing mechanism and only adds administrative cost.

Conversely, many commenters requested that PBMs be required to give at least 7 days prior notice before a maximum allowable cost price change. One commenter opposed the proposal, but recommended as an alternative that maximum allowable cost prices be updated every 7 business days, and not necessarily beginning on January 1 of each year. Another commenter opposed the proposal, but recommended as an alternative that the no-less-than-7 day update requirement for maximum allowable cost prices be extended to no less than every 14 days.

Response: This requirement does not specify any particular time period for advance notice of maximum allowable cost prices to network pharmacies. The requirement is that maximum allowable cost prices of drugs must be updated at least every 7 days and disclosed in advance of their use, if the source for any prescription drug pricing standard is not publicly available. Also, if generic prices generally decrease over time, updating maximum allowable cost prices for drugs at least every 7 days generally should have a downward pressure on overall drug costs. Therefore, we do not agree with the commenters that the requirement will necessarily increase costs. Also, maximum allowable cost prices currently must be disclosed at point-of-sale (POS) in order for a drug claim to process, so we do not believe that mere advance notice changes the drug claims processing system so significantly as to permit gaming of the system, particularly since the commenter that raised this concern provided no detail to back up its assertions about how any such gaming would occur. Furthermore, we do not understand the argument for the status quo—that disclosing maximum allowable cost prices only at POS better incentivizes pharmacies to purchase the least expensive generic drugs compared to requiring some advance notice of those prices to the pharmacies. We think pharmacies will still be incentivized to acquire a drug at the lowest cost possible regardless of whether disclosed maximum allowable cost prices are declining or increasing.

We further were not persuaded by the argument that the requirement is redundant, as it seems to suggest that the Part D sponsors/PBMs will frequently update maximum allowable cost prices anyway and disclose them at POS, but requiring them to be updated at least every 7 days and disclosed in advance adds significant administrative costs. In fact, we think just the opposite—that negligible administrative costs will be incurred by Part D sponsors due to this requirement, since they are using and updating maximum allowable cost prices for reimbursement of drug claims already and must make minimal changes to that current system to comply with this requirement. In other words, so long as Part D sponsors are updating maximum allowable cost prices as frequently as commenters asserted that the prices change and using them for reimbursement, then the new updating and disclosure requirement changes nothing for that sponsor, other than that the sponsor must now disclose the maximum allowable cost prices to its network pharmacies in advance of their use (rather than just at point-of-sale) in a way that enables the pharmacy to connect a claim to the correct drug price at the appropriate point in time in order to validate the price. However, we acknowledge that to the extent the assertions of some commenters are true—that PBMs update maximum allowable cost prices only when drug prices are declining, but not when they are increasing—then we would agree that this requirement may also result in more updating for PBMs.

In addition, we note that the requirement to update prescription drug pricing standards every 7 days beginning on January 1 of each year is a statutory one. We do not have the authority to implement different update timing requirements, nor to disregard the January 1 start date every year.

Comment: Some commenters stated that our proposal was operationally infeasible, as there are different maximum allowable cost lists for different pharmacies, types of pharmacies, types of programs (commercial, Medicare D, TRICARE, etc.) and over 100,000 drugs are subject to maximum allowable cost prices, (sometimes daily). Some other commenters stated that sending network pharmacies a stream of continuous maximum allowable cost pricing updates would be a nuisance and distraction and not helpful to network pharmacies. One commenter did not object to our proposal, as long the requirement can be met in a manner that is efficient, such as on a look-up basis through a secure internet site that network pharmacies can access at any time to obtain the most current maximum allowable cost pricing for a particular drug.

One commenter requested that we require maximum allowable cost prices to be disclosed via a certain consistent format layout and delivery method and include industry standard drug identifiers, such as Generic Pricing Indicators (GPI), and that the data format allow for efficient data analysis such as MS Excel, or a text document that could be converted to Excel.

Response: We were not persuaded by the commenters that stated our proposal was operationally infeasible. It does not make sense to us that Part D sponsors/PBMs can manage the complexity in pharmacy reimbursement described in the comments, but cannot manage to modify that existing system in order to disclose the prices in advance of their use to network pharmacies, and update them at least every 7 days. Rather, we were persuaded by the commenter that described one option for meeting the requirement—through a secure internet site that allowed network pharmacies to look up their drug prices. This option would be compliant with the prescription drug pricing standard requirement, so long as the site or other delivery method to convey maximum allowable cost prices enables pharmacies to connect a claim to the correct drug price at the appropriate point in time in order to validate the price. We decline to require a certain format layout and delivery method for disclosure of maximum allowable cost prices, but note these matters can be addressed by the parties in their negotiations.

Comment: Some commenters asserted that requiring the disclosure of maximum allowable cost methodology would increase Part D program costs by revealing competitive information. Many other commenters requested that we require PBMs to disclose the specific NDCs used to compute maximum allowable cost prices on drugs.

Response: Our proposal did not require Part D sponsors/PBMs to disclose their maximum allowable cost

methodology, nor the proprietary data source or basis used to develop reimbursement rates. We note that 423.505(b)(21)(ii) will require a Part D sponsor to indicate the source for making updates to a prescription drug pricing standard. In the case of publicly available standards, the sponsor would identify the standard. In the case of maximum allowable cost pricing that is not publicly available, the sponsor would indicate that the standard is maximum allowable cost pricing to meet this particular requirement. We also decline to require Part D sponsors to disclose the specific NDCs used to compute maximum allowable cost prices. However, we note that these matters can be addressed in contractual negotiations.

Comment: Some commenters asserted that maximum allowable cost prices are not a prescription drug pricing standard, and that CMS is exceeding its statutory authority in making it one. One commenter asserted that the Congress' intent in enacting section 173 of MIPPA was to ensure that pricing standards are timely adjusted when market prices fluctuate and not to ensure that pharmacies have current data on reimbursement amounts. This commenter also stated that when a payment methodology uses non-public costs for setting prices, payment amounts may have no direct relationship to fluctuations in acquisition costs. Many commenters specifically supported the language ''includes, but is not limited to'' in the proposed definition of prescription drug pricing standard, stating that without this language, PBMs will shift to a different drug claim reimbursement mechanism over time and assert that the new mechanism is not subject to the prescription drug pricing standard regulation. Another commenter helpfully pointed out that our proposed definition of ''prescription drug pricing standard'' mistakenly referred to ''wholesale average cost'' instead of ''wholesale acquisition cost.''

Response: We thank the commenters for their supportive comments and note that we are finalizing the definition of ''prescription drug pricing standard'' as proposed, with the exception of changing ''wholesale average cost'' to ''wholesale acquisition cost.'' We disagree with the commenters that maximum allowable cost prices are not a prescription drug pricing standard, and we disagree that we are exceeding our authority in specifying in regulation that maximum allowable cost prices, like other prescription drug standards, must be updated in accordance with the statutory requirements. In our view, it is clear that Congress believed that if a standard is based on the cost of a drug (whether directly or indirectly), it must be updated to accurately reflect the market price of acquiring the drug. Since the statutory language of section 173 of MIPPA does not exclude maximum allowable cost prices from the term ''prescription drug pricing standard,'' and maximum allowable cost prices are based on the cost of the drug and thus fluctuate and are updated, we believe it is reasonable to interpret the term, ''prescription drug pricing standard,'' to include maximum allowable cost prices. As such, they must be treated as any other prescription drug pricing standard under the statutory and regulatory requirements. In the case of published prescription drug pricing standards, the standards themselves provide pharmacies with current data on reimbursement amounts. In the case of non-published ones, disclosing the prices themselves in advance of their use provides this data. We agree with the commenter who asserted that MIPPA section 173 is intended to ensure that prices are adjusted timely, but we disagree that it necessarily follows that the Congress did not intend to ensure that pharmacies had access to current data on reimbursement amounts. We believe that the requirement for timely updating of reimbursement standards must include sufficient transparency so that pharmacies can determine that the updating requirement is being fulfilled. The disclosure requirements we are finalizing here are consistent with the updating requirement, and are appropriate to ensure sufficient transparency.

Comment: Many commenters stated that having current data on the amount of reimbursement pharmacies can expect in turn impacts costs that plan sponsors submit to CMS, as well as prices displayed on Medicare Prescription Drug Plan Finder (MPDFP). Other commenters asserted that the MPDFP is updated every 2 weeks with pricing that is effectively a month old, and that the validity of estimated prices on the MPDPF does not depend on the ability of pharmacies to verify the prices shown, and that this responsibility is on Part D sponsors. One commenter stated that our requirement would necessitate more frequent updating of the MPDPF.

Response: We thank the commenters for their supportive comments of our similar assertions in the preamble to the proposed rule. Our proposal does not affect the current process for Part D sponsors to submit drug price for the MPDPF. Our point about the MPDPF in the preamble to the proposed rule was that this requirement will enable pharmacies to validate maximum allowable cost prices in the MPDPF. While we agree with the commenters that the MPDPF is not a real-time information system, but rather reflects drug prices at a point in time, we note that these prices should be the correct prices for that point in time. Currently, however, pharmacies have no ready way to validate the prices in the MPDPF that are based on maximum allowable cost prices if they choose to do so. Once maximum allowable cost prices are disclosed to pharmacies in a way that enables pharmacies to connect a claim to the correct drug price at the appropriate point in time, they will be able to validate prices in the MPDPF and alert sponsors, or CMS, to any issues.

Comment: A few commenters requested a delay in the effective date for implementation of this requirement until January 1, 2016. This delay would provide for more preparation time.

Response: We were persuaded by comments to delay the effective date of this proposal until 2016 to give Part D sponsors time to consider the format layout and delivery method for conveying maximum allowable cost prices to network pharmacies in a manner that allows the pharmacies to connect a claim to the correct drug price at the appropriate point in time in an efficient way.

Comment: Many commenters requested that we include a definition for which drugs can be included on a maximum allowable cost list, and requirements for an appeals process for challenging maximum allowable cost prices and for standards related to pharmacy audits. One commenter stated that it sends 200 requests per month to PBMs to increase their maximum allowable cost reimbursement rates to be closer to pharmacy acquisition costs and that very few are ever responded to, and fewer still are ever adjusted.

Response: These comments are out of scope of our proposal.

In light of all the comments received, we are finalizing this proposal without change, except for correcting the error in the definition for prescription drug pricing standard previously noted and delaying the effective date until January 1, 2016.

19. Any Willing Pharmacy Standard Terms & Conditions (§ 423.120(a)(8))

Section 1860D–4(b)(1)(A) of the Act requires Part D plans to permit any pharmacy meeting the plan's Terms and Conditions (T&C) to participate in the plan's network. We used this authority

to establish requirements under § 423.120(a)(8) and 423.505(b)(18) that plan sponsors have reasonable and relevant T&C for network participation in their standard contract, and allow any pharmacy meeting the T&C to participate as a network pharmacy for that plan. Section 1860D–4(b)(1)(B) of the Act permits sponsors to reduce cost sharing ''below the level otherwise required,'' notwithstanding paragraph (A). Thus, the statute permits a ''preferred'' cost sharing level to be offered at some network pharmacies. Since the beginning of the program, we have required sponsors to offer standard T&Cs to any willing pharmacy in order to achieve broad network access, but have permitted sponsors to offer different T&Cs in return for preferred cost sharing to a smaller subset of its network. We have previously stated that we believed our interpretation of these two seemingly conflicting statutory provisions struck an appropriate balance between the need for broad pharmacy access and the need for Part D plans to have appropriate contracting tools to lower costs. In this section we proposed that in place of sponsors having one contract with standard terms for any willing pharmacy and a second preferred cost sharing contract for a limited subset of pharmacies, that sponsors instead have standard T&C for network participation that list all combinations of cost sharing and negotiated prices possible for retail settings under the plan, allowing any willing pharmacy the opportunity to offer preferred cost sharing if the pharmacy can offer the requisite level of negotiated prices.

When discussing cost sharing, distinctions are made in this section between plans offering a preferred cost sharing level and plans that do not. For the purposes of this section, the cost sharing levels offered at retail pharmacies not contracted to offer preferred cost sharing are referred to as standard cost sharing levels. Cost sharing levels offered at retail pharmacies at the preferred T&C are referred to as preferred cost sharing levels.

We have heard from many pharmacies, many of them small independent community pharmacies, that plans do not offer any willing pharmacy the opportunity to offer preferred cost sharing. Instead, some pharmacies are being offered only the plan's standard T&C, at the highest level of beneficiary cost sharing. We received more than 200 comments in response to our discussion of this topic in the Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and PDP Payment Policies and Final Call Letter (2014 Call Letter) pp. 175 and 176 at *http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf.* Most of these comments were from pharmacies concerned about barriers to entry for participation in preferred networks, and many of these argued that such limited networks violate the statutory intent of the network access provisions at section 1860D–4(b)(1) of the Act. In particular, these commenters disagreed that such barriers were consistent with the any willing pharmacy requirement as stated in 1860D–4(b)(1)(A) of the Act.

Consequently, we reviewed our original regulatory interpretation of these provisions, not only in light of these complaints, but also in light of our experience in the Part D program. We believe that an alternative reading of sections 1860D–4(b)(1)(A) and (B) of the Act to reduce barriers is not only permissible, but also it would have the following key policy benefits, which we describe as follows:

- Increased access for beneficiaries to preferred level cost sharing with any willing pharmacy able to agree to the T&C that include preferred cost sharing.
- Improved opportunity for competition among pharmacies contracting with the sponsor to charge no more than the ceiling price stated in the contract for preferred cost sharing, reducing costs charged to the program.
- Improved clarity for beneficiaries surrounding cost sharing levels available at retail and mail order pharmacies.

We have heard the assertion that limited networks achieve greater savings than broader networks, and that moreover, allowing more participants into a limited network than those hand-picked by the sponsor will necessarily lead to increased prices. However, we have been running a natural experiment of sorts relative to this assertion in the Part D program. If limited networks *per se* led to significantly lower costs, we would see consistently significant savings in those network segments relative to the rest of the sponsors' networks. However, an April 2013 analysis by CMS, ''Negotiated Pricing Between Preferred and Non-Preferred Pharmacy Networks'', reviewed actual program experience and indicated that this is not the case across the board (see *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf*). As the 2012 claims show, there is wide variation in discounting across sponsors. Consistent savings are not seen uniformly. In some cases, pharmacies extending high discounts are ones that have been excluded from limited networks offering preferred cost sharing, while some pharmacies within the limited networks offer effectively no discounts compared to the rest of the network.

We have also heard the argument that the pharmacies in currently limited networks are offering deeper discounts solely in return for increased market share and that they will withdraw such offers if the limited network is opened up to other pharmacies that can meet those T&C. We are skeptical that such participants in the highly competitive retail market will abandon their market share by returning to the broader network T&C. As some network pharmacies offering standard cost sharing have been able to extend discounts in pricing even deeper than what is seen in some pharmacies offering preferred cost sharing, it is not obvious that negotiated prices would necessarily increase in the aggregate in the event that a limited number of pharmacies consider changing from preferred to standard cost sharing. We have also been informally told by one sponsor with preferred cost sharing in a limited network that its preferred cost-sharing T&C already are offered to any willing pharmacy. For these reasons, we do not believe that our proposal would result in increased prices.

We also believe that there is a limit to the number of cost sharing levels offered under a benefit plan that can be well understood by beneficiaries. When establishing its network, a Part D sponsor does not offer identical T&C for network participation to every pharmacy. Certain terms will necessarily differ among contracts with the different types of pharmacies needed to provide all Part D drugs, if for no other reason than to address the different access and service standards established by CMS. These various types include at a minimum: Retail, mail-order, long-term care institutional, limited-distribution-drug specialty, and home infusion therapy pharmacies. Terms will also differ with respect to negotiated prices and the level of cost sharing that a pharmacy's claims will be subject to. For instance, long-term care institutional, specialty, and infusion pharmacies are generally offered at the standard level of cost sharing (for the applicable formulary tier) for a month's supply of a covered drug. Retail and mail-order pharmacies, in contrast, currently may contract with plans to be offered at more than one cost sharing level.

Cost sharing at retail and mail-order pharmacies currently vary on three dimensions: Whether the cost sharing is standard or preferred, on the quantity dispensed (or ''days' supply''), and on dispensing location.

We proposed that a more simplified benefit design, incorporating these three variables and accommodating a more clearly defined set of cost sharing levels, would promote better understanding of Part D plan benefits, both in terms of beneficiary cost sharing and prices charged to the program, as well as streamlined contracting options. We also proposed to expressly state the total number of possible cost-sharing levels, to clarify expectations and to preempt the introduction of additional or unauthorized cost-sharing levels in the future.

For prescriptions not subject to Long Term Care, specialty pharmacy, or home infusion pricing, the interaction of the following four provisions of section 1860D–4(b)(1) of the Act point to three authorized levels of cost sharing: Standard, preferred, and extended days' supplies for retail and mail order pharmacies. We proposed to minimize the number of variations on these three levels to the following options and to ensure that standard T&C for network participation offer every level available for each respective pharmacy type. First, we proposed to limit long term care, specialty, and infusion pharmacy cost sharing to the standard monthly rate, as is industry practice today. Second, we proposed to limit retail pharmacies to the three authorized levels; either the standard or preferred monthly rate (for supplies up to 34 days), and one extended days' supply cost sharing rate not exceeding three times the monthly retail rate (either three times the standard monthly retail rate or three times the preferred monthly retail rate, depending upon the T&C of the pharmacy's contract). Third, we proposed to limit the levels of cost sharing at mail-order pharmacies to one monthly rate and one extended day mail order cost sharing rate (for any supplies greater than 34 days) for reasons discussed previously. We additionally solicited comments on the frequency of mail order being used to fill prescriptions lasting one month or less. We note that these proposals would not alter our requirements around the dispensing of any days' supplies less than 30 days, which is still subject to the ''daily cost sharing'' provision at § 423.153(b)(4).

In summary, we proposed to use the authority in section 1860D–4(b)(1)(C)(i) of the Act to establish rules defining convenient access within a Part D pharmacy network, combined with the authority in section 1860D–4(b)(1)(A) of the Act to revise the any willing pharmacy requirements, to ensure that any pharmacy that can meet the applicable T&C for offering standard or preferred cost sharing can join the network on those terms. We believe the network access provisions in section 1860D–4(b)(1) of the Act support expanding § 423.120(a)(8) to all levels of cost sharing offered under a sponsor's benefit plans. We believe that doing so supports the Congressional intent to have plans compete on negotiated prices by making this price competition more open and accessible to pharmacies. Specifically, we proposed to revise § 423.120(a)(8) to require that, in establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage must comply with all of the following requirements:

- Must offer and publicly post standard terms and conditions for network participation for each type of pharmacy in the network subject to the following:

++ May not require a pharmacy to accept insurance risk as a condition of participation in the PDP sponsor's contracted pharmacy network.

++ Must offer payment terms for every level of cost sharing offered under the sponsor's plans consistent with CMS limitations on the number and type of cost sharing levels, and for every type of similarly situated pharmacy.

- Must contract with any willing pharmacy able to meet one set of the terms and conditions offered by that plan for that type of pharmacy.

We also proposed to make conforming changes to the contracting provisions at § 423.505(b)(18) to require Part D sponsors to agree to have standard T&C for network participation that meet the requirements described in § 423.120(a)(8), with reasonable and relevant T&C of participation for each type of pharmacy in its network. We believe these proposed requirements would better ensure that each Part D plan: (1) Provides convenient access to Part D drugs in all Part D settings and to the extent practical, at all cost sharing levels; and (2) offers cost sharing levels that encourage beneficiaries to make choices that minimize costs not only for themselves, but also to the Medicare Part D program as a whole. We solicited comments on these proposals to expand the any willing pharmacy T&C and to streamline the levels of cost sharing offered under those standard T&C. We believe these proposals would increase beneficiary understanding of and access to cost sharing that is better aligned with the lowest negotiated prices, improve market competition, and increase downward pressure on total program costs. We received more than 4,000 comments on these proposals and our response follows:

Comment: This proposal received significant support from commenters citing an interest in expanding access to preferred cost sharing and creating a more level playing field for small and independent pharmacies. Many reported that the lower cost sharing at a limited number of pharmacies offering preferred cost sharing leads many beneficiaries to drive sometimes great distances to access these savings, even when they have a stated preference to stay with a local pharmacy, or one where they have a long-term history with the pharmacist. Many other commenters reported that some current marketing practices are mistakenly interpreted as suggesting that only pharmacies offering preferred cost sharing can be used by enrollees of that plan, also leading many beneficiaries to leave their preferred choice of where to access pharmacy services.

Response: We appreciate the strong support we received for this proposal. We agree with many of the commenters who wrote that beneficiaries should be able to choose where they obtain their pharmacy services, and we are very concerned to hear that the current incentives (and potentially current marketing of pharmacies offering preferred cost sharing) lead many beneficiaries to believe that only those pharmacies offering preferred cost sharing can be used. We are also concerned by the many comments reporting that beneficiaries are now driving 30–60 miles to the nearest pharmacy offering preferred cost sharing, or are feeling forced into using mail-order services, despite a preference to stay with a local pharmacy. We share the concerns of commenters who suggest that current contracting practices by sponsors, only extending preferred cost sharing T&C with select pharmacies, are being interpreted by Medicare beneficiaries as a violation of the Any Willing Pharmacy provision in statute. While the Any Willing Pharmacy provision applies only to participation in a plan's pharmacy network, not the subset of pharmacies offering preferred cost sharing, many commenters reported that access to preferred cost sharing does not align with beneficiaries' expectation for choice of pharmacy service provider. That is, if a plan offers preferred cost sharing, beneficiaries assume they will be able to access that cost sharing at their own ''preferred'' pharmacy.

Comment: Some commenters asserted that requiring plan sponsors to allow any willing pharmacy to accept publicly disclosed terms and conditions to offer preferred cost sharing to plan enrollees, in exchange for requisite drug price discounts, would limit sponsors' ability to negotiate significant discounts from a more limited number of pharmacies. Some of these commenters stated that they did not believe CMS had the authority to make this change. A few commenters suggested that CMS use its current authority to respond to plan offerings that we determine to be discriminatory in the availability and access they provide to preferred cost sharing, and to reject plans failing to offer fair access. Many of the opponents of this proposal objected to publicly posting contract T&C, as potentially undermining price competition. These commenters suggested that this change would ultimately result in higher drug costs, as a higher number of pharmacies offering preferred cost sharing would lead to a decrease in the volume of enrollees electing to use any one of these pharmacies, and as a result pharmacies would not be as willing to negotiate deeply discounted drug prices without the promise of a high volume of enrollees. Some commenters submitted economic analyses in support of their claims. Some, but not all opponents questioned CMS' assumption that pharmacies currently offering preferred cost sharing would not elect to discontinue offering preferred cost sharing if such terms and conditions were available to any willing pharmacy.

Response: We continue to believe that reduced preferred cost sharing offered to plan enrollees should be aligned with reduced drug prices charged to the program, aligning the cost sharing price signals with high value plans offering reduced drug pricing. We believe that opening up these limited networks to any pharmacy willing to charge no more than the contract's ceiling price to qualify for offering the lower preferred cost sharing may be necessary to restore price competition in these networks. We disagree with the comments suggesting that this provision violates the non-interference provision. Expanding access to preferred cost sharing aligns with the authority to establish rules defining convenient access within a Part D network, combined with the authority to interpret the any willing pharmacy requirements. We believe the network access provisions in section 1860D–4(b)(1)(A) of the Act support expanding § 423.120(a)(8) to establish access standards for all levels of cost sharing offered under a sponsor's benefit plans, and that this expansion aligns with Congressional intent to have open competition between plans based on negotiated price.

Numerous comments from opponents of the provision cited published analyses that predate Part D on the elimination of selective contracting practices at the state level and higher drug expenditures noted after this change. However, we are concerned that traditional analyses that study drug expenditures after an expansion of a previously limited network may not be directly relevant to the Part D market. While we recognize the general parallels between the studies submitted for consideration and the any willing pharmacy proposal, any attempt to generalize these studies to the Part D benefit would need to incorporate multiple other variables, especially given the revenue streams other than point-of-sale pricing that may distort other economic incentives. The studies submitted offer only limited explanation of what trends in utilization, pricing, and care management surrounded the state-level changes, and without that context we do not consider these analyses persuasive. Further supporting our concerns, one commenter provided alternative economic analysis that supported our assumption that within the Part D market expanding access to any willing pharmacy may not affect drug prices.

While we continue to believe that there are benefits in increasing transparency and in permitting pharmacies willing to charge reduced prices in exchange for offering preferred cost sharing, in light of these comments we believe it is necessary to further analyze the potential impacts on the Part D market. Considering the conflicting comments and analyses submitted, and the potential consequences of implementing any changes based on incorrect assumptions, we believe it is important to wait and to spend additional time considering the evidence for potential financial impacts within the Part D benefit. We will be closely studying preferred cost sharing practices, including the associated point-of-sale drug pricing, going forward. In response to the comments suggesting that CMS use its current authority to respond to plan offerings that we determine to be discriminatory in its proposed availability and access to preferred cost sharing, we will further explore our authority in this area. In addition, we plan to closely monitor beneficiaries' access to preferred cost sharing, as well as drug pricing by pharmacies offering preferred cost sharing, to determine whether future rulemaking in this area is necessary.

In summary, pending further study, we are not finalizing the any willing pharmacy contracting proposed provision changes to § 423.120(a)(8) or 423.505(b)(18), nor the proposed changes to limit the authorized levels of cost sharing. We will engage in further notice and comment rulemaking on this issue as warranted in the future.

20. Enrollment Requirements for Prescribers of Part D Covered Drugs (§ 423.120(c)(5) and (6))

To improve our ability to oversee the Medicare Part D program, we proposed to implement section 6405(c) of the Affordable Care Act effective January 1, 2015. This section provides the Secretary with authority to require that prescriptions for covered Part D drugs be prescribed by a physician or eligible professional (as defined at section 1848(k)(3)(B) of the Act (42 U.S.C. 1395w–4(k)(3)(B)) who is enrolled in the Medicare program pursuant to section 1866(j) of the Act (42 U.S.C. 1395cc(j)). We generally proposed in revised § 423.120(c)(5) and new paragraph (6) that a prescriber of Part D drugs must have (1) an approved enrollment record in the Medicare program, or (2) a valid opt-out affidavit on file with a Part A/Part B Medicare Administrative Contractor (A/B MAC) in order for a prescription to be eligible for coverage under the Part D program. More specifically, we proposed the following:

- Under § 423.120(c)(5)(ii)(A) and (B), a Part D sponsor must deny or must require its PBM to deny a pharmacy claim for a Part D drug if: (1) An active and valid physician or eligible professional National Provider Identifier (NPI) is not contained on the claim; or (2) the physician or eligible professional (i) is not enrolled in the Medicare program in an approved status, and (ii) does not have a valid opt-out affidavit on file with an A/B MAC.
- Under § 423.120(c)(5)(ii)(C) and (c)(6)(ii), to receive payment for a drug, a beneficiary's request for reimbursement from a Part D sponsor must be for a Part D drug that was dispensed in accordance with a prescription written by a physician or eligible professional who: (1) Is identified by his or her legal name in the request; and (2) is either enrolled in Medicare in an approved status or has a valid opt-out affidavit on file with an A/B MAC.
- Under § 423.120(c)(6)(i), in order for a Part D sponsor to submit to CMS a prescription drug event (PDE) record, the PDE must pertain to a claim for a Part D drug that was dispensed in

accordance with a prescription written by a physician or eligible professional who is either (1) enrolled in Medicare in an approved status, or (2) has a valid opt-out affidavit on file with an A/B MAC.

• Under § 423.120(c)(6)(iii), a Part D sponsor must deny or must require its PBM to deny a pharmacy claim for a drug (or a request for reimbursement from a Medicare beneficiary for a drug) if the claim does not meet the requirements of § 423.120(c)(6)(i) or (ii), respectively.

The overriding purpose of these provisions is to help ensure that Part D drugs are prescribed only by physicians and eligible professionals who are qualified to do so under state law and under the requirements of the Medicare program.

Our proposed enrollment deadline of January 1, 2015 was intended to give physicians and eligible professionals at least 6 months after the publication of a final rule to complete the Medicare enrollment process. We solicited comments regarding the propriety of this effective date.

The Medicare enrollment process requires that an A/B MAC screen and validate each enrollment application submitted by a physician or eligible professional prior to the decision to approve or deny enrollment in the Medicare program. The enrollment application collects identifying information about the applicant and his or her credentials, such as licensure status. We have been concerned about instances where unqualified individuals are prescribing Part D drugs. In fact, in a June 2013 report the OIG found that the Part D program inappropriately paid for drugs ordered by individuals who clearly did not appear to have the authority to prescribe. (See ''Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority'' (OEI–02–09–00608).) There have also been reports that the prescriptions of physicians with suspended licenses have been covered by the Part D program. This should not happen, and we believe we can better address these and similar vulnerabilities by verifying the credentials of prescribers through either the Medicare enrollment process or their submission of a valid opt-out affidavit.

With respect to the latter, we note that under section 1802(b) of the Act and the implementing regulations at § 405.400 et seq., certain physicians and eligible professionals can opt-out of the Medicare program and enter into private contracts with Medicare beneficiaries. By entering into such contracts, these individuals do not bill the Medicare program for non-emergency services they furnish to beneficiaries.

Under our proposal, in short, the prescriptions of a physician or eligible professional who is not enrolled in Medicare and does not have a valid opt-out affidavit on file with an A/B MAC would not be covered under the Part D program. As explained in the proposed rule, CMS would furnish or make available to Part D sponsors a list of physicians and eligible professionals who have an approved Medicare enrollment record or who have a valid opt-out affidavit on file with an A/B MAC.

We also solicited comments on the following issues:

• Whether all pharmacies should be required to enroll in Medicare in order to dispense covered Part D drugs. (Alternatively, we sought comment on whether requiring Medicare enrollment for network pharmacies is a ''best practice'' in pharmacy contracting by plan sponsors, and should be an integral part of sponsors' required fraud, waste and abuse programs.)

• Whether doctors of dental surgery or dental medicine, including family dentists, should be required to enroll in Medicare in order to prescribe covered Part D drugs. (Note that we did not propose to exclude dentists from our requirements. Sections 423.120(c)(5) and (6) were intended to apply to dentists.)

We received a significant number of comments regarding these proposed provisions. Summaries of the comments as well as our responses follow:

Comment: A number of commenters opposed our proposed changes to § 423.120(c)(5) and the addition of § 423.120(c)(6). Several commenters were concerned that these requirements would disrupt Medicare beneficiaries' current relationships with their physicians or otherwise prevent patients from seeing certain physicians, hence denying them care. One commenter stated that it appears that state licensure alone is no longer sufficient for an individual to prescribe drugs, and that § 423.120(c)(5) and (6) would inappropriately limit one's ability to prescribe when he or she is otherwise permitted to do so under state law. The requirement to enroll is particularly disconcerting, the commenter added, considering that the prescribing individual (as opposed to the pharmacy) is not even receiving reimbursement from Medicare for the prescribed drug. Another commenter stated that medication should be based on a patient's needs, rather than on whether a physician is in the Medicare system. Several commenters also requested further clarification regarding the intent of our proposed revisions.

Response: The central purpose of our changes to § 423.120(c), as alluded to previously, is to ensure that we can verify that the prescriber is appropriately licensed and certified, is not excluded or debarred from Medicare, and is otherwise qualified under Medicare regulations to prescribe Part D drugs. Again, we have been concerned that unqualified individuals are prescribing such drugs, and the previously-referenced OIG report bears this out. The enrollment process will help ensure that Medicare beneficiaries and the Trust Funds are protected, which is why we intend to proceed with our proposal. We note further that these changes are fully consistent with our requirement in § 424.507 that physicians and eligible professionals who order or certify certain services and items are either enrolled in Medicare or have a valid opt-out affidavit on file with an A/B MAC.

Comment: Several commenters contended that Medicare should not require physicians who do not participate in or take Medicare to enroll in the program.

Response: Our changes to § 423.120(c) permit a physician or eligible professional who has a valid opt-out affidavit on file with an A/B MAC to prescribe Part D drugs.

Comment: Many commenters, some of whom supported our proposed changes, expressed concern about the proposed January 1, 2015 date. Several of them requested that the implementation of § 423.120(c)(5) and (6) be delayed until 2016 or even 2017 to give CMS, prescribers, and plan sponsors adequate time to prepare and to address all operational and system challenges. Other commenters suggested that CMS utilize a phased-in approach, similar to that which was used for CMS' implementation of § 424.507. These commenters asserted that this would help ensure that patient care is not interrupted, that all information regarding prescribers' enrollment statuses is correct, that appropriate system testing is done, that CMS engages in regular communication with all affected stakeholders, and that CMS can more accurately report the number of physicians and eligible professionals who will be affected by our proposal. Additional commenters recommended that any revised implementation date be on January 1 so as to coincide with the beginning of the new plan year.

Response: We agree with these commenters regarding the need to allow adequate time to prepare. Therefore, we are revising § 423.120(c)(5) and (6) to

establish an effective date of June 1, 2015. We understand the commenters' desire for a January 1 date, but we do not believe a delay until January 1, 2016 is feasible given our aforementioned program integrity concerns. A June 1, 2015 date, we believe, strikes an appropriate balance between the need to have sufficient time to prepare and the need to ensure that only qualified individuals are prescribing Part D drugs.

We wish to assure plan sponsors, prescriber and supplier organizations, and beneficiary advocacy groups that we will regularly communicate with them in the months leading up to the June 1, 2015 effective date to address whatever concerns they have and to keep them abreast of CMS' preparations for implementation.

Plan sponsors, prescribers, beneficiaries, and other affected parties should note that existing policies that will be superseded by our changes remain intact (and should continue to be adhered to) through May 31, 2015.

In order to: (1) Help ensure that stakeholders can effectively determine which provisions apply to them before and after June 1, 2015, (2) simplify and consolidate our proposed changes to § 423.120(c), and (3) eliminate potential duplication between the provisions we proposed in (c)(5)(ii) and in (c)(6), we are making several technical revisions. The existing version of paragraph (c)(5) will remain intact with the exception of the addition of the ''Before June 1, 2015, the following are applicable'' language at the very beginning of the paragraph. We are not finalizing our proposed changes to paragraph (c)(5)(ii), but are instead merging them with our addition of paragraph (a)(6). Hence, our final version of new paragraph (c)(6) will read as follows:

''(6) Beginning June 1, 2015, the following are applicable—

(i) A Part D sponsor must deny, or must require its pharmaceutical benefit manager (PBM) to deny, a pharmacy claim for a Part D drug if an active and valid physician or eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) National Provider Identifier (NPI) is not contained on the claim.

(ii) A Part D sponsor must deny, or must require its PBM to deny, a pharmacy claim for a Part D drug if the physician or eligible professional (when permitted to write prescriptions by applicable State law)—

(A) Is not enrolled in the Medicare program in an approved status; and

(B) Does not have a valid opt-out affidavit on file with an A/B Medicare Administrative Contractor (MAC).

(iii) A Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary for a drug if the request is not for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted by applicable State law, other eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who—

(A) Is identified by his or her legal name in the request; and

(B)(1) Is enrolled in Medicare in an approved status; or

(2) Has a valid opt-out affidavit on file with an A/B MAC.

(iv) In order for a Part D sponsor to submit to CMS a prescription drug event (PDE) record, the PDE must contain an active and valid individual prescriber NPI and must pertain to a claim for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted by applicable State law, an eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who:

(A) Is enrolled in Medicare in an approved status, or

(B) Has a valid opt-out affidavit on file with an A/B MAC.

We note that in our final version of § 423.120(c)(6)(iv), we have included the language ''must contain an active and valid individual prescriber NPI.'' This is not a new mandate, for a PDE must currently have the required NPI under § 423.120(c)(5)(i). We are simply clarifying that this requirement continues on and after June 1, 2015.

Again, these are merely technical revisions. They do not involve any changes to our proposed policies.

Comment: A commenter stated that proposed § 423.120(c)(5) and (6) reflect CMS' continued efforts to protect the Medicare program from inappropriate payments for prescription drugs.

Response: We appreciate the commenter's support.

Comment: A commenter requested that CMS furnish sub-regulatory guidance concerning the following issues related to § 423.120(c)(5) and (6): (1) the pharmacy's capability at point of service (POS) to verify that the prescriber's NPI and Medicare enrollment are valid; (2) whether plan sponsors will be expected to deny at the point of service if the beneficiary's prescriber has not completed either the enrollment process or an opt-out affidavit; (3) how CMS will disseminate relevant information to plan sponsors on a timely basis to enable sponsors to set up point of service edits and prevent negative beneficiary impacts; (4) whether CMS will require sponsors to allow pharmacies to override these denials, similar to other Prescriber ID edits; (5) which party (assuming CMS requires sponsors to pay claims at point of service and investigate post-claim payment) will be financially responsible when it is subsequently confirmed that the prescriber is not enrolled or has not validly opted-out; and (6) how CMS and sponsors will ensure that beneficiaries' access to needed Medicare-covered drugs are not delayed or denied due to this new process. Other commenters requested clarification regarding whether § 423.120(c)(5) and (6) establish any new responsibilities for plan sponsors or pharmacies.

Response: We anticipate disseminating, as deemed necessary, sub-regulatory or other guidance to address the topics raised by the commenter and any new requirements for plan sponsors and pharmacies. Furthermore, and as already stated, we will regularly communicate with plan sponsors, prescriber and supplier associations, and beneficiary organizations prior to the June 1, 2015 effective date to address their concerns.

Comment: A commenter expressed concern that there would be a flood of CMS–855 enrollment application forms or opt-out affidavit submissions by physicians and practitioners. The commenter asserted that this could cause application processing delays and, consequently, the denial of claims for drugs prescribed by practitioners whose applications could not be processed to completion before the implementation date. Another commenter requested information regarding the process and timeline for Medicare enrollment. Another commenter suggested that CMS could give a grace period to accept PDEs for physicians and eligible professionals who have applied for enrollment but are still awaiting the outcome of their application submission. Yet another commenter stated that the large number of revalidation applications being submitted could delay the processing of prescribers' CMS–855 applications.

Response: We believe that our extension of the effective date to June 1, 2015 will give physicians and eligible professionals plenty of time to submit their enrollment applications or opt-out affidavits to their A/B MACs and to have the latter process these materials to completion before § 423.120(c)(6) is implemented. Therefore, we do not believe that the grace period suggested by the third commenter is or will be necessary. As we stated in the proposed rule, we believe that the number of prescribers who are neither Medicare-enrolled nor have validly opted-out is

very low in any event, given that many physicians and eligible professionals furnish or order Part B services. Nevertheless, we will monitor this situation as June 1, 2015 approaches, and will communicate with plan sponsors, prescriber and supplier organizations, and beneficiary advocacy groups about progress in physician and eligible professional enrollment in Medicare pursuant to the requirements of § 423.120(c)(6).

Information on the general provider enrollment process and the timeframes for application processing can be found on CMS' Web site at *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html.*

Comment: Several commenters questioned the accuracy of the verification process, specifically as it relates to PECOS. The commenters stated that PECOS may not capture all enrolled individuals and that the information in the system may either be inaccurate or inconsistent with the data in NPPES. Another commenter requested that CMS permit enrollment via PECOS or a contractor's legacy system.

Response: We are continuously enhancing PECOS and are confident that all enrolled and opted-out prescribers will be accurately reflected in the system. In addition, all current enrollments have been transitioned to the PECOS system and all new enrollments are directly entered into PECOS.

Comment: A number of commenters requested information about how plan sponsors and pharmacies will be able to determine that a prescription was written by a prescriber who is enrolled or has opted-out. One commenter recommended that CMS clarify whether the NPI would be used as the primary identifier of whether a particular physician or practitioner is enrolled. Other commenters requested further clarification regarding: (1) How our proposal will be operationalized; (2) whether the proposed list will include all enrolled and opt-out prescribers and will be sufficiently complete; (3) whether or how often CMS will update the list; (4) how plan sponsors will have access to the file; (5) when CMS will define the standard format; (6) whether there will be start and end-dates in the file; (7) whether there will be an indicator for physicians who are in a pended status; (8) the extent to which NPPES will be used in prescriber validation; (9) whether plan sponsors will still be required to review the OIG/System Access Management ((SAM); formerly GSA) databases; (10) how deceased prescribers and taxonomy data will be handled; and (11) how plan sponsors and pharmacists will identify revoked or limited supplier statuses.

Response: As already indicated, we will make available to plan sponsors and pharmacies a complete list of prescribers who are either enrolled in Medicare or who have opted-out. The list will be regularly updated. The NPI will be one of several identifiers that can or will be used. We will, as deemed necessary, elaborate further on the verification process, the specific contents of the aforementioned list, the specific frequency with which the list will be updated, and various operational aspects of our requirements via sub-regulatory or other guidance.

Comment: One commenter encouraged CMS to include a review of the prescriber's taxonomy code to confirm prescribing authority as part of the Medicare enrollment process for physicians and other eligible professionals.

Response: We appreciate this suggestion and will take it under advisement as we continue our efforts to enhance the provider enrollment process.

Comment: A commenter requested clarification concerning whether an individual who enrolls in Medicare solely to prescribe Part D drugs will be required to revalidate his or her enrollment every 5 years per § 424.515. Another commenter sought clarification regarding whether enrollment pursuant to § 423.120(c)(5) and (6) would subject the enrollee to all of the enrollment requirements outlined in §§ 424.500 through 424.570 (such as revalidation, deactivation, retention of medical documentation).

Response: We reserve the right to apply applicable requirements in §§ 424.500 through 424.570 to individuals enrolled in Medicare solely to prescribe Part D drugs. This would include the requirement in § 424.515 to revalidate one's enrollment every 5 years.

Comment: A commenter requested that CMS conduct a formal analysis to determine the percentage of prescribers with an active enrollment status by comparing the prescriber NPIs submitted on the PDEs to the Medicare enrollment records. The commenter was concerned that if the unenrolled prescribers disproportionately reflect certain supplier types or geographic areas, this could cause disruptions. The commenter also stated that CMS should develop a process for allowing prescribers who are authorized under state law to prescribe but are not eligible to be enrolled in Medicare to still prescribe Part D drugs that would be covered.

Response: Prior to the June 1, 2015 date, we will, as deemed necessary, share information with plan sponsors regarding the numbers and percentages of prescribers who are enrolled in Medicare. As for the final comment, the prescriber must either opt-out of the Medicare program or otherwise comply with all Medicare enrollment requirements. We cannot enroll a prescriber who is ineligible to enroll in Medicare regardless of the individual's status under state law, for we are bound by our established enrollment procedures. Consequently, we cannot establish the exception process envisioned by the commenter.

Comment: To limit POS denials that could affect beneficiary access and compromise patient care, a commenter made several recommendations regarding § 423.120(c)(5) and (6). First, the prescriber enrollment files provided by CMS should be the single and authoritative source of prescriber enrollment for all federal health care programs. This would eliminate duplication of effort, streamline the enrollment process for prescribers, ensure the consistent application of CMS requirements, and eliminate the need to review NPPES, the DHHS OIG List, and the SAM. Second, a CMS and industry task force should be developed to establish data integrity criteria, identify the minimum necessary data elements, establish file dissemination frequency to support real-time validations, and ensure that appropriate information is communicated to the pharmacy and patient. Third, a process should be developed to address changes in a prescriber's enrollment status (and to notify beneficiaries of such changes) after the most recent files have been disseminated and before the next update will be available. Fourth, there should be changes to the PDE to support and accept multiple Submission Clarification Codes, as well as a process for CMS to convey more accurate information to the A/B MACs to update their files. Fifth, a CMS call center should be established to support prescriber and beneficiary inquiries on the prescriber's enrollment status. Sixth, there should be a CMS prescriber outreach and education effort to emphasize the importance of enrollment and to address various prescriber questions.

Response: We appreciate the commenter's suggestions and address them as follows.

Regarding the first recommendation, the aforementioned list will be the authoritative list of prescribers who are

enrolled in Medicare or have opted-out. However, it will not contain information regarding said individuals' enrollment in other federal health care programs. We do not believe such an all-encompassing list is feasible at the present time due to the differing requirements and standards of these various programs.

We will continue to work with the health care industry to ensure that the files CMS disseminates contain the information necessary for plan sponsors, pharmacies, and prescribers to enforce and comply with all CMS requirements. This will include appropriate updates to reflect changes in a prescriber's status, as alluded to in the commenter's third suggestion.

We will consider making changes to the PDE as deemed necessary to facilitate the appropriate implementation of and adherence to § 423.120(c)(6). We will also, as deemed necessary, furnish guidance regarding: (1) appropriate information for prescribers and beneficiaries concerning the enrollment status of prescribers; (2) the importance of enrollment; and (3) vehicles for addressing prescriber inquiries.

Comment: A commenter recommended that in order to stop fraud on a prepayment basis and to ensure that Medicare beneficiaries are protected from physicians and eligible professionals who prescribe controlled substances without a valid DEA registration number, CMS should revise § 423.120(c)(6) to require Part D plan sponsors to make payments to a pharmacy or Medicare beneficiary when a Part D controlled substance is prescribed by a physician or eligible professional who has a valid and active DEA registration number.

Response: We do not believe this revision is necessary, for we will be able to revoke an individual's ability to prescribe such drugs under § 424.535(a)(13) (as explained in more detail later in this section). We believe that § 423.120(c)(6) as currently crafted (aside from the effective date) will achieve our goal of ensuring that only qualified physicians and eligible professionals can prescribe Part D drugs. We further note that having a DEA certificate does not necessarily mean that a prescriber is in compliance with all Medicare requirements.

Comment: A commenter requested clarification regarding whether, if a claim is rejected at the POS, a plan will be required to provide beneficiaries with a list of prescribers that are enrolled in the Medicare program.

Response: No. This will not be required.

Comment: A commenter stated that § 423.120(c)(5) and (6) do not take into account the thousands of patients currently serviced by interns and residents who are yet to be licensed but are authorized by state governments to examine, treat and prescribe for their patients provided they function under the supervision of an attending physician. The commenter sought clarification concerning whether these as yet unenrolled individuals would be able to order prescriptions. Another commenter requested that CMS furnish guidance: (1) On how situations in which a resident's enrollment status has changed should be handled; and (2) for teaching hospitals regarding the importance of ensuring that residents comply with Medicare enrollment rules (including updating enrollment data as needed).

Response: Section 423.120(c)(6) does not prohibit interns and residents from prescribing Part D drugs to the extent that these individuals are otherwise qualified to prescribe such drugs under applicable law and regulations and to either enroll in Medicare or validly opt-out of the program.

We will, as deemed necessary, issue guidance concerning the importance of complying with Medicare enrollment rules.

Comment: A number of commenters requested additional clarification regarding the number of physicians who are not enrolled in Medicare.

Response: Although a sizable majority of physicians nationwide are enrolled in Medicare, we do not have a precise number.

Comment: Several commenters recommended that CMS make available for Medicare Advantage plans and other stakeholders access to national, real-time data—preferably in a single file—to use in identifying excluded, non-enrolled, and opt-out suppliers. One commenter added that any opt-out file should have the physician's NPI and specialty, as well as the expiration date of his or her opt-out agreement.

Response: The file alluded to earlier that will be distributed to plan sponsors will be updated regularly. Specific information regarding the frequency of the updates and the contents of the file will, as deemed necessary, be disseminated via sub-regulatory or other guidance.

Comment: A commenter questioned whether there is evidence of higher levels of fraud, waste, or abuse by suppliers who are not enrolled in the Medicare program versus those who are enrolled, and whether increasing the number of enrolled suppliers per §§ 423.120(c)(5) and (6) will provide an avenue for unscrupulous but unenrolled prescribers to defraud Medicare.

Response: The enrollment process, as explained earlier, is designed to ensure that we can verify that a supplier meets all CMS requirements, such as licensure. Without this process, unqualified and fraudulent suppliers would be able to enter Medicare and bill the program, resulting in billions of dollars being improperly paid to such individuals and organizations. We maintain that CMS' enrollment process reduces the amount of potential fraud, waste and abuse. Furthermore, we do not see how § 423.120(c)(6) will provide an avenue for unscrupulous persons to defraud Medicare. To the contrary, it will protect the Medicare program by ensuring that only qualified and legitimate individuals can prescribe Part D drugs.

Comment: A commenter disagreed with CMS' proposal to allow a physician who has opted-out of the Medicare program to prescribe Part D drugs to Medicare beneficiaries. The commenter stated that CMS does not have the legal authority to revoke the prescribing privileges of a physician or eligible professional who has been convicted of health care fraud but is in an opt-out status or is practicing via private contract.

Response: Section 1802(b) of the Act is clear that certain physicians and practitioners may opt-out of the Medicare program and enter into private contracts with Medicare beneficiaries. We believe that to require such individuals to enroll in Medicare would be inconsistent with this statutory provision.

Comment: A commenter suggested that CMS purge all opt-out affidavits if they are more than 2 years old and establish a systematic process to purge all opt-out affidavits on a regular basis.

Response: We appreciate this suggestion and will take it under advisement as we continue our efforts to enhance the integrity of the Medicare program.

Comment: Several commenters stated that numerous other federal requirements (for example, DEA certificate) and state regulations (for example, state medical licensing boards) already exist to ensure that medications are only prescribed by qualified individuals. Rather than implement another bureaucratic hurdle, the commenters contended that these other federal and state regulations should be tightened as needed. One commenter stated that because there are multiple safeguards currently in place through the OIG, there is no need for § 423.120(c)(5) and (6). Other

commenters stated that § 423.120(c)(5) and (6) are unnecessary because (i) Part D sponsors are already required to review NPPES to verify a prescriber's NPI and other data; (ii) states already license and regulate prescribers; and (iii) pharmacists are responsible for determining that prescriptions are written by licensed individuals.

Response: We disagree with these commenters. Data lists that are prepared, administered and updated by agencies outside of CMS frequently do not capture the information we need to confirm that a supplier meets Medicare requirements. The CMS enrollment process is the most practical, thorough, and effective means of securing and verifying all necessary information on physicians and eligible professionals.

Comment: Several commenters expressed support for our proposed provisions but sought assurances that plans would not be penalized for filling prescriptions if, at the time the drug was dispensed, the plan did not know of the prescriber's termination. Another commenter did not believe there should be retroactive enrollment terminations; this would eliminate recoupment of payment from pharmacies or Part D sponsors for prescribers who were shown as enrolled by the most current information available at the time the prescription was filled. Another commenter requested clarification as to whether there would be performance-score safeguards established for plans that appropriately deny drugs based on the information available to them through the MACs or other parties responsible for maintaining said list. Another commenter expressed concern about the impact that these requirements would have on plan performance measures due to an increased number of complaints from beneficiaries relating to prescriptions that could not be filled, or with respect to which payment would be denied.

Response: It is important to note that our requirements are directed specifically at individuals who prescribe Part D drugs. Individuals who prescribe are required to enroll in Medicare (or validly opt-out of Medicare) in order to do so. As such, plan sponsors would be required to pay only for those prescriptions written by physicians or eligible professionals who, according to CMS, are enrolled in Medicare in an approved status or who have validly opted-out of Medicare. We will, as deemed necessary, further address these issues via sub-regulatory or other guidance.

Comment: Several commenters believed that the administrative burden of these provisions would outweigh any potential benefits in deterring fraud, waste and abuse; this would be especially true for plan sponsors that would have to verify a particular prescriber's enrollment or opt-out status. The commenters requested that CMS more closely study the potential administrative impact of these provisions.

Response: We have studied the impact of these provisions and believe that the benefits to Medicare beneficiaries, the Medicare Trust Funds, and the program as a whole of confirming that physicians and eligible professionals are qualified to prescribe Part D drugs far outweigh the burden to prescribers of completing the enrollment process or submitting an opt-out affidavit. Besides, as mentioned in the proposed rule, a large majority of physicians and eligible professionals who prescribe Part D drugs are already enrolled in Medicare; hence, our provisions will have no impact on these individuals. Furthermore, those who are impacted will have ample time to complete the enrollment or opt-out process due to the extension of the compliance date to June 1, 2015.

Comment: A commenter suggested that CMS issue warnings to prescribers for a 6 to 12-month period prior to rejecting claims that fail to meet the necessary criteria.

Response: We appreciate this suggestion. We are exploring various means of alerting prescribers who are neither enrolled in Medicare nor have submitted a valid opt-out affidavit of the need to comply with the requirements of § 423.120(c)(6).

Comment: A commenter suggested that CMS consider using technology that already exists within the pharmacy industry for validating prescriber data, for this would (when compared to the batch processes): (1) Improve patient access to care as the most timely data is made available at the time of prescription drug dispensing; (2) decrease costs associated with audits and recovery of funds resulting from out-of-date data; and (3) increase consistency of data among the multiple MACs and pharmacies. Another commenter stated that CMS should avoid using a PDF file similar to that which exists for the current ordering/certifying edits and instead create a database containing this information.

Response: We are contemplating various formats in which the previously-discussed list might be disseminated to plan sponsors.

Comment: A commenter requested clarification as to: (1) Whether CMS is proposing a new provider enrollment process for Part D in addition to the current enrollment process for obtaining Medicare billing privileges; and (2) how a Part D revocation would impact Part B billing by the same practitioner.

Response: The provider enrollment process under § 423.120(c)(6) will be the same as that which is used for physicians and eligible professionals enrolling in Medicare in order to comply with § 424.507. A revocation under § 424.535(a) would eliminate the individual's ability to prescribe covered Part D drugs because he or she would no longer be enrolled in Medicare; hence, the requirements of § 423.120(c)(6) would no longer be met.

Comment: Several commenters requested that CMS exclude dentists from proposed § 423.120(c)(5) and (6)'s application because the provisions would place an unnecessary burden on dentists and their Medicare-eligible patients, and would not address CMS' desire to stop fraud and abuse. One commenter added that it is unaware of high-billing levels associated with prescriptions written by dentists for Medicare-eligible patients, yet the administrative burden on dentists would be significant. Another commenter expressed concern that the proposal could negatively impact plan members, in that members who receive prescriptions written by dentists not enrolled in the program would be financially responsible for such prescriptions because they would no longer be covered. Another commenter noted that Medicare beneficiaries enrolled in dual eligible SNPs may receive comprehensive dental benefits, including certain invasive procedures. Dentists may prescribe antibiotics in these circumstances, and these drugs should be covered under Medicare Part D. However, since dentists are not typically enrolled in Medicare, our proposal could interfere with this coverage. Other commenters recommended that CMS exclude from § 423.120(c)(5) and (6)'s purview those suppliers who do not normally see Medicare beneficiaries or receive Medicare payment (including psychiatrists and Veterans' Administration (VA) doctors) and enable them to (after a grace period) register with Medicare in a limited capacity to enable them to write prescriptions for Medicare beneficiaries.

Response: While we recognize the concerns of these commenters, we do not believe dentists, psychiatrists, VA physicians, or any other physicians or eligible professionals should be granted special exemptions from § 423.120(c)(6). The issue of primary concern to us is not the typical volume of drugs these individuals prescribe but the need to

ensure and confirm that Medicare payments are only made for Part D drugs that are prescribed by qualified physicians and eligible professionals. This is precisely the concern that the OIG expressed in its previously-referenced report. Moreover, we believe that our extension of the effective date to June 1, 2015 will afford these individuals more than adequate time to complete the enrollment or opt-out process, hence easing the burden on them.

Comment: One commenter: (1) Favored requiring dentists to enroll in Medicare (or have a valid opt-out affidavit on file) in order to prescribe Part D drugs; and (2) believed that a January 1, 2015 effective date was reasonable.

Response: We agree with this commenter's first comment and intend to apply § 423.120(c)(6) to dentists. While we appreciate the commenter's second comment, we believe that a June 1, 2015 effective date is more appropriate.

Comment: A commenter requested clarification concerning how these provisions would be enforced in cases of out-of-network benefits, which permit plan enrollees to receive healthcare items and services (including prescription medicines) across the country. Another commenter stated that if CMS allows point of service overrides, the Prescription Drug Events (PDEs) should be accepted and final, with no requirement for plans/sponsors to provide a retroactive look back. Other commenters suggested that CMS should: (1) Require plans to hold beneficiaries harmless from the consequences of non-coverage for a non-compliant supplier for at least one fill of the prescription; (2) require plans to reach out to the beneficiary and the supplier to explain the issue, allowing sufficient time for the beneficiary to see another supplier or for the supplier to correct his or her enrollment status; and (3) reach out to policy makers in the states that permit foreign prescriptions, to determine what kind of alternate supplier credential checking might be available to ensure that beneficiaries who spend portions of the year in other countries can access their medications without interruption or the unneeded expense of additional physician visits.

Response: We will, as deemed necessary, address these matters via sub-regulatory guidance or future rulemaking.

Comment: A commenter requested clarification as to whether § 423.120(c)(6) applies even if a physician or eligible professional is state-licensed but is neither Medicare-enrolled nor has opted-out.

Response: Yes, it applies.

Comment: A commenter requested information as to the following: (1) Whether plan sponsors would remain responsible for ensuring that a prescriber is properly enrolled in Medicare; (2) whether prescriber validation should occur at the point-of-sale and whether plan sponsors are not permitted to ''flow down'' the responsibility for this verification process to their network pharmacies; and (3) whether CMS could prohibit Part D plans from reversing pharmacy claims with prescriber verification errors found in audits if the prescriber enrollment verification found by that plan was later found to be inaccurate.

Response: We will, as deemed necessary, address these matters via sub-regulatory guidance or future rulemaking.

Comment: A commenter stated that because the vast majority of prescribing physicians and other practitioners are already enrolled as Medicare suppliers, §§ 423.120(c)(5) and (6) should not impose a great burden on prescribers. However, the commenter encouraged CMS to make any requirements for beneficiary requests for reimbursement from Part D sponsors as clear and concise as possible for beneficiaries. Prescribers should be able to quickly generate forms for patients who want to submit them to their plan sponsors directly.

Response: We agree with the commenter's first statement, and will attempt to ensure that beneficiaries understand the requirements for requesting reimbursement.

Comment: A commenter urged CMS to require plans to cover the costs associated with the charge-back if there is an error in the claim related to Medicare enrollment, and that the cost for verification and correction of any claims be borne by the plan through their administrative costs.

Response: We are not prepared in this final rule to issue a definitive statement regarding costs associated with charge-backs. Any such statement will, as deemed necessary, be addressed via sub-regulatory or other guidance.

Comment: A commenter urged CMS to explore options to reduce member disruptions and to allow plans to manage prescribers not meeting these requirements. Such options could include: (1) Allowing a period of ''soft edits'' to effectively track and manage potential future disruptions; (2) applying our requirements only to new fills; or (3) allowing prescriptions to be grandfathered up to a year after the effective date.

Response: We believe that our extension of the effective date to June 1, 2015, as well as CMS' outreach efforts, will greatly reduce the potential for coverage disruptions. However, we will monitor the progress of the implementation of § 423.120(c)(6) to ensure that such disruptions do not occur.

Comment: A commenter stated that the proposed rule did not address how Part D beneficiaries in the U.S. territories would be impacted by proposed § 423.120(c)(5) and (6).

Response: We anticipate conducting outreach, as needed, for beneficiaries in U.S. territories regarding how they may be affected by these provisions.

Comment: A commenter expressed concern that CMS had proposed to no longer allow Part D coverage for foreign prescriptions.

Response: We did not propose to deny coverage for foreign prescriptions. We simply proposed to require that all prescribers of Part D drugs be enrolled in Medicare or in a valid opt-out status. We may, as deemed necessary, further address this issue via sub-regulatory guidance.

Comment: Several commenters requested clarification concerning whether plan sponsors would be able to accept a pharmacy claim for an automatically-generated refill prescription if the prescriber is not enrolled in Medicare. The commenters also recommended that § 423.120(c)(5) and (6) only be applied to new prescriptions.

Response: The pharmacy claims described by the commenters will not be covered if the prescriber is not enrolled in Medicare and does not have a valid opt-out affidavit on file with an A/B MAC, regardless of whether the prescription is new or a refill.

Comment: A number of commenters opposed the notion of requiring pharmacies to enroll in Medicare in order to distribute Part D drugs. They expressed concern about the burden and cost involved for pharmacies, and the potential disruption to the Part D program that would result if thousands of pharmacies were required to enroll. One commenter stated that Part D sponsors or their PBMs have direct contractual relationships with pharmacies and perform their own credentialing and verifications before allowing pharmacies into their networks; sponsors have the necessary experience and expertise to identify and remove unlicensed, fraudulent or otherwise unqualified pharmacies from their networks.

Response: Because we concur with these contentions, we do not intend to apply § 423.120(c)(6) to pharmacies at this time.

Comment: A commenter requested clarification concerning whether the pharmacy requirement for enrollment refers to Part B DMEPOS supplier enrollment for drugs.

Response: Our earlier reference to pharmacy enrollment pertains to Part D drugs. However, as stated previously, we are not applying § 423.120(c)(6) to pharmacies at this time.

Comment: One commenter supported the notion of requiring pharmacy enrollment.

Response: We appreciate this comment. However, as already stated, we do not intend to apply § 423.120(c)(6) to pharmacies at this time.

Given this, we are finalizing our proposed provisions in § 423.120(c) with several exceptions. First, the January 1, 2015 effective date is changed to June 1, 2015. Second, the existing version of paragraph (c)(5) will remain intact with the exception of the addition of the ''Before June 1, 2015, the following are applicable'' language at the very beginning of the paragraph. Third, we are not finalizing our proposed changes to paragraph (c)(5)(ii), but are instead merging them with our addition of paragraph (a)(6). Our final version of new paragraph (c)(6) will thus read as follows:

''(6) Beginning June 1, 2015, the following are applicable—

(i) A Part D sponsor must deny, or must require its pharmaceutical benefit manager (PBM) to deny, a pharmacy claim for a Part D drug if an active and valid physician or eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) National Provider Identifier (NPI) is not contained on the claim.

(ii) A Part D sponsor must deny, or must require its PBM to deny, a pharmacy claim for a Part D drug if the physician or eligible professional (when permitted to write prescriptions by applicable State law)—

(A) Is not enrolled in the Medicare program in an approved status; and

(B) Does not have a valid opt-out affidavit on file with an A/B Medicare Administrative Contractor (MAC).

(iii) A Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary for a drug if the request is not for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted by applicable State law, other eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who—

(A) Is identified by his or her legal name in the request; and

(B)(1) Is enrolled in Medicare in an approved status; or

(2) Has a valid opt-out affidavit on file with an A/B MAC.

(iv) In order for a Part D sponsor to submit to CMS a prescription drug event (PDE) record, the PDE must contain an active and valid individual prescriber NPI and must pertain to a claim for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted by applicable State law, an eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who:

(A) Is enrolled in Medicare in an approved status, or

(B) Has a valid opt-out affidavit on file with an A/B MAC.

These revisions to our proposed paragraph (c)(6) do not involve any changes from our proposed policy. They are merely technical changes designed to better fit the existing regulatory text.

21. Improper Prescribing Practices (§§ 424.530 and 424.535)

a. Background and Program Integrity Concerns

We stated in the preamble to the proposed rule that notwithstanding our proposed provisions in § 423.120(c), additional program safeguard enhancements were necessary to protect the Medicare Trust Funds from fraud, waste and abuse, and to ensure that Part D drugs are prescribed only by qualified suppliers. Along with the aforementioned OIG report (''Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority'' (OEI–02–09–00608)), we cited another OIG report titled, ''Prescribers with Questionable Patterns in Medicare Part D'' (OEI–02–09–00603). This report highlighted a number of instances in which physicians and eligible professionals prescribed inordinate amounts of drugs to Part D beneficiaries in 2009. For example—

- Medicare paid a total of $9.7 million—151 times more than the average—for one California physician's prescriptions; most of this physician's prescriptions were filled by two independent pharmacies, both of which the OIG had identified as having questionable billing;
- One hundred and eight general-care physicians each ordered an average of 71 or more prescriptions per beneficiary, more than 5 times general-care physicians' national average of 13;
- An Ohio physician ordered more than 400 drugs each for 13 of his 665 beneficiaries; and
- A Texas physician ordered more than 400 prescriptions each for 16 beneficiaries and prescribed 700 or more drugs for 3 of these beneficiaries.

The OIG also noted examples of physicians prescribing a high percentage of Schedule II and III drugs in 2009. In one case, 78 percent of the prescriptions a Florida physician ordered were for Schedule II drugs even though the OIG found that 4 percent of the prescriptions ordered by prescribers nationwide were for Schedule II drugs. For one beneficiary, the physician prescribed a 605-day supply of morphine sulfate, a 524-day supply of oxycodone HCl, a 460-day supply of fentanyl, and a 347-day supply of hydromophone HCl.

The OIG has recommended that CMS exercise greater oversight of the Part D program, not only to curb the specific practices outlined previously but also to stem the overall risk of fraud and abuse that the program presents. The OIG has expressed particular concern over the potential for beneficiaries to become addicted to or otherwise be seriously harmed by certain drugs if they are inappropriately prescribed in dangerously excessive amounts. We share this concern, particularly as we continue to receive reports of improper prescribing practices. The difficulty, as we explained in the proposed rule, is that CMS does not possess the legal authority to take administrative action against the prescriber. This means, in many cases, that the individual can continue prescribing drugs that will be covered under Part D and, if he or she is enrolled in Medicare, remain so enrolled to furnish medical services. We believe this is inconsistent with: (1) The OIG's recommendations in its various Part D reports; and (2) our goals of protecting and promoting the health and safety of Medicare beneficiaries and of safeguarding the Medicare Trust Funds.

To this end, and as we explain in this section, we proposed several changes to Part 424, subpart P.

b. Drug Enforcement Administration (DEA) Certification of Registration

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and the Controlled Substances Import and Export Act, as amended, and collectively referred to as the Controlled Substances Act (CSA) (21 U.S.C. 801–971); the implementing regulations for these statutes are in 21 CFR Parts 1300 through 1321. The CSA makes possession of authority under state law

to dispense controlled substances a requirement for both obtaining and maintaining a DEA Certificate of Registration.

We view a DEA Certificate of Registration to prescribe controlled substances as similar to a state's requirement that a physician or eligible professional be licensed or certified by the state to furnish health care services. Indeed, we are concerned that a physician or eligible professional's improper prescribing practices may be duplicated in the Medicare program. To address these issues, we proposed the following:

- Adding a new § 424.530(a)(11) granting CMS the authority to deny a physician or eligible professional's Medicare enrollment application if: (1) His or her DEA Certificate is currently suspended or revoked; or (2) the applicable licensing or administrative body for any state in which the physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs, and such suspension or revocation is in effect on the date he or she submits his or her enrollment application to the Medicare contractor.
- Adding a new § 424.535(a)(13) granting CMS the authority to revoke a physician or eligible professional's Medicare enrollment if: (1) His or her DEA Certificate is suspended or revoked; or (2) the applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes his or her ability to prescribe drugs. Again, this approach is consistent with our requirement that suppliers maintain compliance with all applicable licensure and certification requirements.

(We also solicited comments on whether our proposed additions of §§ 424.530(a)(11) and 424.535(a)(13) should be expanded to include pharmacy activities.)

We believe that the loss of the ability to prescribe drugs via a suspension or revocation of a DEA Certificate or by state action is a clear indicator that a physician or eligible professional may be misusing or abusing his or her authority to prescribe such substances. We also believe that our proposed provisions were consistent with the OIG's recommendations and, equally important, are necessary to protect Medicare beneficiaries and the Trust Funds.

We received a number of comments related to our proposal. Summaries of the comments and our responses are as follows:

Comment: Several commenters expressed support for §§ 424.530(a)(11) and 424.535(a)(13), stating that these provisions would help reduce abusive prescribing.

Response: We appreciate the support of these commenters.

Comment: Various commenters recommended that CMS: (1) Verify a DEA registration number submitted on the CMS–855I or the CMS–855O with the DEA prior to enrolling a physician or eligible professional into Medicare; (2) require physicians and eligible professionals to report a change (voluntary termination, revocation, suspension) in their DEA registration number within 30 days of the change; (3) modify the CMS–855I and CMS–855O to require that physicians and eligible professionals report a DEA registration number suspension or revocation within 30 days; (4) require that a physician or eligible professional have a DEA number for each state in which the physician or eligible professional is prescribing controlled substances; (5) require its Part D sponsors to establish the necessary edits to deny a prescription for a controlled substance when the physician or eligible professional does not maintain a validly issued and active DEA registration number in the state where the prescription was written; (6) refer to the DEA the name and NPI of any physician or eligible professional who is enrolled in Medicare in multiple states and who is only using a single DEA registration number to prescribe controlled substances to Medicare beneficiaries; and (7) establish a data matching agreement with the DEA to verify the DEA registration numbers assigned by the DEA for all physicians and eligible professionals enrolled in Medicare. Another commenter suggested that CMS establish a 3-year reenrollment bar under § 424.535(c) for any physician or eligible practitioner who is revoked pursuant to § 424.535(a)(13), or at least identify in the final rule what the reenrollment bar length will be. The commenter also recommended that the reenrollment bar apply to Medicare Advantage Organizations, not simply the Part B Medicare program and Part D drugs.

Response: We appreciate these suggestions and will take them into consideration as part of our ongoing efforts to strengthen payment safeguards in the Medicare program.

Comment: Several commenters recommended that CMS allow physicians and eligible professionals to self-report a DEA license revocation or suspension (or a state licensing body revocation or suspension associated with prescribing drugs) within 30 days of the revocation, suspension, or voluntary surrender of their DEA registration.

Response: We do not believe that a physician or eligible professional should be permitted to evade § 424.535(a)(13) and the subsequent reenrollment bar merely by reporting the DEA certificate suspension or revocation to CMS. The issues of concern to us are the certificate revocation or suspension itself and the consequent need to protect Medicare beneficiaries and the Trust Funds, and not so much the physician or eligible professional's voluntary revelation of the revocation or suspension.

Comment: A commenter requested that CMS furnish two lists to Part D sponsors: (1) A list of physicians and eligible professionals who have a DEA registration number that CMS has confirmed with the DEA; and (2) a list of physicians and eligible professionals who do not have a valid and active DEA registration number. The data on these lists, the commenter suggested, could be broken down by state.

Response: We appreciate this suggestion and will take it under advisement as we continue our efforts to strengthen the integrity of the Part D program.

Comment: Several commenters requested clarification concerning whether CMS intends to implement § 424.535(a)(13) retrospectively and revoke the Medicare billing privileges of physicians and eligible professionals who have had their DEA number suspended or revoked. One commenter opposed a retroactive application of our proposal.

Response: We retain the discretion to revoke the billing privileges of an enrolled physician or eligible professional whose DEA certificate is suspended or revoked at the time § 424.535(a)(13) becomes effective.

Comment: A commenter requested CMS' rationale for permitting an individual to enroll in Medicare after the DEA has: (1) Denied him or her a DEA certificate of registration; or (2) suspended or revoked a DEA registration number and the suspension or revocation is still in force.

Response: In the commenter's second scenario, we would be able to deny the individual's enrollment under § 424.530(a)(11). As for the first scenario, our focus in preparing our proposed rule was on individuals who had active DEA certificate suspensions or revocations. We nonetheless appreciate the commenter's apparent suggestion and may consider addressing it in future rulemaking.

Comment: Several commenters recommended that § 424.535(a)(13) not be applied in cases where a physician's DEA number was suspended due to substance abuse issues and the physician is in counseling.

Response: We do not believe that a blanket exemption from § 424.535(a)(13)'s potential application for such individuals is warranted or justified. However, we note that § 424.535(a)(13), like most other revocation reasons in § 424.535, is discretionary, meaning that CMS is not required to exercise its revocation authority. Although we have the discretion to invoke § 424.535(a)(13) regardless of the grounds for the DEA certificate revocation or suspension, we would also be able to take into account the circumstances surrounding the suspension or revocation prior to making a final determination.

Comment: Several commenters requested clarification as to whether: (1) Proposed § 424.535(a)(13) applies to non-controlled substances; and (2) whether a voluntary surrender of a DEA certificate (for instance, a semi-retired physician wishes to prescribe only non-controlled substances) would invoke § 424.535(a)(13). The commenters believed that non-controlled substances should be excluded from § 424.535(a)(13)'s purview if the prescriber otherwise maintains the legal authority to prescribe such drugs, is in good standing with a state professional licensing board, and has not engaged in abusive prescribing. At a minimum, one commenter suggested, CMS should refer a potential case to the state for review prior to making a decision.

Response: We explained in the proposed rule that a DEA certificate of registration is not required to dispense non-controlled substances. Thus, if one's DEA certificate is suspended or revoked, he or she would still be able to prescribe non-controlled substances absent some other restrictive action taken by the DEA or the state (although his or her billing privileges could still be revoked under § 424.535(a)(13)). Yet we note that § 424.535(a)(13) can be invoked if the applicable licensing or administrative body for any state in which the individual practices suspends or revokes his or her ability to prescribe drugs. Therefore, if the state rescinds the person's ability to prescribe any drugs, the individual (should § 424.535(a)(13) be invoked) would be prohibited from prescribing Part D controlled and non-controlled drugs.

The voluntary surrender of a DEA certificate would not constitute grounds for revocation under § 424.535(a)(13). The provision as written is limited to certificate revocations and suspensions. However, we may consider addressing this issue via future rulemaking.

Comment: Several commenters recommended that CMS: (1) Explain how it will obtain information from the DEA regarding registration numbers that are valid, approved, revoked, suspended, voluntarily surrendered, etc.; (2) make available to Part D sponsors the information necessary to deny a Part D claim for controlled substances when a physician or eligible professional does not have a valid and active DEA registration number in the state in which the prescription is written; and (3) explain whether this data will be in the file that is to be used for the enforcement of §§ 423.120(c)(5) and (6).

Response: We will, as deemed necessary, address these issues via sub-regulatory or other guidance.

Comment: Several commenters requested clarification concerning whether a physician would be able to reenroll in Medicare after the suspension or revocation of his or her DEA registration is lifted.

Response: If we revoke a physician's billing privileges under § 424.535(a)(13), the physician would be able to submit a CMS–855 application for enrollment upon the expiration of his or her reenrollment bar.

Comment: A commenter recommended that CMS clarify whether physicians and eligible professionals have 30 days to report a DEA registration number revocation per § 424.516(d).

Response: The individual would be required to report this information to CMS under § 424.516(d) to the extent the CMS–855 mandates that such information be disclosed on the application.

Comment: A commenter suggested that CMS revise and update item B1 in section 3 of the CMS–855I and the CMS–855O, which states ''Any revocation or suspension of a license to provide health care by any state licensing authority; this includes the surrender of such a license while a formal disciplinary proceeding was pending before a state licensing authority,'' to read as follows: ''Any revocation or suspension of a license to provide health care by any state licensing authority or Drug Enforcement Administration Registration number. This includes the surrender of such a license while a formal disciplinary proceeding was pending before a state licensing authority.'' The commenter also sought clarification regarding whether CMS will indeed treat a DEA registration number denial or revocation as a final adverse legal action.

Response: We appreciate this suggestion and will take it under advisement as we continue our efforts to strengthen the integrity of the Part D and Part B programs.

At this stage, CMS does not have the legal authority to treat a DEA certificate revocation or suspension as a final adverse action because the current definition of the latter term in § 424.502 does not specifically include DEA actions. However, we may address this issue through future rulemaking.

Comment: A commenter supported our proposal to require Part D physicians and eligible professionals who prescribe controlled substances to obtain and maintain a valid DEA certificate of registration as a condition of enrollment. Yet the commenter recommended that the provision apply only to those individuals who prescribe controlled substances; this would avoid impacting the ability of practitioners providing services solely in local public health departments to prescribe non-controlled medications.

Response: As stated previously, if one's DEA certificate is suspended or revoked, he or she would still be able to prescribe non-controlled substances absent some other restrictive action taken by the DEA or a state (although his or her billing privileges could still be revoked under § 424.535(a)(13)). However, if the state in which the individual practices suspends or revokes his or her ability to prescribe any drugs, the individual (should § 424.535(a)(13) be invoked) would be prohibited from prescribing Part D controlled and non-controlled drugs.

Comment: Several commenters opposed our proposed addition of § 424.535(a)(13), stating that a suspended DEA certificate or state license does not necessarily reflect one's inability to treat Medicare patients safely and at a high standard. This is particularly true, one commenter contended, considering that many DEA certificate or licensure revocations, suspensions, or restrictions are due to the physician or practitioner's medical illness, usually drug abuse and dependence. Such individuals generally complete treatment programs successfully and should be given a second chance. At a minimum, the commenter maintained, CMS should take into account such situations in determining whether to invoke § 424.535(a)(13).

Response: As explained earlier, § 424.535(a)(13) is a discretionary authority, and CMS can use its discretion to take into account the

individual's particular circumstances in determining whether a revocation is warranted. But we caution that we are not required to do so, and there may be instances in which we decide that the certificate revocation or suspension alone, on its face, is sufficient to justify invoking § 424.535(a)(13).

For the reasons stated in this section, we are finalizing our proposed additions of §§ 424.530(a)(11) and 424.535(a)(13).

c. Patterns or Practices of Prescribing

We also proposed to add a new § 424.535(a)(14) that would permit CMS to revoke a physician or eligible professional's Medicare enrollment if CMS determines that he or she has a pattern or practice of prescribing Part D drugs that—

- Is abusive and represents a threat to the health and safety of Medicare beneficiaries; or
- Fails to meet Medicare requirements.

We chose not to define ''abusive'' and ''threat to the health and safety of Medicare beneficiaries'' in the proposed rule, primarily because the myriad of questionable situations that could warrant the possible application of § 424.535(a)(14) requires that CMS have the flexibility to address each case on its own merits. We believed that the sounder approach was to propose a list of criteria that we would use in determining whether a prescriber is engaging in prescribing practices sufficient to warrant a revocation.

In determining instances of a pattern or practice of prescribing that is abusive and a threat to the health and safety of Medicare beneficiaries, we proposed to consider several factors, including—

- Whether there are diagnoses to support the indications for which the drugs were prescribed;
- Whether there are instances where the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit);
- Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses;
- The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the state or states in which he or she practices, and the reason(s) for the action(s);
- Whether the physician or eligible professional has any history of ''final adverse actions'' (as that term is defined in § 424.502);
- The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined);
- Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination; and
- Any other relevant information provided to CMS.

In determining whether a physician or eligible professional has a pattern or practice of prescribing that fails to meet Medicare requirements, we proposed to consider the following factors, including whether the physician or eligible professional—

- Has a pattern or practice of prescribing without valid prescribing authority;
- Has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA Certificate of Registration;
- Has a pattern or practice of prescribing drugs for indications that were not medically accepted—that is, for indications neither approved by the Food and Drug Administration (FDA) nor medically accepted under 1860D–2(e)(4) of the Act—and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient.

Many patterns and practices of prescribing, though perhaps questionable on their face, do not upon investigation involve abusive or fraudulent behavior nor involve substandard medical care. As such, we proposed to base any revocation under proposed § 424.535(a)(14) on situations that fall outside the norm of appropriate prescribing, and only after carefully considering the relevant factors. A thorough, detailed investigation by CMS of the physician or eligible professional's prescribing practices would be a prerequisite for the use of § 424.535(a)(14). Honest physicians and eligible professionals who engage in reasonable prescribing activities would not be impacted by our proposal. We noted further that CMS, rather than the Part D plans or the A/B MACs, would make all determinations under our proposed provisions, though information contained in referrals from Part D Plan sponsors may be used as part of CMS' analysis to make revocation decisions.

We received a high volume of comments regarding proposed § 424.535(a)(14). Comment summaries and our responses are as follows.

Comment: A number of commenters opposed our proposed addition of § 424.535(a)(14). They generally stated that this revocation reason would negatively impact Medicare beneficiaries by restricting access to important medications and disrupting current care plans, hence creating a chilling effect on the practice of medicine. They asserted that the proposed provision could dissuade physicians from appropriate prescribing. What may be considered excessive prescribing for the general population, they added, could be clinically appropriate given a patient's individual circumstances, particularly in pain management; many ''off-label'' uses are clinically appropriate and represent the standard of care, especially with cancer patients. Several commenters also stated that the process of finding the right medication for a particular individual may involve trial and error over the course of months, if not years; decisions about specific medications to prescribe must be based on clinical observations, knowledge of past history, awareness of side effects, and a process of collaboration between doctor and patient. One commenter stated that policies that markedly limit the use of substances to treat chronic pain could increase the suicide rate.

Response: We appreciate these comments and fully recognize the commenters' concerns. We certainly understand that each patient is different, as is: (1) His or her specific medical condition; (2) the setting in which he or she is being treated; and (3) the types and doses of medications that may legitimately be required. As alluded to in the proposed rule and as we more emphatically state here, we only intend to invoke § 424.535(a)(14) in very limited and exceptional circumstances. For this reason, we do not believe that § 424.535(a)(14) will have a chilling effect on physician or practitioner prescribing activities or will restrict beneficiaries' access to medications. Indeed, it will become clear to honest and legitimate prescribers (once § 424.535(a)(14) becomes effective and is implemented) that our focus is restricted to cases of improper prescribing that are so egregious that the physician or practitioner's removal from the Medicare program is needed to protect Medicare beneficiaries.

Comment: Many commenters contended that state medical licensing boards are the appropriate bodies to review prescribing practices; one such commenter stated that prescription restrictions under Part D should only be imposed if the state board finds a pattern of negligence in prescribing practices. Other commenters recommended that CMS, in lieu of utilizing § 424.535(a)(14), refer cases of improper prescribing to the applicable state board for its review and disposition, with one commenter adding that CMS could then decide whether to take action based on the state's findings. This commenter stated that such investigatory actions should be left to the state; having both CMS and the state undertake separate investigations would be duplicative and redundant, perhaps slowing down both investigations in the process.

Response: We recognize the leading position of state medical boards in monitoring the practice of medicine. However, such bodies operate independently of CMS. They play no role in overseeing the Medicare program, a responsibility that rests exclusively with CMS. As such, we must be able to rapidly take steps on our own volition (without having to wait for possible action by state licensing boards or other bodies) to protect Medicare beneficiaries and the Trust Funds from abusive behavior.

Comment: Several commenters asserted that CMS lacks the statutory authority for § 424.535(a)(14).

Response: We disagree. As we stated in the proposed rule, sections 1102 and 1871 of the Act give the Secretary the authority to establish requirements for the efficient administration of the Medicare program. We believe that § 424.535(a)(14) is necessary to help ensure the integrity and efficiency of the Medicare program.

Comment: Several commenters opposed the use of § 424.535(a)(14)(i)(F), which addresses prescription-related malpractice suits, as a criterion. One commenter contended that CMS' assertion that the existence of such a lawsuit is somehow equivalent to liability is incorrect. The commenter, as well as others, stated that many liability insurers settle cases with little or no merit. Another commenter stated that it would be difficult for CMS to verify the existence of such suits and settlements, while another commenter contended that certain physician specialties at high risk for malpractice suits could be unfairly targeted under § 424.535(a)(14).

Response: We did not assert in the proposed rule (and do not in this final rule) that such a lawsuit automatically equates to liability. We realize that certain cases are settled with no admission or even existence of liability. Nonetheless, it would be inappropriate and even irresponsible for CMS to completely disregard situations where a physician or practitioner has, for example, been sued several times for prescription-related malpractice and has either settled one of the cases or has had at least one final judgment against him or her.

We stress that § 424.535(a)(14)(i)(F) will represent only one of several factors in our § 424.535(a)(14) determinations, and it will not in and of itself be dispositive.

With respect to the next-to-last comment, we included the language ''to the extent this can be determined'' at the end of proposed § 424.535(a)(14)(i)(F) based on our recognition that it may occasionally be difficult to ascertain the specific outcome of such suits.

Regarding the last comment, and as already stated: (1) We only intend to invoke § 424.535(a)(14) in very limited and exceptional circumstances; (2) we will account for the patient's particular situation and setting in determining whether a § 424.535(a)(14) revocation is warranted; and (3) § 424.535(a)(14)(i)(F) is only one of a number of factors we will consider.

Comment: Several commenters stated that CMS' proposal is duplicative of current safety mechanisms, ignores the long history of states regulating the licensure process, adds yet another layer of regulatory burden and administrative costs to the program, and gives the federal government an excessive amount of latitude without furnishing clear objectives. They added that CMS has stepped outside its statutory authority and into regulating the practice of medicine, and has also usurped the authority of state boards to regulate the practice of medicine. They requested that CMS work with the medical community through pre-rulemaking activities, such as listening sessions, town halls, and the issuance of requests for information (RFI), to better develop any future proposals to address the agency's concerns. Another commenter stated that CMS should focus on preventing individuals who do not have the authority to prescribe (such as massage therapists) from prescribing Part D drugs rather than on applying § 424.535(a)(14).

Response: Section 424.535(a)(14) is not an attempt by CMS to regulate the practice of medicine or to usurp state medical boards' roles in doing so. States remain free to take action against physicians and practitioners as they deem fit. Again, though, Medicare is a distinct program that is under the purview of CMS, not the states. We must have the ability to remove abusive prescribers from the Medicare program without having to obtain or wait for approval from state licensing boards or other bodies that do not have oversight of Medicare.

As mentioned earlier, we have the authority under sections 1102 and 1871 of the Act to establish requirements for the efficient administration of the Medicare program. We believe this includes ensuring that the Part D program is properly administered, and that Medicare beneficiaries and the Trust Funds are protected. We believe that § 424.535(a)(14) will be an important part of these objectives.

We appreciate the recommendation that we work with the medical community in developing future proposals and will take it under advisement.

As for the final comment, our addition of (c)(6) is aimed at stemming the problem of unqualified prescribers. Yet we disagree with the implication that this issue should be our sole focus. Other matters, such as egregious and dangerous prescribing practices by physicians and eligible professionals, must be addressed as well.

Comment: Several commenters expressed concern about the potential application of § 424.535(a)(14) to hospice and palliative physicians. They stated that medications furnished in a hospice or palliative setting often require doses and indications that are generally not seen in conventional care. Such doses, they contend, are often necessary to relieve pain and furnish comfort to terminally ill patients, noting also that dosages might vary depending on what stage of the dying process the patient is in; terminally ill patients, they state, require different pain management strategies and often higher doses of opioids than those who are not terminally ill. The possible application of § 424.535(a)(14) to hospice and palliative physicians, they asserted, could prevent these physicians from prescribing needed medications to dying patients due to concerns about prescribing outside the usual norms. They requested an exception to § 424.535(a)(14) when the patient is specifically receiving hospice or palliative services. Another commenter suggested exempting from § 424.535(a)(14) those physicians who are ABMS-board certified in hospice and palliative medicine, or medical directors certified by the Hospice Medical Director Certification Board.

Response: We decline to establish a specific exception for hospice or palliative physicians or services, for this would eliminate our ability to take action against truly egregious and dangerous prescribing practices that may occur in such settings. However, as stated earlier, we fully understand that each patient is different, as is his or her specific condition and needs. We will operate under this overriding principle when considering whether § 424.535(a)(14) should be invoked in a particular instance.

Comment: A number of commenters contended that several of the criteria identified by CMS are beyond the expertise of CMS regulators.

Response: We disagree. We have physicians and other medical personnel on staff who we anticipate may be consulted, as needed, in potential § 424.535(a)(14) cases.

Comment: A commenter stated that because of the limited number of certified hospice and palliative physicians, most hospice and palliative patients will be cared for by their primary care physician or mid-level practitioner. The commenter recommended that CMS add an appeals process with peer-review to ensure that good clinicians are not penalized unduly. Other commenters expressed concern that the proposed rule made no mention of appeal rights, while one commenter requested how physicians can defend themselves against a § 424.535(a)(14) revocation.

Response: A physician or eligible professional whose Medicare billing and prescribing privileges are revoked under § 424.535(a)(14) may appeal the revocation per 42 CFR part 498. Also, as already mentioned, we anticipate that physicians and other medical personnel of CMS may be consulted, as needed, in potential § 424.535(a)(14) cases.

Comment: One commenter stated that CMS should clarify the term ''necessary evaluation'' as it is used in § 424.535(a)(14)(i)(B); the commenter explained that a hospice or palliative physician must often rely on the evaluations of the nurses and is not always able to physically see a homebound patient. The commenter was concerned that he or she would not be able to adjust dosages without seeing the patient. Another commenter stated that in applying this criterion, CMS should focus more on the prescriber's status than on beneficiaries who may be evaluated outside of their normal residence.

Response: We are not in a position to further clarify or define the term ''necessary evaluation'' in this rule, for we must retain the flexibility to address the variety of factual scenarios that could potentially implicate § 424.535(a)(14). However, we recognize the commenter's concern, and as stated earlier we will account for the patient's particular needs and circumstances.

We intend to review all aspects of the prescriber's and the patient's statuses and physical locations when examining this criterion.

Comment: A commenter recommended that in lieu of adopting its proposed new revocation policy, CMS should use its existing regulatory authority under § 405.371 to suspend Part D prescribing privileges when there is a credible allegation of fraud. If CMS believes it lacks the legal authority to implement a payment suspension that precludes a physician or eligible professional from prescribing, ordering, or certifying services for a Medicare beneficiary when a credible allegation of fraud exists, CMS should consider proposing a new policy that expands on the existing provisions in § 405.371 and allow the public to comment on this policy. Another commenter requested that CMS explain how a revocation under § 424.535(a)(14) is different from an OIG exclusion based on a conviction of fraud. Another commenter contended that CMS, through § 424.535(a)(14), would essentially be making fraud determinations that CMS lacks the statutory authority to undertake.

Response: We disagree with the first commenter's recommendation and the third commenter's statement because abusive or inappropriate prescribing does not necessarily involve fraudulent behavior, although it could well involve improper payments. We further believe that revocation is a more appropriate remedy for abusive prescribing than a payment suspension. In the latter situation, the prescriber would remain enrolled in Medicare despite his or her improper prescribing; we believe this goes against the overall objective of § 424.535(a)(14), which is to protect Medicare beneficiaries and the Trust Funds from abusive behavior.

Comment: A commenter suggested that CMS should, prior to finalizing § 424.535(a)(14), solicit comments on a process of notification and opportunity to correct prior to implementing a revocation under § 424.535(a)(14). Other commenters likewise stated that before revoking a supplier under § 424.535(a)(14), CMS should notify the supplier of the potential revocation and enable the supplier to respond.

Response: We disagree. Providing a physician with an opportunity to take corrective action would not be appropriate under these circumstances, given that CMS would have based its revocation action on a prescriber engaging in a pattern or practice of abusive prescribing over some period of time. One of our goals with § 424.535(a)(14) is to place prescribers on notice that abusive prescribing practices can result in the individual's losing his or her Medicare billing privileges. To permit an abusive prescriber to avoid revocation by simply modifying his or her behavior temporarily would undermine this objective and, more importantly, would not undo the harm that may have been done to Medicare beneficiaries because of the prescriber's practices.

Comment: Several commenters suggested that CMS be required to consult with and receive written approval from the OIG and/or the Department of Justice prior to any invocation of § 424.535(a)(14).

Response: We do not agree. As mentioned earlier, CMS administers the Medicare program. We must be able to expeditiously remove abusive prescribers from the Medicare program without having to secure prior approval from law enforcement. Indeed, failure to take such quick action would be inconsistent with the spirit of the two aforementioned OIG reports that urged CMS to exercise greater oversight of the Part D program.

Comment: A commenter opposed the criterion in § 424.535(a)(14)(i)(B) that reads, ''Whether there are instances where the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit).'' The commenter stated that this factor does not address whether the physician or eligible professional is out of the country when the new prescription for a Part D drug was given to a beneficiary. Another commenter stated that the criterion does not: (1) Outline cases where a physician or eligible professional is allowed under state law to prescribe Part D drugs over the phone to a Medicare beneficiary who is on vacation and may need a Part D prescription; and (2) differentiate between a prescription for a new Part D drug a day after the death of a Medicare beneficiary and a refill of an existing Part D medication by the spouse or child after the death of the Medicare patient. This commenter requested that CMS rescind this criterion unless it furnishes more information, such as how it will be used as a factor in making a revocation determination. Another commenter requested the removal of this criterion if it will be based solely on PDE data.

Response: The example cited in § 424.535(a)(14)(i)(B) is not the only one to which the criterion could apply. The term ''for example'' indicates that multiple factual scenarios are envisioned. Such is the case with § 424.535(a)(14)(i)(B). We will consider the specific facts of each situation in determining whether the resolution of this factor weighs in favor of a revocation under § 424.535(a)(14). In addition, we will consider information besides PDE data when evaluating this criterion.

Comment: A commenter opposed the criterion outlined in § 424.535(a)(14)(i)(D) regarding the number and type(s) of disciplinary actions. The commenter contended that CMS did not indicate whether it would use a particular state licensing board decision (for example, a reprimand or fine) as its basis for taking an action under § 424.535(a)(14). The commenter stated that CMS should rescind this portion of its proposal unless it: (1) Provides more information regarding the state medical board actions that would be used as a factor in making a decision under § 424.535(a)(14); and (2) affords the public an opportunity to comment on CMS' implementation approach.

Response: We are not in a position to outline every conceivable disciplinary action that a state medical board could impose. Such actions vary widely by state and by magnitude, which is why § 424.535(a)(14)(D) accounts for the specific type of disciplinary action involved.

Comment: Several commenters stated that the term ''abusive'' should be stricken from the rule because it is too broad and subjective. Others requested that CMS at least provide more clarification and guidance: (1) As to the meaning of the terms ''abusive,'' ''excessive dosage,'' ''improper prescribing practices,'' and ''threat to patient health and safety''; and (2) regarding the steps that would be taken if the agency determines that a prescriber's Medicare enrollment should be revoked; one commenter stated that CMS Publication 100–18, Chapter 9, contains a definition of ''abusive'' whereas our proposed rule did not. Another commenter recommended that this guidance incorporate evidence-based guidelines and research along with the patient's history.

Response: We did not define these terms in the proposed rule and decline to do so in this final rule because of the need to retain our flexibility in addressing a variety of factual scenarios. Any revocation under § 424.535(a)(14) would be processed in the same manner as all other revocations, with the exception that with these revocations, the applicable Part D plan sponsor(s) would also be notified of CMS' revocation action so that the sponsor can terminate the individual's prescribing privileges.

Comment: A commenter stated that while CMS noted in its proposed rule that it would conduct a complete and thorough investigation prior to any revocation, there are no safeguards to ensure a full investigation. The commenter added that CMS did not identify who would conduct these investigations. Other commenters requested information as to the process for determining whether abusive prescribing or a threat to patient health and safety exists. Another commenter stressed the need for a clearly defined protocol that would be followed before any revocation decision is made.

Response: We stated in the proposed rule and reiterate here that in every case we will carefully consider all of the relevant factors before invoking § 424.535(a)(14); this will include a review of all of the evidence before us, including the patient's particular needs, circumstances, and setting. CMS and contractor staff will conduct the investigations, with CMS personnel performing the evaluation of the factors and making the final determination. More detailed information regarding the review process will, as deemed necessary, be disseminated via sub-regulatory or other guidance.

Comment: Several commenters requested clarification regarding whether CMS intends to implement § 424.535(a)(14) retrospectively. They supported a strictly prospective application.

Response: We reserve the right to revoke the billing privileges of a physician or eligible professional enrolled as of the effective date of this rule who has engaged or is engaging in abusive prescribing as described in § 424.535(a)(14). However, the effective date of the revocation would not be earlier than the effective date of this final rule.

Comment: A commenter questioned whether CMS will routinely scour its data for suppliers with suspicious prescribing patterns and, if so, what CMS will then do.

Response: Consistent with our current practices, we will be alert for such prescribing patterns. Once a pattern is detected, we will conduct a review and investigation using our existing procedures. If, based on this review, we believe that a situation involving abusive prescribing may exist, we will determine whether action under § 424.535(a)(14) is warranted.

Comment: A commenter stated that proposed § 424.535(a)(14) is unnecessary because the OIG has the ability to exclude from Medicare (under 42 U.S.C. 1320a–7(b)(6)(B)) any individual who has furnished items or services to patients substantially in excess of the patients' needs or of a quality that does not meet professionally recognized standards of care.

Response: While we recognize that the OIG has its exclusion authority, CMS is the agency directly responsible for administering the Medicare program and for protecting Medicare beneficiaries and the Trust Funds. Consequently, CMS should be able to use its own authority to pursue administrative actions to address our concerns regarding abusive prescribing. We also reiterate that the OIG has recommended that CMS exercise greater oversight over the integrity of the Part D program and has noted its concern about abusive prescribing. Therefore, we believe it is proper for CMS (and consistent with the OIG's recommendations) to implement § 424.535(a)(14).

Comment: Several commenters expressed support for our proposed addition of § 424.535(a)(14). One commenter stated that this will allow for more effective monitoring of improper prescribing behaviors. The commenter noted that inappropriate prescribing can result in overutilization of medications that increase program costs without providing any health benefit and can harm beneficiaries. Another commenter stated that § 424.535(a)(14) will enable CMS to exercise greater control over the Part D program.

Response: We appreciate the support of these commenters.

Comment: Several commenters recommended that CMS explain in the final rule whether CMS or Medicare contractors will use clinical staff (physicians and pharmacists) in determining whether Part D prescription drug abuse has occurred and whether a revocation under § 424.535(a)(14) is warranted.

Response: As stated earlier, we may use clinical staff, as needed, in making § 424.535(a)(14) determinations.

Comment: One commenter recommended that CMS, in lieu of finalizing § 424.535(a)(14), revoke the Medicare billing and/or prescribing privileges of individuals under § 424.535(a)(10) when the medical documentation does not support the Part D prescription written by the physician or eligible professional. The commenter believed that this approach

would be easier and more cost-effective to implement and would avoid the need for CMS to make clinical judgments.

Response: Section 424.535(a)(10) does not apply to Part D prescriptions. Consequently, § 424.535(a)(10) cannot be used in lieu of § 424.535(a)(14).

Comment: A commenter requested clarification concerning whether CMS or its Medicare contractors will conduct medical document reviews to determine whether an abusive prescribing pattern exists.

Response: Medical document reviews are one of several actions we may undertake in determining whether an invocation of § 424.535(a)(14) is warranted.

Comment: With respect to the criterion regarding diagnoses to support indications for which the drugs were prescribed, a commenter: (1) Questioned how CMS will cross-reference Part D prescriptions with appropriate diagnoses; and (2) stated that CMS should include all scientifically-supported indications, whether on the FDA labeling or not.

Response: We will, as deemed necessary, furnish sub-regulatory or other guidance to address the commenter's first issue. We agree with the commenter's second comment, and intend to include all scientifically-supported indications irrespective of whether they are on the FDA labeling.

Comment: One commenter expressed concern about the potential impact of § 424.535(a)(14) on pharmacies and their patients. The commenter stated that beneficiaries may see an interruption in the continuity of their health care if their physician is no longer qualified to be a Medicare supplier; the commenter believed there should be options available to ensure that health care is not interrupted.

Response: As explained earlier, we only intend to invoke § 424.535(a)(14) in exceptional circumstances. Consequently, we do not believe that patient access in general will be impacted.

Comment: In referring to the criterion in § 424.535(a)(14) regarding private insurers, a commenter stated that CMS does not have the statutory authority to make enrollment and revocation decisions based upon the actions of commercial health insurers. The commenter urged CMS to explain its legal justification for invoking § 424.535(a)(14) on this ground. The commenter also suggested that CMS explain how it will obtain information regarding private insurer actions taken against physicians and practitioners and whether these insurers will be required to furnish such data to CMS.

Response: We disagree with the commenter's assertion that we do not have the authority to consider the actions of private insurers in determining whether a § 424.535(a)(14) is appropriate. Again, we have the authority under sections 1102 and 1871 of the Act to establish requirements for the efficient administration of the Medicare program. If private insurers have taken actions against a particular physician or practitioner for questionable prescribing activities, we believe it would be appropriate for us to consider this information in light of our obligation to oversee the Part D program in a responsible manner. We will attempt to work with private insurers to facilitate the appropriate exchange of information.

Comment: A commenter opposed the following criterion: ''Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses.'' The commenter contended that CMS: (1) Did not provide the source or sources that it will use to obtain this information, and (2) already has a similar reason for revocation in § 424.535(a)(3) regarding felony convictions. The commenter stated that if CMS adopts this criterion, CMS should add the following language to the end thereof: ''that result in a felony conviction of criminal neglect or misconduct.'' The commenter also recommended that CMS: (1) Cite the sources it will use to obtain information on patient overdoses; and (2) defer to the state medical boards regarding whether a physician or eligible professional is posing an immediate risk to Medicare Part D beneficiaries (assuming CMS intends to consider state actions in its § 424.535(a)(3) determinations).

Response: We are unclear as to the specific information to which the commenter is referring; namely, whether the commenter is alluding to published clinical data (for example, professional journals) or to information regarding a particular patient's overdose. If it is the latter, as we suspect, we intend to use both publicly available and internal data to determine whether cases of excessive prescribing exist. To the extent this data is obtained from state medical boards, CMS (for reasons alluded to earlier) does not believe a prior determination by the state of an immediate risk to Part D beneficiaries is necessary.

Comment: A commenter suggested that in lieu of revoking an individual under § 424.535(a)(14), CMS should place the physician under a payment suspension and deactivate his or her Medicare billing privileges. Another commenter recommended that CMS consider a sliding scale to include lower-level consequences (such as suspensions) for less severe occurrences.

Response: We disagree. With a payment suspension, the physician would remain enrolled in Medicare and be able to prescribe Medicare Part D drugs and provide Medicare Part B services (although he or she would have Medicare payments withheld for a period of time). Moreover, there would be no legal basis under § 424.540 to deactivate the supplier's prescribing privileges, which is why revocation is the most appropriate remedy to address these situations.

Comment: A commenter stated that the sole use of PDE data to identify prescriber trends is insufficient to determine abusive practices, for such data cannot distinguish between: (1) Legitimate high dose and frequency of prescriptions; and (2) illegitimate prescribing.

Response: We agree and intend to use various data sources to detect such practices.

Comment: Several commenters stated that prescribers may avoid long-term care practice for fear of being revoked from Medicare.

Response: We disagree. We mentioned earlier that we only intend to invoke § 424.535(a)(14) in exceptional circumstances involving truly abusive behavior. Accordingly, we do not believe that § 424.535(a)(14) will deter prescribers from practicing in long-term care settings.

Comment: A commenter suggested that CMS provide additional data to plans in order to improve a plan's ability to identify inappropriate patterns and to apply claims processing edits correctly/timely.

Response: We agree and are considering various means of doing so.

Comment: One commenter stated that a revocation under § 424.535(a)(14) alone will not suspend or revoke the practitioner's right to prescribe drugs under state law, meaning that patients other than Medicare beneficiaries would still be at risk. This is especially true, the commenter added, considering that § 424.535(a)(14) does not require such CMS revocations to be reported to the state.

Response: It is possible that a prescriber revoked under § 424.535(a)(14) may still be able to retain his or her state license. However, we are currently working with the states to facilitate a closer exchange of information regarding Medicare actions taken against physicians and

practitioners, which may facilitate concomitant action taken by states.

Comment: Several commenters requested clarification as to whether a: (1) Part D plan sponsor would be penalized if it fills a prescription from a terminated supplier when information about the termination is not available (for example, in cases of retroactive termination or an error with CMS records); and (2) whether a pharmacy would be penalized for filling a prescription order that has been approved through the claims adjudication process. The commenter opposed the application of such penalties.

Response: We believe these comments are outside the scope of this final rule.

Comment: A commenter recommended that CMS remove the following as a factor for revocation: ''Has a pattern or practice of prescribing for controlled substances outside the scope of the DEA Certificate of Registration.'' The commenter instead suggested that CMS work with the DEA.

Response: We disagree with the commenter. As previously mentioned, we are responsible for administering the Medicare program and must be able to take quick action against abusive prescribers without the prior approval of another agency.

Comment: A commenter stated that, on its face, each criterion appears reasonable. However, the commenter expressed concern that the rule does not provide guidance on the application and weight given to each factor, which could allow for subjective, contradictory, and discriminate revocation decisions (especially with respect to the last criterion that permits CMS to consider ''any other relevant information provided to CMS.'').

Response: We understand the commenter's concern and note that we will, as deemed necessary, be issuing sub-regulatory guidance that explains in more depth the operational details of the § 424.535(a)(14) determination process. In addition, CMS, rather than its contractors, will make all final determinations. This will ensure greater overall uniformity, as well as a more consistent application of the various factors.

Comment: While supporting much of our proposed addition of § 424.535(a)(14), a commenter expressed concerns regarding several criteria. First, the commenter (referring to proposed § 424.535(a)(14)(i)(A)) stated that there are many reasons why a physician might prescribe a particular drug without a formal diagnosis (for instance, the physician may be unable to conduct a full evaluation due to distance, cultural preference, etc.). Second, the commenter recommended that a statute of limitations be imposed regarding the individual's final adverse action history.

Response: We recognize that there may be instances where a formal diagnosis does not or cannot occur. In applying § 424.535(a)(14)(i)(A), we will consider the reason such a diagnosis did not take place. Regarding the commenter's second concern, we do not favor a statute of limitations for the final adverse action criterion; CMS must be able to retain its flexibility in this regard. Nonetheless, we will take into account when the adverse action occurred when analyzing whether it supports a finding of abusive prescribing.

Comment: A commenter recommended that CMS forgo adopting § 424.535(a)(14) and instead work with the Congress to suspend Coverage and Payment for Questionable Part D Prescriptions, as described in the FY 2015 Department of Health and Human Services performance budget.

Response: We continue to work with the Congress in our efforts to enhance Part D program integrity, and we believe that § 424.535(a)(14) is an important step in this direction.

Comment: With respect to the criterion dealing with state disciplinary actions, a commenter suggested that CMS monitor prescriber licensure statuses and status changes in lieu of state disciplinary actions. The commenter stated that many states do not publish state board disciplinary actions in a standardized format that can be easily used to ascertain a prescriber's practicing privileges.

Response: We recognize that state disciplinary data may not always be available. To the extent that it is, though, we do not believe it should be completely disregarded, even if the action did not result in a licensure suspension or revocation.

Comment: A commenter requested that CMS ensure that innovative abuse-deterrent technologies are employed as a tool in working to curb prescription drug abuse in Medicare. Another commenter recommended that CMS utilize health information technology systems to collect and organize data for measuring performance, supporting clinical decisions, and evaluating quality improvement processes; drug utilization procedures and prescription drug monitoring programs (PDMPs), for instance, could be important tools for improving public health and clinical practice.

Response: We appreciate these suggestions and note that we are considering various technological and system-based means of enhancing our oversight of the Part D program.

Comment: A commenter offered several suggestions. First, CMS should furnish examples in the final rule as to the process of identifying and quantifying a pattern or practice as well as the actual revocation process of Medicare enrollment. Second, CMS should offer additional educational opportunities for suppliers regarding Medicare prescribing practices, which would place physicians and eligible professionals on notice that they must meet Medicare requirements and must prescribe properly.

Response: We agree with the commenter's second recommendation and, as stated earlier, plan to conduct outreach regarding prescribing practices. As for the first suggestion, we are not in a position in this final rule to furnish specific examples of when we would conclude that abusive prescribing exists and a § 424.535(a)(14) revocation is warranted; again, we must retain our flexibility to address a variety of factual scenarios.

The revocation process will be the same as that which currently exists for all other revocation reasons under § 424.535(a), the lone exception being that Part D plan sponsors will be notified of a revocation action under § 424.535(a)(14).

Comment: One commenter recommended that CMS revise the regulation to permit denial of an enrollment application due to prescribing practices that are either abusive and/or represent a threat to the health and safety of Medicare beneficiaries.

Response: We appreciate this suggestion and may consider it as part of a potential future rulemaking effort.

Comment: One commenter recommended that CMS obtain and consider a recommendation from the plan sponsor's medical director as to whether the prescribing pattern falls outside the standard of care and represents a therapeutic use for which safety and efficacy is not otherwise supported by available scientific evidence.

Response: We appreciate this suggestion, but note that CMS staff includes medical personnel who, as stated earlier, may be consulted as needed in potential § 424.535(a)(14) cases.

Comment: A commenter requested that CMS eliminate the criterion dealing with patterns and practices of prescribing without authority and instead utilize processes already in place to validate prescriptive authority

at the point of sale. The commenter also recommended that CMS work with industry stakeholders to develop a streamlined process for capturing data that will be used in CMS' § 424.535(a)(14) determinations.

Response: We disagree with the first comment. The issue is not the technical or logistical means of validating prescriptive authority but whether the unauthorized prescribing of drugs is indicative of abusive prescribing. As for the second comment, we are somewhat unclear as to the commenter's specific request; nevertheless, we will consult with plan sponsors and pharmacy interest groups as needed to ensure that our new provisions are effectively implemented.

Comment: A commenter expressed support for CMS' decision not to define ''abusive'' and ''threat to the health and safety of Medicare beneficiaries'' and to allow CMS the flexibility to address each case on its own merits. However, it urged CMS to review the list of criteria on a periodic basis and consider additions and modifications to reflect advances in clinical best practices and the evolution of abusive prescribing patterns or practices.

Response: We appreciate the commenter's support and intend to regularly review (and, if needed, update via further rulemaking) the criteria in § 424.535(a)(14) to account for changes in the medical field.

Comment: A commenter suggested that in making § 424.535(a)(14) determinations, CMS should: (1) Take into account historical information in the National Practitioner Data Bank (such as past DEA registration suspensions); and (2) consider the relative severity of any state licensure sanctions.

Response: We appreciate this comment. As stated earlier, a physician or eligible professional's final adverse action history (both past and present) will be a criterion for us to consider; the severity of any such actions or sanctions will be taken into account as well.

Comment: A commenter stated that proposed § 424.535(a)(14) may run counter to Medicare regulations that protect patient rights, creating the possibility that systematic limitations on prescribing practices may constitute a violation of patients' rights to pain assessments, palliative care, and the provision of hospice care.

Response: We disagree with the commenter. We do not believe that § 424.535(a)(14) will hinder the ability of Medicare beneficiaries to receive appropriate medications, particularly considering that: (1) § 424.535(a)(14) will only be applied in egregious instances; and (2) the patient's particular needs, circumstances, and setting will be taken into account.

Comment: A commenter stated that there needs to be additional information in the final rule as to how this information would be provided to PBMs and how PBMs should administer it; for example, guidance is needed on how to manage suppliers that are licensed in multiple states but have an action against them in one state but not the other(s).

Response: We will, as deemed necessary, disseminate sub-regulatory or other guidance that addresses the issues the commenter has raised.

Comment: Several commenters believed that § 424.535(a)(14) could be strengthened even further by permitting revocation of enrollment based on prescribing practices that are abusive and/or represent a threat to the health and safety of Medicare beneficiaries, as opposed to requiring that both of these criteria be met. The commenters stated that some prescribing practices might be fraudulent and abusive but not necessarily representative of a threat to the health and safety of Medicare beneficiaries.

Response: We agree, and will revise § 424.535(a)(14) accordingly. Specifically, the language in § 424.535(a)(14)(i) that reads, ''The pattern or practice is abusive and represents a threat to the health and safety of Medicare beneficiaries,'' will be changed to ''The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries or both.'' This will give us further flexibility in addressing cases of abusive prescribing, which in turn will enable us to better protect Medicare beneficiaries and the Trust Funds.

Given these comments and our responses, we are finalizing our addition of § 424.535(a)(14) with the exception noted in the previous paragraph.

We also received a number of comments that, in general, either applied to all of our proposed provisions or were not precisely related to any specific proposal. Our summary of the comments and are responses are as follows.

Comment: Several commenters opposed the use of the CMS–855O on various grounds. First, the CMS–855O does not collect practice location or medical storage information, which the commenter believes is a significant vulnerability and is inconsistent with CMS' existing regulations. Second, use of the CMS–855O is inappropriate because proposed and final regulations (in which the notice-and-comment process is used) regarding its use and implementation were not published in the **Federal Register**. Third, the commenter contended that CMS does not have the statutory or legal basis to use an enrollment application other than for the express purpose of enrolling a provider or supplier; as such, CMS exceeded its legal authority to implement the CMS–855O for the sole purpose of ordering and certifying services and items in the Medicare program. Fourth, the commenter contended that CMS lacks the statutory and regulatory basis to establish a registration process for Medicare. Fifth, the CMS–855O is duplicative of the CMS–855I form, the latter of which was subject to notice-and-comment; also, requiring a physician who is enrolled (via the CMS–855I) solely to order or certify services or items to then complete the CMS–855I if he or she wishes to bill Medicare increases the paperwork burden.

Response: These comments are outside the scope of this final rule.

Comment: A commenter recommended that to improve transparency, CMS should post the name, NPI, and reason for each Medicare enrollment revocation or payment suspension and the duration of the revocation or payment suspension on the Medicare Provider/Supplier Enrollment Web site. The commenter believed that this information would be useful for Medicare Advantage Organizations, Part D sponsors, and the public.

Response: We appreciate this suggestion, and will take it under advisement as we continue our efforts to strengthen the integrity of the Part D program.

Comment: Several commenters recommended that CMS: (1) Explain why it does not believe the inclusion of the practice location on the CMS–855O is essential to identifying the physician or non-physician practitioner; (2) require that all physicians and non-physician practitioners report their practice locations; (3) mandate that only physicians with a defined specialty be permitted to prescribe Part D drugs; (4) remove from the list of physicians and eligible professionals with an approved enrollment record any physician or non-physician practitioner with an undefined or unlisted physician or non-physician specialty code; (5) explain why it did not solicit comments on the use of an electronic signature in the Internet-based versions of the CMS–855O and the CMS–855I; (6) provide the authority to implement and use the CMS–855O beginning in July 2011 and explain why it did not choose to solicit

public comments on changes to regulatory provisions found in §§ 424.502 and 424.505 for almost 3 years after adopting and using the CMS–855O; (7) explain why it is using the CMS–855O rather than the CMS–855I since the CMS–855O, in the commenter's view, essentially duplicates the CMS–855I; (8) modify and use the CMS–855I (rather than continue using the CMS–855O) because CMS cannot verify the practice location of a physician who registers using the CMS–855O; (9) explain why CMS has not proposed to revise § 424.500 to accommodate the registration of physicians and non-physician practitioners for the sole purpose of ordering/certifying services and items in the Medicare program; (10) disenroll all physicians and practitioners enrolled via the CMS–855O and require them to enroll via the CMS–855I; and (11) provide the number of individuals enrolled or registered into the Medicare program using the CMS–855O since July 2011.

Response: These comments are outside the scope of this final rule.

Comment: A commenter suggested that the final rule take action against physicians who report via the Internet that they are board certified when in fact they are not.

Response: We appreciate this suggestion. While we are unable to include such a provision in this final rule because we did not propose it, we will take it under advisement as we continue our efforts to strengthen the integrity of the Part D program.

Comment: A commenter recommended that CMS require physicians and eligible professionals to have an active Medicare enrollment to order Part B drugs.

Response: This comment is outside the scope of this final rule.

Comment: A commenter recommended that CMS not allow physicians and eligible professionals who have opted-out of Medicare to order or certify services and items when they have been suspended or revoked by a state licensing body.

Response: This comment is outside the scope of this final rule.

Comment: A commenter recommended that CMS clarify whether a Part D Medicare beneficiary will need to provide his or her physician's name and NPI to his or her plan sponsor if he or she submits a Part D claim for payment.

Response: We will, as deemed necessary, address this issue via sub-regulatory or other guidance.

Comment: A commenter recommended that CMS exclude physicians and eligible professionals who have opted out of the Medicare program from prescribing Part D covered drugs because CMS does not have the legal authority in either the Social Security Act or existing regulations to revoke the prescribing privileges of a physician or eligible professional who has opted-out of the Medicare program.

Response: As we stated previously, section 1802(b) of the Act is clear that certain physicians and practitioners may opt-out of the Medicare program and enter into private contracts with Medicare beneficiaries. We believe that to require such individuals to enroll in Medicare would be inconsistent with this statutory provision.

Comment: A commenter recommended that CMS explain why the April 14, 2012 and September 11, 2011 **Federal Register** Notices soliciting comments on the CMS–855O state that physicians and practitioners submitting this form are registering rather than enrolling in Medicare, while the April 2013 proposed rule states that they are enrolling in Medicare; the commenter stated that existing regulations do not provide for a registration process.

Response: This comment is outside the scope of this final rule.

Comment: A commenter stated that diagnosis codes should be placed on prescriptions to assess their appropriateness.

Response: This comment is outside the scope of this final rule.

Comment: A commenter: (1) Requested clarification regarding whether a revocation under our proposed provisions would affect a physician or eligible professional's Medicaid enrollment; (2) requested clarification concerning how a State Medicaid agency would differentiate between one's enrollment via the CMS–855I and an enrollment via the CMS–855O; and (3) suggested that CMS provide a complete list of individuals who can only order, certify or prescribe in the Medicare program.

Response: With respect to the first comment, any Medicare revocation results in the termination of the provider or supplier's Medicaid enrollment pursuant to § 455.416(c). The second comment is outside the scope of this final rule. As for the third comment, and as alluded to in both the proposed rule and in this final rule, we plan to make available to Part D sponsors a list of physicians and eligible professionals who have an approved enrollment record or a valid opt-out affidavit on file with an A/B MAC. We do not intend at this time to modify this list (nor to create a separate list) to identify those individuals who are enrolled solely to order, certify, or prescribe in the Medicare program. However, we may consider this as part of a future enhancement.

Comment: A commenter suggested that CMS require private insurers in Part D to report suspected fraud, waste and abuse to Medicare's fraud contractor. Another commenter stated that CMS should: (1) Encourage Part D sponsors to voluntarily report suspected instances of physician and eligible professional misconduct or abusive prescribing, and (2) institute measures to ensure a two-way working dialogue between the sponsors and the MEDIC.

Response: We are working to ensure that Part D plans consistently and regularly refer suspected fraud, waste, and abuse to the MEDIC and that there is appropriate communication between them.

Comment: A commenter requested that steps be taken to ensure that a beneficiary is notified when his or her physician's billing privileges have been revoked, and that an exception be made for emergency or urgent care situations. Similarly, another commenter requested clarification as to whether claims will be processed for emergency and urgent care services furnished by opt-out physicians and, if so, how processors will identify claims in that scenario. One commenter requested that CMS furnish guidance regarding: (1) How Part D prescribers can complete an opt-out affidavit; (2) how opt-out prescribers will be identified in the file; (3) which (if any) edits will apply to opt-out prescribers; (4) how various enrollment statuses (for example, an enrollment application or opt-out affidavit is pending) should be handled; (5) how terminations should be handled and whether changes in enrollment (including suspensions and revocations) will be communicated to plan sponsors at least 30 business days in advance; (6) whether the enrollment/opt-out file will be made available to prescriber data vendors; (7) whether an alert process will be established for reinstated or new enrollments that occur between file deliveries; (8) whether override processes will be developed; (9) whether procedures for notifying beneficiaries of a change in an individual's ability to prescribe Part D drugs will be established; (10) whether a special call center for Part D prescribing issues related to enrollment will be created; and (11) how felony convictions, exclusions, debarments, and State Medicaid program prescriber sanctions should be treated for purposes of claim denials and coding (for instance, whether they should be treated

as Medicare revocations or OIG exclusions for purposes of claim denials and coding).

Response: We will, as deemed necessary, address the aforementioned issues via sub-regulatory or other guidance.

Comment: A commenter recommended that CMS reestablish the systematic deactivation of Medicare billing and prescribing privileges if the physician or non-physician practitioner has not billed the Medicare program in more than a year to ensure consistency with an OIG recommendation to this effect. The commenter also recommended that CMS provide the number of physicians and eligible professionals who have completed the CMS–855I and who have not billed the Medicare program in more than a year as of March 7, 2014, the ending comment date for this proposed rule.

Response: These comments are outside the scope of this final rule.

Comment: A commenter stated that a revocation would be too serious a penalty for a DEA registration suspension or revocation or for improper prescribing.

Response: While we recognize commenter's concern regarding the severity of a revocation action, this action will in some cases be necessary to protect Medicare beneficiaries and the Trust Funds.

Comment: A commenter sought clarification regarding whether CMS would notify the prescriber at least 30 days in advance of a forthcoming revocation.

Response: As already stated, the operational procedures for revoking suppliers under §§ 424.535(a)(13) and (14) will be the same as those which currently exist for other revocations under § 424.535(a), the sole exception being that Part D plans will be notified of the revocation.

Comment: A commenter suggested that CMS centralize all exclusion, opt-out, and other lists in one location (to the maximum extent possible), preferably via a format that Part D plans can download and convert into a file format compatible with data analytics programs. This would enable plans to act more quickly against excluded suppliers. Another commenter urged that CMS update such lists expeditiously so that plan sponsors can take action as needed.

Response: We appreciate the first commenter's suggestion and may consider this as part of a future enhancement. We agree with the second commenter's recommendation and stress that CMS attempts to update its existing lists (and will attempt to update the aforementioned enrolled/opted-out prescriber list) as quickly as possible.

Comment: A commenter requested clarification concerning whether: (1) Plan sponsors are only supposed to deny coverage in the state in which a physician's license is revoked or whether denials should be for all states; and (2) whether CMS will continue to permit a physician with a CMS waiver to continue practicing in rural areas when he or she is the only physician available, even though he or she is revoked.

Response: We believe these comments are outside the scope of this final rule.

Comment: A commenter requested clarification regarding whether a physician who is prohibited from prescribing controlled substances for the treatment of non-cancer related chronic pain or obesity would have their Medicare billing privileges and/or prescribing privileges revoked by the Medicare program.

Response: As stated in § 424.535(a)(13), if the applicable licensing body for any state in which the physician practices suspends or revokes his or her ability to prescribe controlled drugs, we have the discretion to revoke his or her Medicare billing and prescribing privileges. Should we exercise this discretion, the physician would be unable to prescribe covered Part D drugs because he or she would no longer be enrolled in Medicare.

Comment: A commenter recommended that CMS explain the process it uses to identify medical licenses that are surrendered while a formal disciplinary proceeding was pending before a state licensing authority.

Response: This comment is outside the scope of this final rule.

Comment: A commenter encouraged CMS to consider participation in the Council for Affordable Quality Healthcare (CAQH) universal credentialing application process used by many private sector healthcare systems. Having one ''portal'' for physicians to become credentialed for both Medicare and private sector health plans, the commenter believed, would reduce the administrative burden for physicians.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: One commenter, while expressing support for §§ 424.530(a)(11) and 424.535(a)(13) and (14), requested that CMS delay its implementation until CMS (1) has fully field-tested the Medicare enrollment and reporting program, and (2) demonstrates that the program will operate at a high level of accuracy, with frequent updates, and with consistently reliable linkages to and from other federal and state databases. Another commenter recommended that the criterion in § 424.535(a)(14) regarding diagnosis codes be delayed until the effects of the ICD–10 transition are reviewed.

Response: While we appreciate the first commenter's support, we do not believe that the implementation of these provisions (including the criteria in (a)(14)) should be delayed. As explained earlier, CMS must take steps to ensure the integrity of the Part D program and to protect both Part D beneficiaries and the Trust Funds.

We are neither finalizing nor proposing any regulatory changes as a result of these miscellaneous comments.

22. Broadening the Release of Part D Data (§ 423.505)

We proposed to revise our regulations governing the release of Part D data to expand the release of unencrypted prescriber, pharmacy, and plan identifiers contained in prescription drug event (PDE) records, as well as to make other changes to our policies regarding release of Part D PDE data. For background, in the May 28, 2008 **Federal Register** (76 FR 30664), we published a final rule entitled, ''Medicare Program; Medicare Part D Claims Data,'' (hereinafter referred to as the ''Part D data final rule'') to implement regulations that govern the collection of PDE data under the authority of section 1860D–12(b)(3)(D) of the Act and the disclosure of this data in accordance with section 1106 of the Act. The provisions governing the collection and disclosure of PDE data are codified at § 423.505(b)(8), (f)(3), (1) and (m). The Part D data final rule governed the collection and disclosure of the original 37 elements of PDE data, but was updated to apply to any additional elements that were added to the PDE record. This update was in a final rule issued in April 2010 (75 FR 19678) entitled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (hereinafter referred to as the ''April 2010 final rule'').

In the preamble to the Part D data final rule (73 FR 30671), we stated, ''we [ ] believe that it is in the interest of public health to share the information collected under [the authority of 1860D–12(b)(3)(D)] with entities outside of CMS.'' We explained that the release of PDE data assists CMS in evaluating the Medicare Part D program and assessing related policies. We further stated such release was in the interest of public

health and would improve the clinical care of beneficiaries.

In addition to setting forth the significant public policy reasons for disclosure of PDE data, we made clear in the preambles of both the Part D data final rule and the April 2010 rule that our primary concerns in releasing PDE data are protecting the confidentiality of beneficiary identifiable information and commercially sensitive data of Part D sponsors. Therefore, as described in the Part D data final rule and the April 2010 rule, the release of PDE data is subject to certain protections, described here generally, such as encryption of beneficiary information and aggregation of commercially sensitive data of Part D sponsors. In addition, whenever PDE data is released, we only release the minimum data necessary for a given purpose, as determined in the sole discretion of CMS after review of the requestor's detailed request for data. If releasing data to an external entity for research purposes, CMS indicated in the Part D data final rule that the requestor must be a legitimate researcher, meaning the requestor has the requisite experience and is working for, or on behalf of, a reputable institution. (In the preamble to the Part D data final rule (73 FR 30674 citing 45 CFR 164.501), we used the definition of ''research'' contained in the HIPAA Privacy Rule, which defines the term as ''a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.'') In the Part D data final rule (73 FR 30674), we also indicated that, consistent with our current policies for Part A and B data, identifiable Part D data would not be disclosed for commercial purposes.

In the preamble to the proposed rule, we stated that we believe the current limitations on the release of certain data elements hinder the use of PDE data in a health care environment that is substantially transforming due to the Affordable Care Act, and that these limitations therefore also inhibit accompanying insights into prescription drug benefit plans that could result from broader release of the data. We further stated that our experience has led us to conclude that broader release of PDE data to external entities can increase the positive contributions researchers make to the evaluation and function of the Part D program and improve the efficiency of the program and the clinical care of its beneficiaries, which is in the interest of public health. For these reasons, we stated that increased access to prescriber, pharmacy, and plan identifiers by all categories of requestors is of utmost importance and will facilitate research by entities outside CMS that involves identifiable plans, prescribers, and pharmacies. Furthermore, we stated that we could relax the current policies on the release of this PDE data, while still protecting beneficiary confidentiality and commercially sensitive data of Part D sponsors.

Specifically, we proposed to permit the release of unencrypted prescriber, pharmacy, and plan identifiers (including internal plan/pharmacy identification numbers on the claim that represent reference numbers assigned by the plan at the time a drug is dispensed) contained in PDE records to all current categories of requestors (including other HHS entities and the Congressional oversight agencies, non-HHS executive branch agencies and states, and external entities). We noted that because the minimum necessary policy will still apply to all such releases, our proposal was more a formality with respect to HHS entities/Congressional oversight agencies and non-HHS executive branch agencies/states, since this data is available in unencrypted format to these same entities under the current Part D data regulations ''if needed.'' For this reason, in the proposed rule, we focused on the release of unencrypted prescriber, pharmacy, and plan identifiers to external entities as discussed later in this section.

We acknowledged in the preamble to the proposed rule that there still may be concerns about releasing unencrypted prescriber, plan, and pharmacy identifiers to outside entities based on comments that were received in response to our original proposed Part D data regulations, and that were discussed in the Part D data final rule (73 FR 30675). In particular, we addressed concerns that this information could be used by pharmaceutical companies and others who may want to influence physicians' prescribing patterns and interfere with their professional judgment. As we stated in the proposed rule, it is our view today, however, that the vast majority of physicians have prescribed and do prescribe what they believe are the appropriate medications for their patients, and they should have no concerns with transparency in their prescribing patterns. Moreover, we stated that there are other measures in place to prevent inappropriate influence by external entities on prescribers, such as section 6002 of Affordable Care Act and the federal Anti-Kickback Law (section 1128B(b) of the Act). We also pointed out that when data are completely transparent, it is easier for the attempts of some to use the data for purposes of inappropriate manipulation to be countered by others who have access to the same data. We also noted that it appears prescriber data are already available commercially from pharmacy data aggregators. For these reasons, we stated that we believe that our earlier concerns expressed in the Part D data final rule about the release of unencrypted prescriber identifiers in PDE data to external entities are no longer warranted.

In the proposed rule, in conjunction with our proposal to broaden the release of unencrypted prescriber identifiers, we also highlighted our response to a comment discussed in the Part D data final rule, which argued that providing access to linked physician identifiable claims in order to pool them with employer data would allow analysis to reduce cost of care delivery and improve the quality of care (73 FR 30676). We noted that in response to the comment, we did not disagree with the commenter, but referenced a variety of pay for performance and value-based health care initiatives being undertaken by CMS at the time in an effort to encourage health care providers to furnish high quality health care and to provide cost and quality information to consumers. We also noted that in our response to the comment, we had stated that we intended to use PDE data in those activities, but we declined to adopt a policy that would include making unencrypted prescriber identifiers available for release to external entities (except when needed to link to another data set). In this proposed rule, however, we acknowledged that, in light of the goals of the Affordable Care Act to improve the quality of health care, including through better access to information, we now agree with the commenter regarding the importance of providing access to prescriber-identifiable claims in order to allow researchers to pool them with employer data and conduct broader research.

We noted in the proposed rule that our current policy on release of ingredient cost and dispensing fee data would not change under our proposal, meaning the minimum necessary data regarding ingredient costs and dispensing fees would continue to be available for release in disaggregated form only to other HHS entities and congressional oversight agencies. Non-HHS executive branch agencies and external entities could still only obtain the minimum necessary ingredient cost and dispensing fee data, and only in aggregated form.

With respect to our proposal to broaden the release of unencrypted plan

identifiers, we also explained in the proposed rule that an analysis of Part D plans, their network pharmacies, and average drug costs, can already be accomplished through data posted on CMS' Web site and/or purchased in public use files. Additionally, the Medicare Prescription Drug Plan Finder (''MPDPF'') allows users to view and compare all available prescription drug plan choices, including plan and pharmacy specific estimates of the costs of individual drugs. These data can be manipulated by researchers to reveal information about specific plans and pharmacies that contribute to the evaluation and functioning of the Part D program and can be used to improve the public health. Therefore, in light of the fact that plan data is already publicly available and the public policy rationale for increasing access to PDE data by all categories of requestors, we stated that plan identifiers should be available in an unencrypted format.

For the same reasons that we proposed to make prescriber and plan identifiers available for release in an unencrypted format, we explained in the proposed rule that we no longer see a reason that pharmacy identifiers should not be available for release in an unencrypted format. Accordingly, we also proposed to release unencrypted pharmacy identifiers to all categories of requestors.

We addressed one final aspect of our policies governing the release of Part D data in the proposed rule. As discussed previously, in the preamble to the Part D data final rule (73 FR 30664), we explained that consistent with CMS's existing policies with respect to Parts A and B data, CMS would not release PDE data for commercial purposes (but external researchers may be funded by commercial firms if the researchers are free to publish their results regardless of the findings). However, for the same reasons that we proposed to make changes to our rules governing the release of PDE data, we also solicited comment on the current restriction on the release of PDE data for commercial purposes. We noted that we were not making a specific proposal in this regard, but rather, that we wished to receive comments on this issue for consideration.

In addition to the proposed changes with respect to prescriber, pharmacy, and plan identifiers described previously, and our request for comment on the restriction on the release of Part D PDE data for commercial purposes, we proposed a few other changes to our regulations governing the submission, use, and release of PDE data, including some changes intended to clarify our existing policies with respect to several issues related to PDE data. First, we proposed to add supporting program integrity purposes, including coordination with states, as an additional purpose deemed necessary and appropriate by the Secretary for which a Part D sponsor must agree to submit all data elements included in all its drug claims under section 1860D–12(b)(3)(D) of the Act. The regulation at § 423.505(f)(3) currently contains a non-exclusive list of purposes deemed necessary and appropriate. Thus, we indicated that we believe the use of these data for supporting program integrity purposes has always been included, even though not explicitly listed. However, given the importance of our ability to release PDE data for program integrity purposes, including for coordination with states on program integrity, we proposed to add this purpose explicitly to the non-exclusive list in § 423.505(f)(3).

Second, we proposed to clarify that non-final action data (for example, information on claims subject to subsequent adjustment) are available to entities outside of CMS. We explained that non-final action data are captured through the data element, ''Original versus Adjusted PDE (Adjustment/Deletion code).'' We further explained that this is a PDE field which distinguishes original from adjusted or deleted PDE records, which allows sponsors to make adjustments to the original PDE record to ensure accurate payment. The information included in these revised PDE records is thus not point-of-sale data. With the increasing focus on coordination of care, we noted that requests for access to non-final action PDE data have understandably also increased, and that non-final action data are also routinely requested for evaluation and research projects. We noted that the Part D data final rule (73 FR 30683) included an appendix that explained in more specific detail the restrictions relative to the available PDE elements for the different categories of requestors. Specifically, we noted that this appendix stated (73 FR 30685) that the data element ''Original versus Adjusted PDE (Adjustment/Deletion code)'' was available to other (that is, non-CMS) HHS entities and the congressional oversight agencies, while for non-HHS executive branch agencies, states, and external entities, it stated that ''Final Action claims would be provided, so this element should not be needed.'' Thus, we noted that this appendix did not explicitly address the question of whether non-final action data would be available for release to non-HHS executive branch agencies, states, and external entities, because such data were not expected to be needed by these requestors. However, since it is clear that these entities do need access to non-final data, we proposed to clarify that non-final action data are also available for release to non-HHS executive branch agencies, states, and external entities under the Part D data final rule.

Due to our proposals to make changes to our policies governing the release of PDE data described previously, we proposed to make corresponding changes to the current applicable regulatory text. In addition, we also proposed to eliminate the appendix that accompanied the Part D data final rule (73 FR 30683) that explained in more specific detail which PDE elements would be available to different categories of requestors, and any restrictions that applied. We stated that we believed this appendix is no longer necessary, as our proposed changes in policy would eliminate most of the distinctions with respect to the PDE data available for release to the different categories of requesters, with the exception of Total Drug Costs, which will continue to be available in disaggregated form only to other (that is, non-CMS) HHS entities and the congressional oversight agencies, and we proposed to revise the regulation at § 423.505(m)(1)(iii)(B) to account for this distinction. We also proposed to revise this provision to clarify that we will continue to exclude sales tax from the aggregation, if necessary for the project. Finally, we proposed changes to the regulatory text to incorporate notes from the current Appendix that are not addressed by the existing reference to CMS data sharing procedures in § 423.505(m)(1)(ii).

We received the following comments on our proposed revisions to the regulations governing the release of Part D data:

Comment: We received a number of comments regarding these proposed revisions, many of which strongly supported our proposed revisions to the Part D data regulations. Several commenters commended CMS' ongoing work to improve the efficiency of the Medicare program and the clinical care of its beneficiaries, which these commenters asserted will be better facilitated through increased data transparency that facilitates additional research. These commenters stated that releasing unencrypted physician, plan, and pharmacy identifiers in Part D PDE data under the parameters we proposed will allow researchers to answer a broader range of questions about the

program. These commenters further stated that greater access to Part D PDE data will help ensure that this data is used to maximum effect in the creation of knowledge and understanding about the program and around clinical care received by beneficiaries. Commenters additionally noted that the increased availability of PDE data will enable researchers to conduct in-depth comparisons of medications provided through different outlets, which could enable CMS to take proactive measures to achieve cost savings. One commenter also stated that the public has a significant interest in provider, plan, and pharmacy professional conduct, as these entities are government licensed and regulated, and Medicare payments are publicly funded. Finally, these commenters noted that our existing ''minimum necessary'', ''legitimate researcher'', and ''aggregation'' policies are sufficient to provide some common sense parameters for release of unencrypted identifiers.

Potential areas of research suggested by the commenters were linking information on Part D plan features (such as premiums, cost-sharing, and formularies) to health outcomes and the quality of health care provided to Medicare beneficiaries. Other commenters asserted that broader access to prescriber, plan, and pharmacy identifiers in PDE data will facilitate research in particular for conditions for which there are very few viable treatments, no available cure, and much more work to be done with respect to researching and developing safe and effective medicines. These commenters welcomed the availability of additional information to spur further knowledge, investigation, and progress on how to best treat—and ensure appropriate coverage for treating—complex health conditions.

Response: We thank these commenters for their comments in support of our proposed changes.

Comment: Other commenters opposed our proposed revisions to the policies governing the release of Part D data. These commenters asserted that the existing framework for release of Part D PDE data fully accommodates the needs of government entities and legitimate researchers, and strikes the appropriate balance between these needs and the legitimate concerns of health care providers and Part D plan sponsors regarding the widespread dissemination of sensitive data, including data that specifically identifies them. One commenter stated that CMS had not articulated a reason for the need to identify specific plans, pharmacies, and prescribers, and that necessary research can be accomplished with encrypted identifiers. One commenter requested a clarification on the meaning of ''new health care environment.'' Some commenters asserted that prescriber, plan, and pharmacy identifiers in PDE data are commercially sensitive information, and that release of these identifiers would undermine competition and may lead to higher costs in the Part D program and less choice. A few of these commenters asserted similarly that prescription drug benefit plans could potentially reverse engineer competitively sensitive data regarding other plans, which could have an anti-competitive effect on the Part D bidding process.

Response: We think the preamble to the proposed rule provided a clear description of the ways in which the Affordable Care Act is transforming the health care system in this country—by spearheading the drive toward an information- and value-based system, and the compelling reasons for the release of unencrypted prescriber, plan, and pharmacy identifiers in Part D PDE data to allow for additional research to achieve this goal. Specifically, it is in the interest of public health to share this information with entities outside of CMS, as the work of these entities will assist CMS in evaluating the Medicare Part D program and assessing related policies to improve the clinical care of beneficiaries. We also note that when more data is released about the Medicare Part D program, the potential research topics expand as well. For instance, commenters supportive of the proposed expansion in the release of Part D data offered examples of potential areas of new research, such as linking information on Part D plan features (such as premiums, cost-sharing, and formularies) to health outcomes and the quality of health care provided to Medicare beneficiaries. Such research is not possible with encrypted plan identifiers, because the researchers would not know the specific features of the unidentified plans.

In addition, we are not persuaded that these identifiers are commercially sensitive data. As we stated in the preamble to the proposed rule (79 FR 1990), an analysis of Part D plans, their network pharmacies, and average drug costs, can already be accomplished through data posted on CMS' Web site and/or purchased in public use files. Additionally, the MPDPF allows users to view and compare all available prescription drug plan choices, including plan and pharmacy specific estimates of the costs of individual drugs. Moreover, we noted that it appears that prescriber data are already available commercially from pharmacy data aggregators. These data can currently be manipulated by researchers to reveal information about specific plans, pharmacies and prescribers. For these reasons, we have concluded that prescriber, plan and pharmacy identifiers are not commercially sensitive information, and that it is appropriate to share this information in an unencrypted format when it is needed for a particular study or project.

Comment: Some commenters supported our assertion in the proposed rule that release of unencrypted identifiers in Medicare Part D PDE data subject to our current data release policies, including our minimum necessary and legitimate research policies, will not result in data recipients using the data inappropriately, such as to influence physicians' prescribing patterns or interfere with physicians' professional judgment. These commenters stated that physicians are trained to use their best medical judgment in making prescription decisions for their patients.

Other commenters disagreed, asserting that the release of unencrypted identifiers has the potential, for instance, to influence prescribing patterns and physician judgment, or otherwise to be used to draw incorrect or inaccurate conclusions that could be damaging to the reputations of professionals and health care organizations. These commenters asserted that inappropriate influence may adversely affect the quality of care for beneficiaries. One commenter stated that the Affordable Care Act's additional reporting requirements with respect to physician prescribing do not address this type of influence, and that CMS has assumed that release of this data will not adversely affect beneficiaries, rather than carefully considering the impact of release. Another commenter stated that data and statistics are valuable in observing trends among patient populations, but that they are a blunt instrument when applied to individuals. One commenter opposed the indiscriminate release of data to any requesting external entity, including to data aggregators that have little knowledge of the Medicare Part D program. A few commenters encouraged CMS to present the data in a way that considers the quality of the services provided, including an explanation of the data limitations, and allows for the opportunity to correct information, for instance, to include patient non-compliance in the case of release of prescriber identifiers. Finally, these commenters stated that disputing inaccurate findings takes significant

time, effort, and expense, and even then, it is often impossible to fully mitigate the harm caused.

Response: While we are sensitive to the concerns regarding undue influence raised by the commenters, for the reasons discussed in the proposed rule, we agree with those commenters that did not believe releasing these data would result in improper influence on physician prescribing patterns or otherwise interfere with the exercise of professional judgment. In addition, we believe CMS' current release policies will also limit inappropriate use of the data. In order for a researcher to gain access to CMS data, the researcher must submit a research protocol and receive approval of the protocol from CMS. In addition, all requestors are required to sign a Data Use Agreement with the agency that limits the use of the data to only the approved purposes. The agency carefully considers all data requests to ensure that the use of the data will not exploit or negatively impact Medicare beneficiaries. Furthermore, we do not believe the professional research community would support the dissemination of faulty analyses and would be quick to offer criticisms of poor research, should this happen despite our careful evaluation of all data requests. We also disagree that data and statistics are only valuable in observing trends among patient populations. As we lead the effort to provide high quality care and better health at lower costs, data analysis at various levels of specificity is crucial. For example, analyses at the provider or supplier level, when properly adjusted to account for differences in patient populations, could provide insight into differences in the way a given condition is treated and help develop best practices. In addition, unencrypted prescriber identifiers have valuable uses beyond reporting on individual physician prescribing patterns. For example, unencrypted identifiers in Part D data can be linked to other sources of data, such as claims data from other payers, electronic health records, and clinical data such as lab results, in order to facilitate broader and more complex research projects.

Additionally, we were not persuaded that CMS should release data in a way that considers the quality of the services provided, includes an explanation of the data limitations, or allows for the opportunity to correct information. This is precisely what professional researchers do, and as we previously noted, we think the professional research community would be quick to offer criticisms of poor research, should a project fail to address these issues appropriately. Moreover, if CMS were to analyze data before its release for research, this practice would undermine the independent nature of the analyses performed by outside researchers.

Comment: Some commenters specifically supported the release of non-final action PDE records, asserting such data would permit researchers to explore data for a better understanding of the Medicare Part D program. The comments included a specific example of how non-final action data can assist researchers in exploring prescription adherence and abandonment by tracking and accounting for adjusted or deleted prescriptions. In contrast, other commenters specifically opposed the release of non-final data, asserting that this information can easily be misinterpreted and may cause false conclusions that impact providers. One commenter opposed our proposed clarification regarding release of non-final action data stating that CMS had failed to articulate a reason for releasing non-final action data other than that it had received requests for it.

Response: We disagree with the commenter that asserted that CMS failed to articulate a reason for releasing non-final action data. We think we did articulate a reason for releasing non-final action data. It is the same as the overarching reason to release Part D PDE data, which we discussed at length in the proposed rule. Specifically, it is in the interest of public health to share this information with entities outside of CMS, as research conducted by these entities may assist CMS in evaluating the Medicare Part D program and assessing related policies to improve the clinical care of beneficiaries. In addition, as we stated in the preamble to the proposed rule, the release of non-final action data is necessary due to the increased focus on coordination of care in the Medicare program and indeed in the health care system as a whole.

Comment: One commenter opposed the proposal to allow release of unencrypted prescriber and pharmacy identifiers stating that the current release policies already allow external entities to link unencrypted identifier elements to another data set.

Response: We disagree. Under our current regulations, the identifiers must be re-encrypted after the link has been made. Under the regulations as finalized, once linked, research at higher levels of specificity can be conducted that is not possible with encrypted identifiers. For instance, a researcher conducting a study on medication adherence will have many more factors to consider and explore when the prescribers, plans, and pharmacies involved in the research are identifiable. Is adherence related to plan features? Physician location and/or specialty? Pharmacy organization filling the prescription? All three? The research possibilities will expand, as the additional connections that can be explored by researchers expand. Drilling down to higher and higher levels of specificity to understand and potentially solve a problem is the very nature of 21st century data-driven research, and we believe it is essential that the Part D data release policies keep current.

Comment: One commenter opposed our proposal to release unencrypted plan identifiers, asserting that plan information is gathered only for Part D administration purposes.

Response: We disagree. Section 423.505(f)(3) of the regulations states that a plan sponsor agrees to submit to the Secretary all data elements for purposes deemed necessary and appropriate by the Secretary, including, but not limited to conducting evaluations of the overall Medicare program. As we noted previously, commenters offered examples of potential areas of research that will be enabled through access to unencrypted plan identifiers, such as linking information on Part D plan features (including premiums, cost-sharing, and formularies) to health outcomes and the quality of health care provided to Medicare beneficiaries.

Comment: One commenter stated that CMS should more specifically define ''legitimate researcher'' to ensure that Part D data is not released for competitive or commercial purposes contrary to CMS' current policy.

Response: Under current CMS data sharing policies, the agency evaluates all research requests to ensure that the researcher has the expertise to conduct the proposed study. In addition, we must approve the research protocol before any data is shared with a researcher. We believe that this review process contains appropriate safeguards to prevent inappropriate use of the data and, as such, we do not believe it is necessary to define a ''legitimate researcher.'' Furthermore, we believe a variety of different types of individuals could submit a valid research request.

Comment: Some commenters supported our proposal to broaden the release of Part D data, so long as beneficiary privacy is protected. One commenter suggested that a bio-statistician conduct an expert review of the data sets to be released in the context of the permitted use(s) to ensure beneficiary privacy in the context of the permitted uses of the data. Another

commenter stated that our proposed expansion of the available data will compromise beneficiary privacy and requested that an approval process similar to an IRB be established to evaluate requests for such information to weigh the risks and benefits of disclosure. Another commenter stated that CMS should ensure that its efforts to protect beneficiary confidentiality do not create such onerous data request processes that qualified researchers are discouraged from attempting to access Part D data. Another commenter stated that CMS should establish and impose appropriate penalties for any breach of privacy related to beneficiary identifiable information.

Response: All users accessing beneficiary identifiable data are required to sign CMS' Data Use Agreement (DUA), which addresses privacy and security for the data CMS discloses. In addition, the DUA currently does, and will continue to have, enforcement mechanisms, including criminal penalties. CMS would make use of these provisions in the event of any breach or violation of the terms of the DUA. The DUA also contains provisions regarding access to and storage of CMS data to ensure that beneficiary identifiable information is stored in a secure system. We believe these restrictions are necessary in order to ensure that data is only requested in compliance with the requirements of the regulations and CMS data sharing procedures, and that data shared by CMS is appropriately protected and is not reused or redisclosed without the necessary approval. Given that researchers have successfully been accessing to CMS data under the terms of this DUA for years, we do not believe these requirements are too burdensome. With regard to the suggestion that CMS have a bio-statistician review the data sets to be released to ensure beneficiary privacy, we do not believe this is necessary given the beneficiary privacy protections in the DUA. However, to the extent that CMS releases any de-identified, summarized data sets based on the Part D data, the agency carefully reviews the proposed release to ensure that it does not put beneficiary privacy at risk. Finally, we disagree that the expansion of the available data will compromise beneficiary privacy or that additional procedures are necessary in order to safeguard beneficiary privacy. CMS has an established process to evaluate requests for data to ensure that there are appropriate safeguards in place to protect beneficiary privacy. We believe this process contains the necessary checks to ensure that the risks of the disclosure are minimal.

Comment: One commenter stated that CMS should be as transparent as possible under its data use agreements, asserting that the public, as well as the parties involved, must be able to readily determine the manner in which data are released, the purpose for the release of the data and the parties to whom the data are released.

Response: We are strongly committed to transparency. In particular, we have established processes to ensure that beneficiaries can request information about to whom their protected health information or personally identifiable information has been disclosed, as well as the purpose for the release of the data. Beneficiaries interested in requesting access to this information should contact the CMS Freedom of Information Act (FOIA) Office (*http://www.cms.gov/center/freedom-of-information-act-center.html*).

Comment: One commenter stated that CMS should consider whether a proliferation of analyses of outdated Part D data will truly benefit the Part D program, when CMS has the ability to commission studies and data analysis that would more knowledgeably take into account a comprehensive understanding of the continually changing dynamics of the Part D prescription drug market.

Response: We use Part D data to conduct a variety of studies and analyses. However, this work does not even begin to cover the scope of possible analyses that could be performed using Part D data. We believe that by limiting Part D data analysis to that supported by CMS, the agency would be inhibiting important research and innovation that has the potential to result in higher quality care at lower costs in the Medicare Part D program, and indeed for all Americans.

After review of the comments we received, we are finalizing our proposed changes to the regulations governing the release of Part D data. Specifically, we are finalizing the following revisions to the applicable regulatory text:

- Section 423.505(f)(3) is revised to add supporting program integrity purposes, including coordination with states, as an additional purpose.
- Section 423.505(m)(1)(iii) is revised to remove references to encrypting certain identifiers since prescriber, plan, and pharmacy identifiers are no longer be subject to encryption when released.
- Section 423.505(m)(1)(iii)(A) is revised to clarify that, subject to the restrictions contained in paragraph (m)(1), all elements on the claim are available not only to HHS, but also to other executive branch agencies and states, since there is no longer any distinction between the two categories.
- Section 423.505(m)(1)(iii)(B) is revised to incorporate a note from the appendix that is being eliminated, which states: ''Upon request, CMS excludes sales tax from the aggregation at the individual level, if necessary for the project'' at the end of the provision.
- Section 423.505(m)(1)(iii)(C) is deleted as no longer necessary since unencrypted plan identifiers, including the internal plan/pharmacy identification numbers, are available for release.
- Section 423.505(m)(1)(iii)(D) is re-lettered as (C) and references to encryption of pharmacy and prescriber identifiers are deleted, since these identifiers are available for release in unencrypted format. Additional language regarding beneficiary identifiers is added to reflect the current policy on release of this identifier. In addition, we are including the statement, ''Public disclosure of research results will not include beneficiary identifying information,'' at § 423.505(m)(1)(iii)(C)(2), which also reflects current policy as described in the appendix that is being eliminated.
- Section 423.505(m)(3) re-lettered as (m)(3)(i) and (m)(3)(ii) is added to incorporate a note from the appendix that is being eliminated about the status of the Congressional Research Service as an external entity when it is not acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1).

With respect to our policy not to release Part D data for commercial purposes, we did not make a specific proposal but solicited comments for general consideration. We received comments on both sides of this topic, and thank all the commenters. The following is a summary of the comments:

Comment: Commenters that desire a change in the policy applauded CMS for soliciting comment on this topic. These commenters stated that in order to improve and modernize the U.S. health care system, greater alignment of stakeholder incentives is required, and that CMS is keenly aware of this pivotal requirement for success. These commenters stated that the challenge of quantifying greater efficiency and evidence of improvement as part of overall health reform requires more access to the unique data sets in federal data, and that the current restriction on the use of these data for commercial purposes will grow increasingly challenging in the future as Medicare employs more value-based payment incentives, and as Medicare data are

included in broader multi-payer sets, such as those being established by the Patient-Centered Outcomes Research Institute. These commenters further stated that because the quality and efficiency of all physician groups, health plans, hospital systems, and other providers and suppliers can be enhanced using data, any notion that commercial interest is limited and discrete is outdated. They stated that PDE data is a valuable asset to all types of commercial health care entities in limiting the incidence of fraud, obtaining practice pattern feedback, managing health care delivery to deliver value, developing best practice standards, and conducting comparative effectiveness research.

The commenters also stated that eliminating or reducing this current restriction on the release of data for commercial purposes is consistent with CMS' desire to foster transparency and competition in the Part D program during a period of sweeping change to the health care system. These commenters asserted, for example, that suppliers need to incorporate accurate data into their product pricing and discounting strategies to align their approaches with the system-wide drive toward value-based decision-making and high quality care.

Commenters additionally stated that the more access there is to Medicare data, the more dramatically the bandwidth for research will be increased, leading to increased quality of care, system efficiency, and consumer satisfaction in the Medicare programs and health care system in general. These commenters noted that there is deep scientific and analytic expertise within organizations that are currently excluded from accessing CMS data. These commenters asserted that the standard for data release by CMS should be whether the research proposed is of high quality and whether it has the potential to improve program administration or the health of the covered population, rather than financial benefit and profit status of the organization proposing the research. These commenters further noted that CMS has in place strong research merit criteria, rules, and obligations for data use and individual privacy protections, and that these processes and this oversight are sufficient to determine whether a requestor should have access to PDE or other identifiable data, regardless of the researcher's affiliation.

Some commenters stated that broader release of Part D data would not only further public health research and analysis of the Part D program, but also would serve to further educate consumer organizations, patient advocates, and ultimately beneficiaries about the program generally, as well as coverage and prescribing patterns under various plans.

Some commenters stated that they would support changing the policy on non-release of Part D data for commercial purposes, so long as CMS ensured that release of the data would be conditioned on its use for improvement of one or more aspects of the Part D program, and CMS carefully screened potential recipients of the data for demonstrated expertise in using research data to improve health programs, as well as for any potential conflicts of interest or other concerns.

Commenters that believe that the policy of non-release for commercial purposes should remain unchanged stated that health care entities have legitimate concerns regarding the widespread dissemination of sensitive data, such as data that specifically identifies them. These commenters also stated that strong program oversight and public health and public policy imperatives do not exist to counterbalance these concerns.

One commenter stated that CMS lacks the authority to release Part D data for commercial purposes, because the authority cited by CMS limits releases to those required for program purposes and for improving public health. The same commenter asserted that the right to make data available for purely commercial reasons is a right inherent in the ownership of the data, and that CMS has never previously asserted an ownership over, or right to control the use of, data not obtained through access to a CMS system. This commenter stated that by granting itself this right to release Part D PDE data for purely commercial purposes, CMS would be exercising a right inherent in ownership of the data.

In light of all the comments received on both sides of this particular topic, we continue to believe that the best approach is for our policy regarding the release of Part D data for commercial purposes to remain consistent with the policies for the release of data from Medicare Parts A and B. As we discussed, in the Part D data final rule (73 FR 30672), the procedures that we use to make Part D data available are built upon the practice that was already in place with respect to the release of Part A and B data. Furthermore, absent specific reasons for treating the data differently, we believe it is appropriate to have consistent policies for the release of data across Medicare Parts A, B, and D. Therefore, although we are not changing our policy against releasing Part D data for commercial purposes at this time, we note that in the event the policy regarding the release of Parts A and B data for commercial purposes were to change, we would also revise our Part D data sharing policies to be consistent with that change.

23. Establish Authority To Directly Request Information From First Tier, Downstream, and Related Entities (§§ 422.504(i)(2)(i), and 423.505(i)(2)(i))

Under section 1857(d)(2) and 1860D–12(b)(3)(c) of the Act, existing regulations at §§ 422.504(i) and 423.505(i) establish various conditions that entities contracting as a first tier, downstream, or related entity (FDR) to an MA organization or Part D sponsor must agree to in order to participate in the MA or Part D program. One such condition at §§ 422.504(i)(2)(i) and 423.505(i)(2)(i) is that HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related (FDR) entities related to CMS' contract with the Part C and D sponsor.

CMS (or its designee(s)) conduct routine audits of Part D sponsors and MA organizations, as well as conduct audits to investigate allegations of noncompliance with Part C and/or Part D rules and requirements. While §§ 422.504(d) and 423.505(d) address Part D and MA organizations' own maintenance of records and the rights of CMS to inspect those records, §§ 422.504(i)(2)(i) and 423.505(i)(2)(i) also require plan sponsors to require their FDRs to agree to a CMS right to inspection. Plan sponsors regularly contract with FDRs to perform critical Part C and D operating functions. For example, many (if not most) Part D sponsors delegate critical Part D functions to their PBMs. As a result, many of the records that we or our designees would need to review and evaluate when we audit a Part D sponsor or MA organization reside with its FDRs.

Our existing regulation at § 423.505 (i)(3)(iv) states that the contracts between the Part D sponsor and its FDRs must indicate whether records held by the FDR pertaining to the Part D contract will be provided to the sponsor to provide to CMS (upon request), or will be provided directly to CMS or its designees by the FDR (the Part C regulation is silent on this matter). As such, we have not previously required Part C or Part D FDRs to provide information directly to CMS.

Two separate reports by the OIG (OEI–03–08–00420, dated October 2009 and OEI 03–11–00310, dated January 2013), have highlighted barriers experienced by the Medicare Drug Integrity Contractor (MEDIC), the entity contracted by CMS to be responsible for detecting and preventing fraud, waste, and abuse in the Medicare Parts C and D programs nationwide, in obtaining requested information in an expeditious manner. The 2009 OIG report discussed that CMS' and its designees' (in this case, the MEDIC) lack of authority to directly obtain information from pharmacies, PBMs, and physicians has hindered the MEDIC's ability to investigate potential fraud and abuse and the OIG recommended that CMS change its regulations to establish its authority to obtain necessary information directly from FDRs. The OIG's 2013 report reiterated the recommendation that CMS have a more direct route to obtain records held by FDRs so that CMS would be able to obtain necessary records in a timely fashion. While the 2013 report pointed out that sponsors and their FDRs generally cooperate in providing the information requested by the MEDIC, it often takes months for it to reach the MEDIC because the MA organization or Part D sponsor acts as a gatekeeper.

In the past, we chose not to be prescriptive regarding whether a first tier, downstream, or related entity must make its books and records available to us directly or through the Part C or D sponsor. As a consequence of what we have learned through the OIG investigations and the seriousness with which we approach our fraud, waste, and abuse oversight obligations, we proposed to specify at §§ 422.504(i)(2)(ii) and 423.505(i)(2)(ii) that HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records by obtaining them directly from any first tier, downstream, or related entity.

We further proposed to revise the regulation at §§ 422.504(i)(2)(i) and 423.505(i)(2)(i) to make clear that CMS and its designees may ''collect'' records, in addition to our existing authority to ''audit, evaluate, and inspect'' information. The addition of ''collect'' removes any doubt that, in addition to our other options for obtaining records, we have the authority to request information to be reviewed in some location other than onsite at a sponsor's or FDR's facility. Furthermore, this proposed provision is intended to clarify only that CMS may contact FDRs directly and request that they provide Part C or D-related information directly to CMS. The question as to whether CMS has the authority to enter the premises of FDRs is to be determined by interpreting other applicable statutory and regulatory authority.

Finally, we also proposed to delete the existing provision at § 423.505(i)(3)(iv) which gives Part D sponsors the choice as to how information sought from their FDRs will be provided to CMS. Section 423.505 would be renumbered so that paragraphs (v) through (viii) would become paragraphs (iv) through (vii).

We received the following comments and our responses follow:

Comment: Several MA organizations, Part D sponsors, and industry associations (about a dozen organizations all together) raised their opposition to this proposal. The main argument made by these parties is that CMS lacks the legal authority to directly access information from FDRs since our contractual relationship in these situations is with the MA organizations and PDP sponsors, not the FDRs themselves. One physician's group raised the concern that this provision would increase the likelihood of audits.

Response: We acknowledge that we do not have the authority to directly regulate FDRs. However, we believe our proposal allows us to achieve our goal of securing the right of access to FDR records because it relies on our ability to require the sponsors to incorporate such a right of access as part of the contractual relationship between the sponsors and their FDRs. That is, the proposal requires MA organizations and PDP sponsors to require their FDRs to agree to respond to direct requests for information made by CMS. As a practical matter, the mechanism for sponsors to require their FDRs to agree to such a provision is through the contractual relationship between the parties. We do not believe that this proposal in any way changes the likelihood of an audit, but merely affects the flow of information which we would be otherwise requesting.

Comment: The MA organizations and PDP sponsors that commented also maintained that since they are ultimately accountable to CMS for the work performed under their Medicare contracts, they have the right to participate in and manage the information provided to their contracting partner (CMS) on their behalf by their FDRs. The MA organizations and PDP sponsors further asserted that allowing the MEDIC or other government-related entities to circumvent the plan sponsors would lead to the collection of potentially erroneous information since the plan sponsor would not have the opportunity to properly vet the information flowing from the FDR to CMS. As a result, CMS' and the MEDIC's information collection from FDRs may become less efficient than it is under the current regulatory regime. Several commenters argued that the proposal would in fact increase burden, in contrast to CMS' suggestion in the proposed rule that the proposal would reduce burden.

Response: We maintain that having direct access to information from FDRs is an essential tool in combating fraud, waste, and abuse which we should be authorized to use. That said, we appreciate concerns raised about MA organizations and PDP sponsors' interests in managing information flowing to CMS, and the concern that such information could at times be flawed or erroneous without the quality review performed by the MA organization or PDP sponsor. Consequently, we wish to clarify that CMS and the MEDICs will default to the current practice of requesting information held by FDRs via an initial request to the MA organization or PDP sponsor. However, we will use the ''direct access'' route in circumstances where either (a) the results of data analytics, complaints, and/or investigations indicate a suspicion of fraud, waste, or abuse in the Medicare Part C or D programs or (b) in the case of an urgent law enforcement matter. We will publish sub-regulatory guidance on CMS' standards for determining when direct requests of FDRs would be appropriate. We believe that this approach promotes CMS' anti-fraud efforts by increasing fraud investigators' access to critical Part C and D program information and will likely increase the speed with which investigators may get access to critical FDR information, but at the same time allows for continued MA organization and PDP sponsor control and review of information in appropriate circumstances. We also wish to provide assurance that CMS' contractor, the MEDIC, would not be permitted to independently determine under what circumstances it would be appropriate to bypass the MA organization or PDP sponsor in favor of requesting information directly from the FDR; CMS would be directly involved in all such determinations. This approach also minimizes any loss of quality or potential for errors in the requested information as well as the placement of any additional burden on sponsors or FDRs.

Comment: Several commenters requested that if CMS finalizes the provision, that we revise the regulatory

language to state that CMS would notify the MA organization or PDP sponsor upon a direct request to one of its FDRs.

Response: While we had previously stated in this final rule discussion that MA organizations and PDP sponsors would be notified when there is a direct request for information made of an FDR, we agree that it is reasonable for us to specify this commitment in regulation. As such, we have added at §§ 422.504(i)(2)(iii) and 423.505(i)(2)(iii) language stating that except in exceptional circumstances, CMS will provide notification to the MA organization or PDP sponsor that a direct request for information has been made to one of its FDRs. The exceptional circumstance exception is included to allow for the possibility that the MA organization or PDP sponsor could be one of the parties to the fraud investigation, in which case it may not be appropriate to provide such notification.

Therefore, we are finalizing this provision with the modification that CMS will provide notification to the MA organization or PDP sponsor that a direct request for information has been made to one of its FDRs, except in exceptional circumstances.

24. Eligibility of Enrollment for Incarcerated Individuals (§§ 417.1, 417.460, 422.74, 423.44)

Entitlement and enrollment in the Medicare program (Part A and Part B) is contingent on entitlement to Social Security retirement and disability benefits as outlined in sections 226 and 226A of the Act, and enrollment in the Medicare program for individuals not receiving retirement or disability benefits is outlined in sections 1818 and 1818A of the Act. These sections do not preclude entitlement to or enrollment in the Medicare program for individuals who are incarcerated in prisons or other penal facilities. However, section 1862(a)(3) of the Act excludes Medicare payment for services which are paid directly or indirectly by another government entity, including federal, state and local prisons, and penal facilities. Given that Medicare entitlement flows from entitlement to Social Security retirement and disability benefits, we established regulations at § 411.4(b) and implemented section 1862(a)(3) of the Act through a payment exclusion process in the FFS program, outlined in section 50 of Chapter 16 of the Medicare Benefit Policy Manual and section 10.4 of the Medicare Claims Payment Manual.

The Medicare payment exclusion process includes the receipt of incarceration status for individuals via regular data transfers from the SSA to CMS. Once we receive the data, the incarceration status is noted on the individual's record and is retained in the FFS claims processing systems. Upon receipt of submitted FFS claims, CMS denies payment of both Part A and Part B claims for individuals with records on which incarceration is denoted, subject to the narrow exception provided in § 411.4(b). The denial of claims continues until the individual is no longer incarcerated and that information is reported by SSA to CMS. Individuals who are entitled to premium-free Part A will maintain their entitlement and will remain enrolled in Part B as long as premiums are paid. Similarly, individuals who are enrolled in premium Part A and/or Part B maintain their enrollment as long as premiums are paid. Sections 1851(a)(3)(B), 1860D–1(a)(3)(A), and 1876(a)(1)(A) of the Act outline the eligibility requirements to enroll in MA, Part D, and Medicare Health Maintenance Organization/Competitive Medical Plans (cost plans). In all options, individuals must have active Medicare coverage. Specifically, to enroll in MA, an individual must be entitled to Part A and enrolled in Part B; to enroll in a PDP, an individual must be eligible for Part D by either being entitled to Part A and/or enrolled in Part B; to enroll in a Medicare cost plan, an individual must be enrolled in Part B but Part A is not required.

In addition, sections 1851(b)(1)(A), 1860D–1(b)(1)(B)(i), and 1876(d) of the Act provide that Medicare beneficiaries are eligible to enroll in an MA plan, PDP, or cost plan only if they reside in the geographic area served by the plan, known as the plan's ''service area.'' As noted earlier, an individual who is incarcerated still meets the eligibility requirements for Part A and Part B and is eligible generally to enroll in an MA plan, PDP, or cost plan. However, residence in a plan's service area is also a condition for eligibility to enroll in an MA plan, PDP or cost plan. See §§ 422.50(a)(3)(i) for MA plans, 423.30(a)(1)(ii) for PDPs, and 417.422(b) for cost plans. If a member no longer resides in the service area, plans must disenroll that individual per rules at §§ 422.74(a)(2)(i) and 422.74 (d)(4) for MA plans, 423.44(b)(2)(i) for PDPs, and 417.460(b)(2)(i) for cost plans.

a. Changes in Definition of Service Area for Cost Plans (§ 417.1)

In order to implement the exclusion from Medicare coverage for incarcerated individuals under section 1862(a)(3) of the Act in the case of MA plans and PDPs, we explicitly excluded facilities in which individuals are incarcerated from an MA plan's service area by including this exclusion in the definition of ''service area'' when those regulatory definitions were adopted (54 FR 41734 and 72 FR 47410). Specifically, ''service area,'' under §§ 422.2 for MA plans and 423.4 for PDPs, is defined so that facilities in which individuals are incarcerated are considered outside of the service area.

We did not include a similar service area exclusion in the case of cost plans. To the extent that cost plans do not incur costs for incarcerated enrollees because their health care costs are covered by the facility, there would be no costs claimed on the cost report, and therefore, no Medicare payment. Nonetheless, to ensure that no cost payments are made, we proposed to revise the definition of service area in § 417.1 to specifically note that facilities in which individuals are incarcerated are not a part of the service area. This adjustment will ensure parity among the various Medicare plan coverage options and be the basis for ensuring that services are not paid by the Medicare Trust Funds for those who are not eligible for them.

b. Involuntary Disenrollment for Incarcerated Individuals Enrolled in MA, PDP and Cost Plans (§§ 417.460, 422.74, and 423.44)

Sections 1860D–1(b)(1)(B)(i), 1851(b)(1)(A), and 1876(a)(1)(A) of the Act provide that individuals whose permanent residence is outside the plan's service area are ineligible to enroll in or to remain enrolled in the MA, Part D, or cost plan. Based on the definition of service area established in §§ 422.2 and 423.4, this applied to individuals who were incarcerated as well. As such, individuals who became incarcerated while enrolled were ineligible to remain enrolled because they did not meet the eligibility criterion of residing in the MA plan or PDP's service area. As noted previously, the regulations for cost plans currently do not exclude incarcerated individuals from enrolling or remaining enrolled in these plans.

At the time of the implementation of Part D, the data regarding incarceration were not as robust as they are at the present time. To compensate, we provided instructions in sub-regulatory guidance that required MA plans and PDPs to investigate a notification from CMS of an individual's incarcerated status. If a plan could not confirm an enrollee's status, the plan would then apply the more-general policy for investigation of a possible out-of-area status, which would allow an

incarcerated individual to remain enrolled in the plan for up to 6 or 12 months for MA plans or PDPs, respectively. Cost plans, on the other hand, are not currently subject to similar instructions. Therefore individuals are currently not disenrolled from cost plans solely because they are determined to be incarcerated.

Given that the data CMS receives from SSA today regarding the incarceration status of Medicare beneficiaries are reliable enough for the purpose of involuntary disenrollment from MA, Part D, and cost plans, we proposed in the preamble of the January 2014 notice of proposed rulemaking to amend §§ 417.460(b)(2)(i), 417.460(f)(1)(i), 422.74(d)(4)(i), 422.74(d)(4)(v) and add 423.44(d)(5)(iii) and 423.44(d)(5)(iv) to establish that MA organizations, PDPs, and cost plan organizations must disenroll individuals incarcerated for 30 days or more upon notification of such status from CMS. Our proposal indicated that CMS, as a part of this change, would review the incarceration data provided by SSA and, where possible, involuntarily disenroll individuals who are incarcerated based on the data provided by SSA and notify the plan in which the individual is enrolled of this involuntary disenrollment. For all such disenrollments under our proposal, the effective date of disenrollment would be the first of the month after the incarceration start date, as reported by SSA. Such disenrolled individuals would maintain Medicare Part A and Part B coverage through FFS, provided they continue to pay premiums, as applicable, and payment of FFS claims would be based upon existing regulations outlined at 42 CFR 411.4(b). In connection with this change, we also proposed to deny enrollment requests for individuals if data received by CMS indicates an active incarceration status of at least 30 days. Based on the data received from SSA, if incarceration is denoted, we will deny that enrollment and notify the plan of the denial. This would replace the current process requiring plans to accept the enrollment and immediately begin the process to verify that the individual was out of the plan's service area. We indicated our intent to provide operational instructions in subregulatory guidance.

We received the following comments on our proposal:

Comment: We received general support for our proposals. Specifically, commenters appreciated the clarification that individuals released from incarceration are eligible for a special election period (SEP) to enroll in an MA or Part D plan.

Response: We appreciate the support expressed by the commenters. We note that the SEP related to release from incarceration (that is, change in residence) is not new or tied to this proposal. Details about this SEP can be found in section 30.4.1 of Chapter 2 of the Medicare Managed Care Manual and section 30.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Comment: A few commenters had suggestions for how we should implement this proposal. Specifically, they suggested that we issue updated guidance and develop new model notices. They also suggested that the best vehicle for providing updates to incarcerated status on members would be through the MARx system or daily transaction reply reports (DTRRs).

Response: We agree that manual and operational guidance will be necessary in order for MA, Part D and cost plans to implement this provision appropriately. We will evaluate whether new or revised model notices are needed and we will share these with plans as soon as possible. We also agree that transmission of data through MARx and DTRRs would make the most sense in terms of sharing incarcerated status with plans.

Comment: A commenter requested that CMS notify MA organizations and Part D sponsors of involuntary disenrollments on the day of incarceration. This commenter also suggested that we consider permitting MA and Part D plans to disenroll members as of the incarceration start date (as opposed to the first day of the month following the incarceration start date) to be in line with rules governing Qualified Health Plans (QHPs).

Response: Notification to plans and sponsors on the day that incarceration begins is not possible, since CMS receives the data from SSA once a month, and only after the correctional facility provides it to SSA. We would also note that plan enrollment and the corresponding payment to plans by CMS occurs in full calendar month increments. Even if we were able to provide plans with real time incarceration data, an involuntary disenrollment date other than the last day of the month is not possible.

We understand that QHPs may have different disenrollment effective dates because they can disenroll on days other than the first of the month. However, as previously stated, MA, Part D and cost plan effective dates begin and end on a monthly basis (that is, the first day of the month). Therefore, we cannot use the date of incarceration as the disenrollment effective date.

Comment: A commenter requested that we clarify if there will be an option for plans to disenroll a member if they receive information from the State Medicaid agency that an individual is incarcerated.

Response: If a plan receives information from an entity other than CMS or receives from CMS, via existing MARx processes, an indication of possible out of area status due to incarceration, there is already a process outlined in sub-regulatory guidance for plans to determine whether an individual is residing outside of the service area, which is what incarceration is considered. For cases in which CMS does not receive data confirming the incarceration of the individual, the MA organization or Part D sponsor must establish that the individual is no longer residing in the plan's service area due to incarceration as outlined in Section 50.2.1 in Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual.

In addition, as outlined in Section 50.2.1 in Chapter 17, Subchapter D of the Medicare Managed Care Manual, cost plans must disenroll individuals who permanently move out of the service area based upon written statement from the beneficiary or other reasonable evidence that establishes the individual no longer resides in the plan's service area. With the change in definition of service area for cost plans as reflected in the proposed change at § 417.1, cost plans must establish that the individual is no longer residing in the plan's service area if they receive information regarding incarceration from CMS or another entity.

Comment: Two commenters suggested creating a Part B SEP to ease the transition for beneficiaries after they are released from incarceration to ensure access to Medicare Part B benefits as they re-enter the community. Oftentimes, the commenters cited, these beneficiaries lose their Medicare Part B coverage because they are unable to pay their premiums during their incarceration and are not eligible for a Part B SEP upon their release. As a result, if these individuals sign up for Part B at a later date, there is the likelihood that they will have to pay a late enrollment penalty.

Response: This comment is outside the scope of this rulemaking. However, we would like to note that SEPs for Part B and premium Part A are outlined in statute and CMS does not have the authority to establish additional SEPs.

After consideration of the public comments received, we are taking the following action on our proposals:

- The definition of service area for cost plans at § 417.1 is finalized without modification.
- To articulate that the geographic area is the HMO or CMP's service area as defined in § 417.1, we are finalizing the language at § 417.460(b)(2)(i) with the minor modification of adding the word ''service.''
- To articulate that the basis of the disenrollment for incarceration is due to the individual not residing in the plan's service area, the regulation text at §§ 417.460(f)(1)(i), 422.74(d)(4)(i)(A), and 422.74(d)(4)(v)) is finalized with modification.
- Due to an inadvertent omission, the proposed regulatory text changes to § 423.44(d)(5)(iii) and (iv) were not published in the proposed rule. Because our preamble was clear that our proposed changes were applicable to Part D, and the comments received demonstrated that readers understood our intent, we are adding and finalizing regulatory text changes at § 423.44(d)(5)(iii) and (iv).
- A proposed change to the definition of ''service area'' was inadvertently published in the January 2014 proposed rule at § 422.2. That revised definition is not being finalized.

Finally, we recognize that in our discussion of the proposed rule we described our intent that ineligibility for—as well as involuntary disenrollment from—MA, Part D, and cost plans would be based on a period of incarceration of 30 days or more. As we will note in implementing guidance for these final rules, we will determine eligibility based on confirmed incarceration data from SSA, not a 30-day timeframe.

25. Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134)

Every year, CMS receives inquiries from MA organizations that wish to expand the scope of the rewards and incentives that currently may be offered to beneficiaries enrolled in their MA plans. In some cases, MA organizations wish to extend rewards and incentives already offered to their commercial members to their Medicare enrollees. There is some evidence to suggest that health-driven reward and incentive programs for currently enrolled members of health plans may lead to meaningful and sustained improvement to their health behaviors and health outcomes.[1]

CMS would like to enable MA organizations to offer health-driven rewards and incentives programs that may be applied to more health-related services and activities than are allowed under our current guidance. We proposed to amend our regulations to establish parameters for rewards and incentives programs offered to enrollees of MA plans. Because we are concerned about the possibility that such programs would be targeted only to healthier enrollees, and discourage sicker enrollees from participating in such incentives and in remaining enrolled in the plan, we also proposed to include specific requirements regarding rewards and incentives so as to ensure that such programs do not discriminate against beneficiaries on the basis of health status or disability, or other impermissible bases for discrimination.

Section 1856(b)(1) of the Act provides authority for the establishment of MA standards by regulation that are consistent with and carry out Part C, and section 1857(e)(1) of the Act provides authority to impose contract requirements that CMS finds ''necessary and appropriate'' and that are not inconsistent with Part C. Section 1852(b)(1)(a) of the Act states that MA organizations may not discriminate against beneficiaries on the basis of health status and that CMS may not approve an MA plan if that offering is susceptible to discrimination based on an individual's health status. Furthermore, section 1857(g)(1)(D) of the Act provides authority for taking intermediate sanction action against an MA organization which ''engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by eligible individuals'' as a result of their health status or history. We proposed to rely upon the aforementioned rulemaking and substantive authority to establish requirements for rewards and incentives programs offered by MA organizations to Medicare beneficiaries enrolled in their MA plans.

Specifically, we proposed adding a new provision at § 422.134 that would authorize MA organizations to offer reward and incentive programs to their current Medicare enrollees to encourage their participation in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources. We proposed requiring that reward-eligible activities be designed so that all enrollees are able to earn rewards without discrimination based on race, gender, chronic disease, institutionalization, frailty, health status, and other impairments. This proposed requirement would not preclude MA organizations from offering rewards and incentives programs that target a specific disease, chronic condition or preventive service. Rather, the goal of having a non-discrimination requirement is to prevent particularly vulnerable populations from being disproportionately underserved. MA organizations may not use this provision to ''cherry pick'' healthier enrollees. Therefore, any rewards and incentives program implemented by an MA organization under this proposal must accommodate otherwise qualified beneficiaries who receive services in an institutional setting or who need a modified approach to enable effective participation.

To meet the proposed CMS requirements, a reward or incentive would have to be earned by completing the entire health-related service or activity and may not be offered for completion of less than all required components of the eligible service or activity. An MA organization would define what qualifies as an ''entire service or activity'' within its program design. This proposed requirement is tied to interpreting the value of the service provided as it relates to the value of the reward. Under this proposal, rewards and incentives would be subject to a monetary cap in an amount CMS determines could reasonably be expected to affect enrollee behavior while not exceeding the value of the health-related service or activity itself. As part of our proposal, we indicated the intent to provide guidance on this qualitative standard on a regular basis.

In addition, our proposed regulation would require MA organizations that offer rewards and incentives programs to provide information about the effectiveness of such programs to CMS upon request. If CMS determines that the rewards and incentives programs are not in compliance with our regulatory standard, we proposed that we may require that the MA organization modify the basic parameters of the program.

We received the following comments and our responses are as follows:

Comment: We received several comments in support of this proposal, approving of our effort to allow MA organizations to make rewards and incentives programs more widely available to enrollees. Several

[1] Ali Shirvani-Mahdavi, Ph.D. & Melissa Haeffner, Ph.D., *Rewarding Wellness: The Science Behind Effective Wellness Incentive Programs* (2014).

commenters noted that facilitating beneficiary engagement in health behaviors and practices will help to achieve better health outcomes.

Response: We thank the commenters for their support.

Comment: Several organizations expressed concern over the requirement that rewards and incentives programs be non-discriminatory and available to all enrollees. They requested clarification that such programs may target specific chronic conditions, diseases and other health care needs.

Response: In response to comments, we have strengthened the regulation to ensure that rewards and incentives programs will not be discriminatory. As revised, the non-discrimination requirement of the provision is based on the substantive requirement of section 1852(b)(1)(A) of the Act (which states that MA organizations may not discriminate against beneficiaries on the basis of health status) and expands upon it by identifying other impermissible bases for discrimination, including race, national origin, and gender. The regulation is meant to prevent rewards and incentives programs from being used to unfairly benefit healthier enrollees while excluding or disadvantaging enrollees who are less healthy or have a disability. MA organizations may establish rewards and incentives for specific chronic conditions, diseases, or other health care needs so long as the rewards and incentives program is not discriminatory.

Comment: We received several comments stating that the requirement that a beneficiary must complete a whole service or activity is too narrow to permit effective program designs and requesting that CMS provide greater flexibility in this area.

Response: We proposed to require that rewards and incentives be offered in connection with an entire service or activity so that CMS and MA organizations can interpret the value of a reward or incentive in relation to the service or activity for which it is being given. MA organizations may reasonably define the scope of the ''entire service or activity'' in their program design. For example, a MA organization may decide to offer rewards and incentives for participation in a smoking cessation program. The MA organization may decide to give smaller rewards for each class attended or give one larger reward for completing a set number of classes, as long as the value of the reward reflects the value of the service and adheres to the monetary cap designated by CMS. We are revising § 422.134(c)(1)(i) to eliminate the phrase ''completion of'' to make it possible for portions of a service or activity to be defined as the ''entire service or activity.'' We emphasize that the value limitation applies to each ''entire service or activity'' such that the value of the reward or incentive offered may not be greater than the value of the service or activity itself.

Comment: Several commenters cautioned against rewards and incentive programs because they have the potential to disproportionately penalize low-income, minority beneficiaries, and beneficiaries with disabilities.

Response: We understand the commenters' concerns and consequently emphasize here (and elsewhere in this preamble) that all rewards and incentives programs must be non-discriminatory and may not disproportionately penalize any groups, specifically the vulnerable. Additionally, as discussed in a previous response, we have revised the regulation text to strengthen the non-discrimination language.

Comment: Several commenters suggested that CMS solicit data from rewards and incentives programs on a regular basis rather than ''on request.'' Commenters are particularly interested in outcomes data. In addition, one commenter asked about CMS' requirements for the format of that information.

Response: We have noted these comments and will consider adopting a rewards and incentives program reporting cycle in the future.

Comment: Several commenters do not support rewards and incentive program designs that include increased beneficiary cost-sharing as a penalty for not participating in such a program.

Response: The provision as finalized only allows programs that will provide rewards and incentives to beneficiaries. It does not allow MA organizations to penalize beneficiaries for non-participation by any means, including through increased cost-sharing. We also note that § 422.134(c)(2)(i) prohibits rewards and incentives from being offered in the form of cash or monetary rebates; we would consider a discount on cost-sharing to be such a prohibited reward and incentive. Furthermore, CMS regulations requiring uniformity of benefits (42 CFR 422.100(d)(2)) preclude MA plans from charging enrollees of a plan different premiums or cost-sharing for the same service.

Comment: A few commenters asked how this new provision will impact the rewards and incentives guidance that is currently located in the Medicare Marketing Guidelines.

Response: This provision will supersede any previously issued rewards and incentives program guidance. Upon finalization of this rule, we will update our subregulatory guidance accordingly.

Comment: A few commenters asked CMS to provide more specific information regarding rewards and incentives programs. They asked for guidance on calculating the value of the activities for which the plan would like to offer rewards and incentives, whether the rewards and incentives may be used to decrease cost-sharing or premiums and whether there is a limit on how often an MA organization may offer a reward or incentive.

Response: The provision provides an MA organization with great flexibility in designing its own rewards and incentives program. At this time, we will rely on the MA Organizations to reasonably value the activities/services for which they offer rewards and incentives. In this final rule, we neither identify limits for how often rewards and incentives may be offered nor do we set a maximum monetary value for the rewards and incentives. However, if we determine such guidance is needed to apply the standard in § 422.134(c)(1)(iii) that the reward or incentive be expected to impact enrollee behavior without exceeding the value of the health-related service or activity itself, we will provide it through subregulatory guidance.

Rewards and incentives may never be used to decrease cost-sharing or plan premiums. In addition to the prohibition at § 422.134(c)(2)(i), CMS regulations requiring uniformity of benefits (42 CFR 422.100(d)(2)) preclude MA plans from charging enrollees of a plan different premiums or cost-sharing for the same service. Thus, a MA plan may not offer lower cost-sharing or premiums for plan benefits, as a reward or incentive.

Comment: Two commenters asked that we expand this provision to include Part D plans.

Response: We have noted the comment. At this time, the rewards and incentives program provision only applies to Part C.

Comment: One commenter requested that SNPs be allowed greater flexibility in rewards and incentives program design.

Response: The current provision and the parameters set forth are applied to all types of MA plans, including SNPs. At this time, we do not intend to provide SNP-specific rewards and incentives program rules or guidance.

Comment: Several commenters asked how rewards and incentives will be accounted for in plan bids and one

commenter suggested that the costs should be identified as an administrative cost for care management services in the bid.

Response: A rewards and incentives program would be included in the bid as a non-benefit expense and would not be entered in the PBP. Per CMS OACT Bidding Guidance, (available at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Forms-and-Instructions.html*), ''non-benefit expenses are all of the bid-level administrative and other non-medical costs incurred in the operation of the MA plan.'' We also wish to clarify that the costs of a rewards and incentives program would not necessarily be related only to care management services and that plans must comply with applicable bidding requirements.

Comment: Several commenters requested that CMS clarify whether rewards and incentives programs would be offered as a benefit or otherwise.

Response: Our policy has been, and continues to be, that rewards and incentives programs are not benefits.

Comment: One commenter requested that CMS, in considering additional parameters for reward and incentive programs, consider shared decision-making and tiered networks. The same commenter also stated that our proposal removes a great deal of flexibility for plans to develop these programs and constrains employer group plans from providing these programs to the entire employer group.

Response: We are not clear what is meant by the request that in our consideration of additional parameters we consider shared decision-making and tiered networks. We note that shared decision-making and tiering of medical benefits are strategies that MA organizations may use to influence enrolled beneficiaries' health care decisions. Rewards and incentives are another tool CMS is making available to MA organizations to encourage enrollees to engage in activities/services that are intended to improve health and/or decrease enrollee risk for illness. MA organizations have the flexibility to use these tools together or as separate programs designed to improve enrollees' health.

We are not aware of what flexibilities plans may be using currently in providing rewards and incentive programs to enrollees that the commenter believes CMS proposed to remove. We specifically solicited information on this topic from MA organizations in both the proposed rule and in the CY 2014 Call Letter and have received no information that would lead us to believe that our proposed rewards and incentives program would limit, rather than expand, current plan flexibilities. The current guidance on rewards and incentive programs that may be offered to plan enrollees, included in the Medicare Marketing Guidelines, allows a very limited use of rewards and incentives to promote enrollee use of Medicare-covered preventive services. Therefore, we do not see how our proposed rewards and incentives program framework could remove plans' flexibilities rather than expand them.

After consideration of the public comments received, we are finalizing the proposed Rewards and Incentives Program Regulations for Part C Enrollees rule with modifications to subparagraph (b)(1) to include ''national origin, including limited English proficiency,'' and ''disability.'' In subparagraph (b)(1) we are also changing the text from ''institutionalization'' to ''whether a person resides or receives services in an institutional setting'' and from ''other impairments'' to ''other prohibited basis.'' These changes clarify the scope of the categories of beneficiaries included in the context of prohibited discrimination and address comments expressing concern about the possible disproportionate impact of rewards and incentives programs.

Additionally, we are modifying paragraph (c)(1)(i) to eliminate the phrase ''completion of'' from the regulation text to make it possible for smaller increments of service or activity to be defined as the ''entire service or activity.'' However, we emphasize that the value of any reward must reflect the value of the service and adhere to any monetary cap that has been determined by CMS under § 422.134(c)(1)(iii). Finally, we note that we have made a technical change to delete the phrase ''all of the following'' from the introductory language at paragraph (c).

B. Improving Payment Accuracy

1. Implementing Overpayment Provisions of Section 1128J(d) of the Social Security Act (§ 422.326 and 423.360)

This section of the final rule implements Section 6402 of the Affordable Care Act, which established new section 1128J(d) of the Social Security Act (''the Act'') entitled Reporting and Returning of Overpayments. Section 1128J(d)(4)(B) of the Act defines the term overpayment as any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title. The definition of person at section 1128J(d)(4)(C) includes a Medicare Advantage organization (as defined in section 1859(a)(1) of the Act) and a Part D sponsor (as defined in section 1860D–41(a)(13) of the Act). The definition does not include a beneficiary.

Section 1128J(d)(1) of the Act requires a person who has received an overpayment to report and return the overpayment to the Secretary, the state, an intermediary, a carrier, or a contractor, as appropriate, at the correct address, and to notify the Secretary, state, intermediary, carrier or contractor to whom the overpayment was returned in writing of the reason for the overpayment. Section 1128J(d)(2) of the Act requires that an overpayment be reported and returned by the later of (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. Section 1128J(d)(3) of the Act specifies that any overpayment retained by a person after the deadline for reporting and returning an overpayment is an obligation (as defined in 31 U.S.C. 3729(b)(3)) for purposes of 31 U.S.C. 3729.

Finally, section 1128J(d)(4)(A) of the Act defines ''knowing'' and ''knowingly'' as those terms are defined in 31 U.S.C. 3729(b). Specifically, the terms ''knowing'' and ''knowingly'' ''mean that a person with respect to information: (1) Has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.'' There need not be ''proof of specific intent to defraud.''

To implement section 1128J(d) of the Act for the Part C Medicare Advantage program and the Part D Prescription Drug program, we proposed two new sections, §§ 422.326 and 423.360, respectively, both titled, ''Reporting and Returning of Overpayments.'' These sections proposed rules for MA organizations and Part D sponsors to report and return an identified overpayment to the Medicare program. We use the term Part D sponsor, as defined at § 423.4, to refer to the entities that offer prescription drug plans (PDPs) under part 423 and thus are subject to section 1128J(d) of the Act.

We also proposed conforming amendments to §§ 422.1, 422.300, and 423.1 that add a reference to section 1128J(d) of the Act to the existing list of statutory authorities for the regulations governing the MA organizations and Part D sponsors. We also proposed to amend §§ 422.504(l) and 423.505(k) to

incorporate a reference to the proposed §§ 422.326 and 423.360, respectively, in order to extend the existing data certification requirement to data that MA organizations and Part D sponsors submit to CMS as part of fulfilling their obligation to return an overpayment under section 1128J(d) of the Act. Section 422.504(l) refers to certification of data ''as a condition for receiving a monthly payment'' and § 423.505(k) refers to certification of data for enrollees ''for whom the organization is requesting payment.'' Thus, we proposed to add a requirement that applies after CMS has completed prospective monthly payments for a year, and organizations are no longer ''requesting payment'' because applicable reconciliation has occurred. Applicable reconciliation, we stated, is the point when organizations submit their final data for the previous payment year. Accordingly, if an MA organization or Part D sponsor has identified an overpayment, there clearly is a different state of ''best knowledge, information, and belief'' than the state of knowledge, information, and belief that existed prior to applicable reconciliation. Thus, we proposed to require that the CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that information the MA organization or Part D sponsor submits to CMS for purposes of reporting and returning of overpayments under §§ 422.326 and 423.360 is accurate, complete, and truthful.

We reminded all stakeholders that even in the absence of a final regulation on these statutory provisions, MA organizations and Part D sponsors are subject to the statutory requirements found in section 1128J(d) of the Act and could face potential False Claims Act liability, Civil Monetary Penalties (CMP) Law liability, and exclusion from Federal health care programs for failure to report and return an overpayment. Additionally, MA organizations and Part D sponsors continue to be obliged to comply with our current procedures for handling inaccurate payments.

In response to the January 10, 2014 proposed rule, we received approximately 30 pieces of correspondence from organizations and individuals. In this section of the final rule, we describe our proposals, respond to the public comments, and state our final policies.

We did not receive any comments on our proposed amendments to §§ 422.504(l) and 423.505(k) to incorporate a reference to the proposed §§ 422.326 and 423.360, respectively, in order to extend the existing data certification requirement to data that MA organizations and Part D sponsors submit to CMS as part of fulfilling their obligation to return an overpayment under section 1128J(d) of the Act. We did not receive any comments on our conforming amendments to §§ 422.1, 423.300, and 423.1. Therefore, we are finalizing these amendments as proposed.

a. Terminology (§§ 422.326(a) and 423.360(a))

We proposed definitions of 3 terms. First, we proposed to adopt the statutory definition of overpayment, where an overpayment exists when—after ''applicable reconciliation''—an MA organization or Part D sponsor is not entitled to funds it has received and/or retained. In order to clarify the statutory definition of overpayment, we proposed definitions of 2 key terms at §§ 422.326(a) and 423.360(a): ''Funds'' and ''applicable reconciliation.''

We proposed to define ''funds'' as payments an MA organization or Part D sponsor has received that are based on data that these organizations submitted to CMS for payment purposes. We also noted that MA organizations and Part D sponsors have responsibility for the accuracy, completeness, and truthfulness of data they submit under existing §§ 422.504(l) and 423.505(k). For Part C, the data submitted by the MA organization to CMS includes §§ 422.308(f) (enrollment data) and 422.310 (risk adjustment data). For Part D, data submitted by the Part D sponsor to CMS includes data submitted under §§ 423.329(b)(3), 423.336(c)(1), 423.343, and data provided for purposes of supporting allowable costs as defined in § 423.308 of this part which includes data submitted to CMS regarding direct or indirect remuneration (DIR).

There are additional payment-related data CMS uses to calculate Part C and Part D payments that are submitted directly to CMS by other entities, such as the Social Security Administration (SSA), which is the authoritative source for data they submit to CMS. We believe that MAOs and Part D sponsors cannot be held accountable for the accuracy of data controlled and submitted to CMS by other entities.

For example, the SSA is the authoritative source for date of death. An MA organization or Part D sponsor generally does not submit a date of death directly to CMS' systems; it comes from the SSA data feed. When the SSA submits to CMS corrected data regarding a beneficiary's date of death, CMS' systems recalculate the payments made to the plan for that beneficiary and recoup the incorrect payment in a routine retroactive payment adjustment process.

We stated that when CMS recoups an incorrect payment from an MA organization or Part D sponsor based on data corrections submitted by authoritative sources such as the SSA, CMS would not consider this recoupment to be the return of an overpayment by an MA organization or Part D sponsor under proposed §§ 422.326 and 423.360. Therefore, the proposed meaning of ''funds'' refers to a payment amount that an MA organization or Part D sponsor received from CMS that is based on data that the MA organization or Part D sponsor controls and submits to CMS.

We stated that the term ''applicable reconciliation'' refers to an event or events after which an overpayment can exist under section 1128J(d) of the Act, and we proposed definitions of the term applicable reconciliation that are specific to Part C and Part D.

For Part C, we proposed that applicable reconciliation occurs on the date that CMS announces as the final deadline for risk adjustment data submission. For each payment year, we apply three sets of risk scores to adjust payments: Initial and midyear risk scores during the payment year (both sets are based on incomplete diagnosis data from the data collection year); and final risk scores after the payment year using data MA organizations submit on or before the final deadline for risk adjustment data (which reflects complete data for the data collection year). We also stated that the final risk adjustment data submission deadline would function as the Part C applicable reconciliation date.

For Part D sponsors, we proposed that applicable reconciliation is the later of either: The annual deadline for submitting prescription drug event (PDE) data for the annual Part D payment reconciliations referred to in § 423.343 (c) and (d) or the annual deadline for submitting DIR data. The annual deadline for submitting PDE data is the last federal business day prior to June 30th of the year following the benefit year being reconciled. The annual deadline for submitting DIR data is announced annually through subregulatory guidance and generally occurs around the last business day in June the year following the benefit year being reconciled. We selected these events to define the Part D applicable reconciliation because these data are used for the purposes of determining final Part D payment reconciliation. We noted that MA organizations would still have to submit all final risk adjustment

diagnoses for Part D by the final risk adjustment data submission deadline.

In summary, we proposed an approach to defining applicable reconciliation that establishes dates that differ for Part C and Part D. We asked for comment on this approach.

We noted that payment errors identified as a result of any corrections to risk adjustment data submitted by MA organizations (and other organizations required to submit risk adjustment data to CMS) on or before the annual final risk adjustment data submission deadline are handled as part of the current annual process of risk adjustment payment reconciliation. Because these payment errors are prior to the date defined in this final rule as ''applicable reconciliation'', we stated that we do not consider these errors to be overpayments for the purpose of §§ 422.326 and 423.360. That is, any deletions of risk adjustment data in the file submitted on or before the final risk adjustment data submission deadline for a payment year, would result in payment errors that are addressed with processes that have been in place prior to our codification of section 1128J(d) of the Act in proposed §§ 422.326 and 423.360.

Likewise, for Part D, any payment errors identified as a result of any corrections to PDE or DIR data submitted on or before the later of the annual deadline for submitted PDE and DIR data are handled as part of the current Part D reconciliation process, and we do not consider these errors to be overpayments for the purpose of § 423.360.

Finally, we stated our expectation that MA organizations and Part D sponsors must be continuously diligent regarding the accuracy and completeness of payment-related data they submit to CMS for a payment year, whether during or after that payment year, and whether before or after applicable reconciliation dates. This expectation is based on existing requirements at §§ 422.310, 422.504(l), 423.329(b)(3)(ii), and 423.505(k), and proposed amendments that clarify and strengthen these requirements.

We did not receive any comments on the proposed definitions of the terms ''funds'' or ''overpayment.'' (See the next section for comments and responses on the provision regarding ''identified overpayment''.) We received the following comment on the term ''applicable reconciliation'', and our response follows.

Comment: Some commenters supported CMS' proposal to have separate applicable reconciliation dates for the Part C and Part D programs, noting that this approach is simpler and more practical than the alternative CMS described (where there would be 2 applicable reconciliation dates for the Part D program—one for risk adjustment and another for PDE and DIR data).

Response: We appreciate the support. We will finalize our proposal that the Part C applicable reconciliation date will be the same as the final risk adjustment data submission deadline, and the Part D applicable reconciliation date will be the later of: The annual deadline for submitting prescription drug event (PDE) data for the annual Part D payment reconciliation referred to in § 423.343(c) and (d) or the annual deadline for submitting DIR data.

We would like to note that the final risk adjustment data submission deadline will still apply to diagnosis data for both Part C and Part D risk scores for beneficiaries in MA–PD plans.

After consideration of the public comments received, we are finalizing the provisions at §§ 422.326(a) and 423.360(a) as proposed.

b. General Rules for Overpayments (§ 422.326(b) Through (c); § 423.360(b) through (c))

We proposed at §§ 422.326(b) and 423.360(b) that if an MA organization or Part D sponsor has identified that it has received an overpayment, the MA organization or Part D sponsor must report and return that overpayment in the form and manner set forth in the section. In paragraphs §§ 422.326(c) and 423.360(c), we proposed that the MA organization or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. We noted that the terms ''reckless disregard'' and ''deliberate ignorance'' are part of the definitions of ''knowing'' and ''knowingly'' in section 1128J of the Act, which provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the False Claims Act (31 U.S.C. 3729(b)(3)). We stated that without such a proposal to include ''reckless disregard'' and ''deliberate ignorance'', some MA organizations and Part D sponsors might avoid performing activities to determine whether an overpayment exists. We also provided that if an MA organization or Part D sponsor has received information that an overpayment may exist, the organization must exercise reasonable diligence to determine the accuracy of this information, that is, to determine if there is an identified overpayment.

Finally, in paragraphs §§ 422.326(d) and 423.360(d), we proposed the requirements for reporting and returning an identified overpayment. An MA organization or Part D sponsor must report and return any identified overpayment it received no later than 60 days after the date on which it identified it received an overpayment. The statute provides an alternative deadline: The date any corresponding cost report is due, if applicable. We proposed that this alternative deadline is not applicable to the Parts C or D programs because, in general, MA organizations and Part D sponsors are paid based on their bids, and not based on their actual incurred costs.

The MA organization or Part D sponsor must notify CMS, using a notification process determined by CMS, of the amount and reason for the overpayment. Also within this 60-day time period, the organization must return identified overpayments to CMS in a manner specified by CMS, including the amount and reason for the overpayment. We proposed to codify at paragraph (3) the statutory requirement that any overpayment retained by an MA organization or Part D sponsor after the 60-day deadline for reporting and returning is an obligation under 31 U.S.C. 3729(b)(3).

We also emphasized that an MA organization and Part D sponsor are deemed to have returned the overpayment when they have taken the actions that we will specify, in forthcoming operational guidance, to submit the corrected data that is the source of the overpayment. We will recover the returned overpayment through routine processing according to the systems schedule established in the annual operations budget. That is, payments are recovered through the established payment adjustment process, not on the 60-day schedule that applies to each MA organization or Part D sponsor that has identified an overpayment. Rerunning reconciliation each time an entity identifies an overpayment that triggers its 60-day clock is simply not feasible for CMS.

Finally, we proposed that there will be circumstances when we may ask the MA organization or Part D sponsor to provide an auditable estimate of the overpayment amount, reason for overpayment, and make a payment to CMS. This may occur, for example, when an overpayment is identified after the final Part D reopening for a contract year has occurred but prior to the end of the look-back period or if an MA organization or Part D sponsor had a thoroughly-documented catastrophic loss of stored data. Information about the nature of such a request would be

detailed in forthcoming operational guidance.

We received the following comments on general rules for overpayments and our responses follow.

Comment: Several commenters requested that CMS clarify when the 60-day period begins. Specifically, does the period begin once the MA organization or Part D sponsor has identified that there is an overpayment or once the organization has determined the exact amount of the overpayment? A commenter expressed concern that the proposed rule does not appear to acknowledge that the amount of an overpayment must be quantified before it is ''identified.'' Another commenter requested that CMS address the situation where an MA organization or Part D sponsor becomes aware of an issue or error that may have resulted in one or more overpayments, but could not determine, with reasonable certainty, the amount of the overpayment(s) within a 60-day period.

Response: It is important to understand the distinctions among identifying, reporting, and returning an overpayment in this rulemaking for the purposes of the MA and Part D programs. Once an organization has identified that it has received an overpayment, the 60-day period for reporting and returning the overpayment begins. Because of the nature of the Part C and Part D programs, we did not propose that ''identified'' includes completion of the act of quantification of an overpayment amount. Rather, we proposed that identification of an overpayment means knowing that the MA organization or Part D sponsor has submitted erroneous data to CMS that caused CMS to overpay the organization.

An organization can identify or assess that there is a problem with data submitted to CMS, and determine that it is incorrect data, prior to actually calculating what the payment impact is of that erroneous data. For the MA and Part D programs, the relevant factor is identifying that the data is incorrect and will result in an overpayment. For example, a risk adjustment diagnosis that has been submitted for payment but is found to be invalid because it does not have supporting medical record documentation would result in an overpayment. Under this provision, the day after the date on which the organization has confirmed an identified overpayment—because the organization knows that the diagnosis is not supported by documentation—is the first day of the 60-day period for reporting and returning the overpayment. As another example, an MA organization may find that data used to calculate Healthcare Effectiveness Data and Information Set (HEDIS) measures that the organization submitted to CMS are found to be invalid; when the organization has confirmed that it has identified invalid data leading to an overpayment, this is the first day of the 60-day period for reporting and returning the overpayment.

Then, during the 2-month period for reporting and returning the overpayment, the organization must determine what data should be submitted to CMS to correct the identified overpayment, and then must engage in the reporting and returning process that we will describe in forthcoming guidance. This reporting and returning process will involve: (1) Notifying CMS that an overpayment exists, including notification of the reason and estimated amount for that overpayment; and (2) submitting the corrected data to CMS.

In other words, we believe that the MA organization and Part D sponsor will discover through appropriate payment evaluation procedures when a 60-day period would begin under the requirements of this provision, because ''day one'' of the 60-day period is the day after the date on which organization has determined that it has identified the existence of an overpayment. Once the organization ''starts the clock,'' it has 60 days to submit to CMS the corrected data that is the basis of the overpayment. It is the act of submitting the corrected data to CMS, along with a reason and an amount of the overpayment (which may be an estimate), that constitutes fulfillment of the requirement to report and return the overpayment.

As we stated in the January 10, 2014 proposed rule preamble (79 FR 1997), ''It also is important to note that the MA organization and Part D sponsor are deemed to have returned the overpayment when they have taken the actions that we will specify, in forthcoming operational guidance, to submit the corrected data that is the source of the overpayment''. We will recover the returned overpayment through routine CMS payment processes. That is, payments will continue to be recovered through the established payment adjustment processes and schedules. As a result the payment recovery may not occur within the 60-day window triggered by identifying an overpayment. Rerunning payment reconciliations and conducting payment recovery within CMS payment systems each time an entity identifies an overpayment that triggers its 60-day clock is simply not feasible for CMS.

We will release operational guidance on the process an organization will use for informing CMS that it has identified a Part C and/or Part D overpayment. This guidance will also address how an organization will be required to provide a reason for and the amount of the overpayment (which may be estimated). We seek to reduce burden and implement an efficient process for administering the reporting and return of overpayments, so we are considering making use of existing procedures for organizations to communicate payment data issues to CMS. For example, MA organizations and Part D sponsors have used the Remedy system for a number of years to inform CMS of payment issues and provide relevant information on that issue.

In the forthcoming operational guidance, we will address the question of how to report the overpayment amount, including estimation of the overpayment amount and updates under certain scenarios.

Comment: A commenter contended that, applying the principles adopted by CMS in the RADV audit context, an overpayment cannot exist for a particular MA contract unless CMS' payments as a whole to the MA organization pursuant to the contract are inaccurate in light of an appropriate FFS Adjuster applied to the entire contract. Potential overpayments can be determined, therefore, based only on processes such as CMS' RADV audits, which are designed to measure whether contract-level payments to an MA organization are accurate when compared to an appropriate FFS Adjuster. The commenter further contended that to the extent an MA organization develops processes intended to measure payment accuracy at the contract-level, the MA organization would be required to report and repay inaccuracies calculated after applying CMS's FFS Adjuster, and consistent with prior CMS guidance, this is the sole instance in which an ''overpayment'' can be determined for purposes of proposed § 422.326.

Response: We disagree with the commenter. Our RADV methodology does not change our existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS. Further, this decision does not change the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must

be supported by medical record documentation.

However, we are clarifying the link between the § 422.326 overpayment provisions and RADV audits under § 422.311 by adding a condition to the requirement at § 422.326(d), as follows: an MA organization must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment. We are adding to paragraph (d) the provision ''unless otherwise directed by CMS for the purpose of § 422.311.'' Thus, when an MA organization has a contract selected for a RADV audit, during the audit the MA organization will not be allowed to report and return an overpayment under § 422.326 that is due to errors in the data used to risk-adjust payments for the audited contract for the payment year that is the subject of the RADV audit. We will notify the MA organization about the timeline for reporting and returning any overpayments for a contract under a RADV audit. This new provision protects the integrity of the RADV audit process, including the sampling frame of beneficiaries in a selected MA plan, whose diagnoses will be audited.

Comment: A commenter stated that there will be many circumstances and situations where entities receiving an overpayment will not have the ability to repay funds within the 60-day period without undue hardship.

Response: MA organizations and Part D sponsors have an obligation to pay an overpayment owed under Section 1128J(d). As noted previously, our recovery of overpayments will occur through routine payment processing cycles and schedules. In most circumstances, MA organizations and Part D sponsors will be submitting corrected data, which will be re-run by CMS and then CMS will recover the overpayment.

Comment: A commenter noted that 60 days is not a sufficient timeframe, as identifying and quantifying overpayments can be a very involved process. Another commenter stated that most overpayments are identified through analyses and studies, such as internal RADV studies; the commenter requested that the 60-day time period begin at the conclusion of the internal study, so that overpayments can be referred to CMS after all issues have been identified and confirmed.

Response: We provide that the 60-day period is the time period for reporting and returning an identified overpayment, after the organization has conducted the activities needed to identify that it has received an overpayment. As explained previously, for the purposes of the MA and Part D programs, the MA organization or Part D sponsor must report and return the identified overpayment, which is due to incorrect data it has submitted to CMS, no later than 60 days after the date on which the organization identified it received the overpayment. Subsequently and within the 60-day period the MA organization or Part D sponsor is required to report and return the overpayment. Reporting the overpayment involves notifying CMS of the reason for and the amount of the overpayment. Returning the overpayment is deemed to have occurred through the act of correcting the erroneous data submitted to CMS, for example, by deleting incorrect PDEs or risk adjustment data. Note that if an organization identifies one set of erroneous data that has caused an overpayment, the organization must begin the 60-day clock on that date, and if subsequent overpayments are identified, the organization must begin subsequent 60-day reporting and returning periods.

Comment: A commenter questioned whether CMS will be identifying criteria for organizations to use to determine an overpayment.

Response: We have specified in this final rule the specific types of ''funds'' that are subject to the provisions under this section through the definition of ''funds''. Funds are payments an organization has received that are based on data that the organization submitted to CMS for payment purposes. We will not provide additional criteria or a checklist.

Comment: A commenter stated that logically, an MA organization or Part D sponsor cannot return an overpayment until it has calculated the exact amount that it must return. It might take a considerable amount of time for the MA organization or Part D sponsor to audit its records to determine the amount, whether there is an issue in previous years, and whether extrapolation, or case by case analysis, is appropriate. The commenter was concerned that while a plan sponsor might be able to report to CMS that it has identified an issue within 60 days, a plan sponsor may not have enough information after identification to be able to report the exact amount. Therefore, the commenter requested that CMS clarify that the 60 days begins once the organization has identified the exact amount of the overpayment. The commenter suggested, as an alternative, that if the MA organization or Part D sponsor has notified CMS that it believes there is an overpayment, but it will take more than 60 days to determine the exact amount, CMS consider allowing a ''tolling'' of the 60 days so that the organization may determine the amount it must return to CMS. Under this ''tolling'' process, the organization would be required to notify CMS within 60 days of identifying that an overpayment likely exists, but would be provided additional time by CMS to determine the exact amount.

Response: We have not used the phrase ''exact amount'' in this rule-making. For the MA and Part D programs, we define overpayment in the regulation as ''funds'' the organization has received to which it is not entitled, and then defines ''funds'' as any payment based on data submitted by an MA or Part D organization. Because of the nature of the Part C and Part D programs, the key focus in implementing these statutory provisions for the MA and Part D programs is thus correcting the incorrect data that the organization submitted to CMS that resulted in an overpayment. We will then run reconciliation on its routine operational schedule to recover overpayment amounts based on the corrected data. The purpose of the 60 days is to provide the MA or Part D organization with sufficient time to correct the incorrect data submitted to CMS using established data correction processes. MA organizations and Part D sponsors are deemed to have returned the overpayment when they have taken the actions to submit the corrected data that is the source of the identified overpayment. Within the 60 days the MA organization and Part D sponsor must also report the overpayment amount (or estimated amount). If an estimated overpayment amount is reported, it may be higher or lower than the actual overpayment amount recovered because additional payment data submitted into the CMS payment system from other sources may be incorporated into the payment calculations.

Comment: A commenter stated that it is unclear what may occur post-reconciliation if both parties have been overpaid. For example, if CMS owes the Part D sponsor $10 million due to activity post-reconciliation and a $2 million overpayment is discovered, the commenter questioned whether we will still require that the $2 million be refunded within 60 days or whether the sponsor will be allowed to offset amounts owed by CMS. The commenter recommended that if an overpayment would be reduced or fully covered by a reopening, that CMS allow sponsors to request a reopening and offset the reopening amount due from the

overpayment pending completion of the reopening.

Response: For both the Part C and Part D programs, the provisions regarding reporting and returning identified overpayments become effective the day after the date of applicable reconciliation. As we have stated, MA organizations and Part D sponsors are deemed to have returned the overpayment when they have submitted corrected data that is the source of the overpayment. We will recover the overpayment amount through routine processing. For Part D, that means that if an overpayment is discovered after the initial reconciliation but prior to the reopening described at § 423.346, a Part D sponsor may request a reopening and submit the corrected data to fulfill its obligation to return the overpayment. The overpayment will be reconciled through the routine reopening process.

Comment: A commenter stated that the onus on plans for the calculation of an overpayment amount creates a risk that CMS may be overpaid/underpaid in the monies returned.

Response: As explained in proposed rule (79 FR 1997), we will recover overpayments through the correction of erroneous data and established payment adjustment processes. Therefore, we believe that the risk the commenter mentions does not exist because CMS' systems will calculate the exact amount to be recovered.

Comment: A few commenters objected to the fact that the proposed rule does not address situations in which a sponsor has overpaid CMS, and requested that this regulation also set forth rules by which CMS handles an organization's overpayments to CMS.

Response: This final rule is intended to implement section 1128J(d) of the Act, which pertains only to overpayments the government made to contracting MA organizations and Part D sponsors.

Comment: A commenter requested that MA organizations and Part D sponsors be able to submit auditable estimates of an overpayment in lieu of determining which data is in error and submitting corrected data, given the fact that the administrative costs of determining a specific set of data deletes is significant relative to the size of the issue. The commenter recommended that CMS permit plans to proactively suggest the use of such tools to resolve potential overpayments.

Response: The use of auditable estimates is intended only for a limited set of circumstances. This may occur, for example, when the Part D reopening occurs prior to the end of the look-back period or if an MA organization or Part D sponsor had a thoroughly-documented catastrophic loss of stored data. Information about the nature of such a request would be detailed in forthcoming operational guidance. Therefore, we will not allow, on a routine basis, submission of auditable estimates in lieu of submission of corrected data. By recovering overpayments based on the corrected payment data, we will be more likely to ensure that the most accurate overpayment amounts are returned to the Medicare Trust Fund.

Comment: A commenter expressed concern that this final rule could impose a boundless duty to troll medical records in search of unknown vulnerabilities, and requested that CMS make clear that Part C and Part D plans are not obliged to proactively search for an overpayment without reason to believe that a specific overpayment exists.

Response: The focus of this final rule is on ensuring that MA and Part D organizations return an overpayment when it is identified. For many years organizations have been obliged to submit accurate, complete, and truthful payment-related data, as described at §§ 422.504(l) and 423.505(k). Further, CMS has required for many years that diagnoses that MA organizations submit for payment be supported by medical record documentation. Thus, we have always expected that MA organization or Part D sponsor implement, during the routine course of business, appropriate payment evaluation procedures in order to meet the requirement of certifying the data they submit to CMS for purposes of payment. Therefore, we do not believe that §§ 422.326 and 423.360 represent such a new requirement.

Comment: A commenter requested that CMS confirm that the data submission requirement under this section is based on enrollment data and risk adjustment scores, and thus does not apply to direct overpayments from providers.

Response: Once an overpayment is identified, the MA or Part D organization is responsible for correcting the data that caused the overpayment. This is data that is routinely submitted to CMS for payment purposes, such as, risk adjustment data.

Comment: A commenter requested that CMS clarify if changes in a beneficiary's low income subsidy (LIS) status could result in an overpayment under this provision.

Response: As we stated in the proposed rule, we believe that MA organizations and Part D sponsors cannot be held accountable for the accuracy of the data controlled and submitted to CMS by other entities. (We emphasize here that the term ''other entities'' used to discuss these overpayment provisions does not include the following parties referenced in §§ 422.504(i) and 423.505(i): first tier, downstream, and related entities, contractors, or subcontractors to the MA organization or Part D sponsor.) It is the Social Security Administration and the states that notify CMS of individuals whom they have determined to be eligible for the Part D LIS. We in turn provide the subsidy information, including effective date and level of subsidy, to the Part D plan in which the beneficiary enrolls. Although, we will not consider an overpayment to have occurred strictly due to changes in a beneficiary's LIS status, Part D sponsors are required to adjust prescription drug event (PDE) data to accurately reflect the beneficiary's LIS status.

Comment: A commenter supported our proposal for when overpayments have been identified.

Response: We appreciate the commenter's support for our proposal.

Comment: A few commenters requested that CMS provide more clarity or an example of what is meant by ''acts in reckless disregard or deliberate ignorance.''

Response: We are revising our definition of an identified overpayment to state that an MA organization or Part D sponsor has identified an overpayment when it has determined, or should have determined through the exercise of reasonable diligence, that the MA organization or Part D sponsor has received an overpayment.

As to the circumstances that give rise to a duty to exercise reasonable diligence, we are not able to anticipate all factual scenarios in this rulemaking. MA organizations and Part D sponsors are responsible for ensuring that payment data they submit to CMS are accurate, truthful, and complete (based on best knowledge, information, and belief), and are expected to have effective and appropriate payment evaluation procedures and effective compliance programs as a way to avoid receiving or retaining overpayments. Thus, at a minimum, reasonable diligence would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments. However, conducting proactive compliance activities does not mean that the person has satisfied the reasonable diligence standard in all circumstances. In certain circumstances, for example, reasonable diligence might require an investigation conducted in good faith and in a timely manner by

qualified individuals in response to credible information of a potential overpayment.

We note that in discussing the standard term ''reasonable diligence'' in the preamble, we are interpreting the obligation to ''report and return the overpayment'' which is contained in section 1128J(d) of the Social Security Act. We are not seeking to interpret the terms ''knowing'' and ''knowingly'', which are defined in the Civil False Claims Act and have been interpreted by a body of False Claims Act case law.

Comment: Some commenters thought that we had an overly broad interpretation of the statute and that there was no statutory basis for CMS to interpret the term ''identified'' in section 6402 of the Affordable Care Act to include ''reckless disregard or deliberate ignorance of the existence of the overpayment.'' A commenter stated that the term ''knowing'' is not actually used in the overpayment standard set forth in section 6402(d) of the Affordable Care Act, so the mere existence of an errant reference to the False Claims Act definition of ''knowing'' does not give CMS sufficient basis to apply the expansive False Claims Act knowledge standard to the definition of ''identified'' under section 6402. This commenter noted that in an earlier version of the Affordable Care Act, H.R. 3962, used the False Claims Act knowledge standard in the section on reporting and returning of overpayments. The commenter also stated that the final version of the Affordable Care Act enacted by the Congress used the term ''identified,'' and not the word ''knowledge.'' This commenter believed that the Congress's explicit rejection of the False Claims Act knowledge standard, and use of the term ''identified'' in the final legislative language weighs against incorporating the False Claims Act knowledge standard into the regulatory provision.

Response: We disagree with the commenters' arguments. While we acknowledge that the terms ''knowing'' and ''knowingly'' are defined but not otherwise used in section 1128J(d), we believe that the Congress intended for section 1128J(d) to apply broadly. If the requirement to report and return overpayments applied only to situations where the MA organization or Part D sponsor has actual knowledge of the existence of an overpayment, then these entities could easily avoid returning improperly received payments and the purpose of the section would be defeated. Thus, we decline to read a narrow actual knowledge limitation into the law as suggested by commenters.

Comment: Several commenters recommended that CMS remove the language relating to ''reasonable diligence'' from the proposed regulation. These commenters believed that an identified overpayment should be limited to actual knowledge of an overpayment.

Response: For the reasons discussed previously, we decline to read a narrow actual knowledge limitation into the law as suggested by commenters.

Comment: A few commenters were concerned that by adding a reasonable diligence requirement, CMS appears to be suggesting that a much lower level of sponsor behavior—a failure to act reasonably—could trigger potential False Claims Act liability. One commenter stated that the phrase ''reasonable diligence'' is not a recognized or defined standard and is overly vague as to the obligations of plans to follow through on information received regarding a potential overpayment. The commenters have serious concerns about the implication of such a standard.

Response: We understand the commenters' concerns. However, we do not believe that it is inappropriate to expect that MA organizations and Part D sponsors act reasonably. We note that it is the statute that establishes liability under the False Claims Act for failure to report and return identified overpayments, pursuant to section 1128J(d)(3).

c. Look-Back Period for Reporting and Returning Overpayments

We proposed at §§ 422.326(e) and 423.360(e) to codify a look-back period for MA organizations and Part D sponsors. MA organizations and Part D sponsors would be required to report and return any overpayment that they identify within the 6 most recent completed payment years. The statute of limitations related to the False Claims Act is 6 years from the date of the violation or 3 years from the date the relevant government official learns of the situation, but in no case more than 10 years from the date of the violation. CMS proposed 6 years as the look-back period because we believe this best balances government's interest in having overpayments returned with entities' interest in finality. Six years also is consistent with the CMP provisions, and maintenance of records requirements under the contracts. We also proposed that overpayments resulting from fraud would not be subject to this limitation of a look-back period.

We received the following comments on the look-back period, and our responses follow.

Comment: We received a few comments recommending that we shorten the 6-year look-back period. A commenter noted that permitting greater finality in overpayment reporting and recovery will decrease administrative costs and free up resources to focus on benefits. This commenter also stated that an organization would have to retain a significant amount of documentation to fully support and justify payments, more than what they would retain under CMS's 10-year record retention requirement. Several commenters recommended that the look-back period be 3 years to align with the RAC look-back period. A commenter noted that the 3-year period would also be consistent with the federal government's treatment of government contractors that are subject to the Federal Acquisition Regulation. A couple of commenters recommended that we implement a 4-year look-back period to align with the 4-year period that Medicare Administrative Contractors can reopen Medicare fee-for-service payment determinations.

Response: We disagree with the commenters' recommendations to shorten the look-back period. We note that section 1128J(d) of the Act has no time limit to the obligation to report and return overpayments received by a provider or supplier. However, as we stated in the preamble to our proposed rule and again in this preamble to our final rule, we proposed 6 years as the look-back period because we believe this best balances government's interest in having overpayments returned with entities' interest in finality. Six years is consistent with the CMP provisions, and maintenance of records requirements under the contracts. It is also consistent with the False Claims Act in that the statute of limitations related to the False Claims Act is 6 years from the date of the violation or 3 years from the date the relevant government official learns of the situation, but in no case more than 10 years from the date of the violation. We believe that our final rule does not create additional recordkeeping burden or cost. Under § 422.504(d) and § 423.505(d), MA organizations and Part D sponsors are required to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices related to costs, financial statements, cash flow, etc.

Comment: A commenter requested that CMS clarify the parameters of the 6-year look-back provision.

Response: As we stated in the preamble to the proposed rule and this

final rule and again in §§ 422.326(e) and 423.360(e), MA organizations and Part D sponsors are required to report and return any overpayment that they identify within the 6 most recent completed payment years. That would mean, for example, after the initial reconciliation that takes place for Part D payments (that is, the determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336) for contract year 2015 (which will take place at the end of 2016), Part D sponsors are obligated to report and return overpayments under § 423.360 for contract years 2010 through 2015.

Comment: A few commenters recommended that CMS impose the same limitation on the look-back period for all overpayments, even those relating to fraud. A commenter noted that under the statutory scheme set forth in section 6402 of the Affordable Care Act, the existence of an overpayment does not depend on, or otherwise reflect, the existence of fraud. Commenters also requested clarification from CMS whether MA organizations and Part D sponsors that become aware of an overpayment prior to the look-back period have an obligation to investigate and determine whether that overpayment resulted from fraud. These commenters were concerned that MA organizations and Part D sponsors would have to investigate potential overpayments indefinitely, no matter how far in the past they may have occurred, because these organizations would have to determine whether there was any fraud in connection with the potential overpayment in order to determine whether a reporting obligation exists.

Response: Upon further review, we agree with the commenters' suggestion that CMS impose the same limitation on the look-back period for all overpayments. Six years is consistent with the more commonly applicable FCA statute of limitations as well as the statute of limitations under section 1128A of the Act. Therefore, we have elected to establish a 6-year look-back period regardless of the nature of the overpayment, and we have amended the regulation text at §§ 422.326(e) and 423.360(e) accordingly. We note that the government may have other avenues for pursuing the return of overpayments due to false and fraudulent claims outside of these provisions.

Finally, we note that an MA organization's and Part D sponsor's obligation to investigate and identify false and fraudulent claims is outside the scope of this final rule.

After consideration of the public comments received on the overpayment provisions, we are finalizing as proposed the following provisions: §§ 422.1, 422.300, 422.504(l), 423.1, and 423.505(k). We are finalizing the provisions at § 422.326, with the following modifications. First, we add at the end of paragraph (d) the phrase ''unless otherwise directed by CMS for the purpose of § 422.311.'' Second, we strike the following sentence in the proposed paragraph on the six-year look-back period: ''Overpayments resulting from fraud are not subject to this limitation of the lookback period.'' To increase clarity we also revise paragraph (c) regarding identified overpayments. We also are making a technical correction by redesignating proposed paragraph (d)(3) on enforcement as paragraph (e), and redesignating proposed paragraph (e) on the six-year look-back period as paragraph (f), and revising new paragraph (e) on enforcement to say ''Any overpayment retained by an MA organization is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) above.''

Finally, we are finalizing the provisions at § 423.360 with the following modifications. We strike the following sentence in the proposed paragraph on the six-year look-back period: ''Overpayments resulting from fraud are not subject to this limitation of the lookback period.'' To increase clarity we also revise paragraph (c) regarding identified overpayments. We also are making a technical correction by redesignating proposed paragraph (d)(3) on enforcement as paragraph (e), and redesignating proposed paragraph (e) on the six-year look-back period as paragraph (f), and revising new paragraph (e) on enforcement to say ''Any overpayment retained by a Part D sponsor is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d).''

2. Risk Adjustment Data Requirements (§ 422.310)

We proposed several amendments to § 422.310 to strengthen existing regulations related to the accuracy of risk adjustment data. We proposed to renumber existing paragraph § 422.310(e) as paragraph (e)(2) and add new paragraph (e)(1), which would require that any medical record reviews conducted by an MA organization must be designed to determine the accuracy of diagnoses submitted under §§ 422.308(c)(1) and 422.310(g)(2). Under our proposal, medical record reviews conducted by an MA organization could not be designed *only* to identify diagnoses that would trigger additional payments by CMS to the MA organization; medical record review methodologies would have to be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments.

We also proposed to amend § 422.310(g) regarding deadlines for submission of risk adjustment data; our proposal was to restructure and revise subparagraph (g)(2) and add subparagraph (g)(3). Our current procedures generally permit submission of risk adjustment data after the final risk adjustment submission deadline only to correct overpayments. Thus, we proposed, at § 422.310(g)(2)(ii) to explicitly permit late submissions only to correct overpayments but not to submit diagnoses for additional payment so that the regulation text would be consistent with our procedures.

Finally, we proposed to make two additional changes in paragraph (g). First, we proposed the deletion of the January 31 deadline in paragraph (2) and replacing it with the statement that CMS will announce the deadline by which final risk adjustment data must be submitted to CMS or its contractor. We noted that the risk adjustment data submission deadline would also function as the Part C applicable reconciliation date for purposes of proposed § 422.326 on overpayment rules, also discussed in this final rule. Second, we proposed adding paragraph (3) to § 422.310(g). Proposed paragraph (3) cites § 422.326 as the source of rules for submission of corrected risk adjustment data after the final risk adjustment data submission deadline, that is, after applicable reconciliation as defined at § 422.326(a).

In response to the January 10, 2014 proposed rule, we received approximately 25 pieces of correspondence from organizations and individuals regarding these proposals. We received the following public comments and our responses follow.

Comment: Many commenters expressed concern about the vagueness and overly broad statement of CMS' proposal to amend § 422.310(e) to require that medical record reviews conducted by MA organizations be designed to determine the accuracy of diagnoses they submitted to CMS. Some commenters thought this implied a requirement to verify every diagnosis

submitted by every provider, while others thought this implied a restriction on the ability of plans to identify what medical records to review. Other commenters believed the proposed amendment limited plans' ability to review medical records for operational purposes other than risk-adjusted payment, such as focusing on only a portion of a medical record for a subset of beneficiaries in order to enhance HEDIS scores, conduct contract compliance reviews, and validate claims processing and billing.

Finally, a few commenters argued that CMS should offset the payment impact of diagnoses an MA organization submitted to CMS that were later found through medical record reviews to not be supported by medical record documentation by adjusting the amount of CMS' overpayment to the MA organization for the level of error in equivalent diagnoses in FFS claims data. Specifically, the commenters argued that CMS should give MA organizations a credit for erroneous diagnoses they submitted from their providers' claims up to the rate identified by CMS as the applicable FFS Adjustor in the RADV program. The commenters also argued that there is no reason to require that both MA and FFS diagnosis data be scrutinized for error rates when determining retroactive payment adjustments, while not engaging in a similar adjustment process when paying plans prospectively.

Response: We thank the commenters for their input. We are not finalizing the proposed amendment to § 410.322(e).

However, we emphasize that our decision to not finalize this regulatory proposal does not change CMS' existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS. Further, this decision does not change the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation.

Comment: A few commenters supported CMS' proposal to remove the current date of January 31 as the annual final risk adjustment data submission deadline and replace it with the provision that CMS will announce the deadline annually, with the proviso that CMS' timing of this annual deadline always allows sufficient opportunity for organizations to make final data submissions. Several other commenters stated their concern about this proposed change in deadline, including a concern that CMS might announce a deadline earlier than January 31 in some years. These commenters requested that CMS clarify that the annual deadline would never be before January 31, and a few commenters suggested that the regulation state that the deadline is January 31 but may be extended. Finally, a few commenters requested that CMS not change the January 31 date to a floating date, in order to allow operational stability.

Response: We are not finalizing this proposal at this time.

Comment: Many commenters disagreed with CMS' proposal under § 410.322(g)(2) that, after the final risk adjustment data submission deadline, CMS would permit submission of data to correct overpayments but not permit late submission of diagnosis data that would result in additional payment, asserting that this asymmetrical approach does not promote CMS' stated goal of improving payment accuracy. The commenters maintained that an MA organization should be allowed to submit additional diagnoses after the final risk adjustment data submission deadline to correct not only an overpayment to the MA organization, but also an underpayment. A commenter recommended that, after the final deadline, MA organizations should be able to submit paired deletions-additions of diagnoses as long as the result is not an increased payment to the organization but a smaller reduction in payment than would otherwise occur if only the deletion were submitted; for example, an MA organization may want to delete the diagnosis code for diabetes with acute complications and replace it with the code for diabetes without complications so that it loses only some of the payment. Finally, a commenter requested that CMS allow exceptions to the general rule that no new diagnoses may be submitted after the final risk adjustment data submission deadline for special circumstances such as system failures, file formatting issues, and other technical problems.

Response: For a given payment year (which is a calendar year), CMS applies diagnoses from the previous year (the data collection year) to calculate beneficiary risk scores used to risk-adjust payments to MA organizations in the payment year. MA organizations must finalize any corrections and new submissions of diagnosis data for a data collection year by January 31 of the year after the payment year. That is, we allow 13 months after the end of the diagnosis year for MA organizations to identify errors in data they have submitted (that is, deleting diagnoses from CMS' systems) and to identify and submit additional diagnoses that were not submitted during the diagnosis year. We believe that is a very reasonable period of time to finalize risk adjustment data for a diagnosis year.

These risk adjustment processes have been in place for many years, and we believe it is the responsibility of MA organizations to have internal audit processes in place allowing them to finalize their risk adjustment data for a payment year by the conclusion of this 13-month period. Therefore, we are finalizing, as proposed, the provision codified at § 422.310(g)(2)(ii) that, after the final deadline, an MA organization may submit risk adjustment data to correct overpayments but not to add payments.

Comment: A commenter supported CMS' proposal to limit post-deadline modifications to deletions of incorrect diagnoses but requested that CMS offer one additional opportunity to eliminate unsupported diagnosis codes in advance of a RADV audit.

Response: When we are preparing to initiate a RADV audit cycle, all MA organizations are notified that they should eliminate unsupported diagnoses from CMS' systems by a date specified in the notice. Subsequently, we inform the contracts that have been selected for RADV.

In summary, after consideration of the public comments received, we are not finalizing the proposed amendment to § 410.322(e). Also, we are not finalizing at this time our proposal at § 422.310(g)(2)(ii) to remove the current date of January 31 as the annual final risk adjustment data submission deadline and replace it with the provision that CMS will announce the deadline annually. We are finalizing as proposed the restructuring of §§ 422.310(g)(2) and the 422.310(g)(2)(ii) provision to prohibit submission of diagnoses for additional payment after the final risk adjustment data submission deadline. We did not receive any comments on subparagraph (g)(3) and are finalizing it as proposed.

3. RADV Appeals

a. Background

We published final Risk Adjustment Data Validation (RADV) appeals regulations in the April 15 2010 **Federal Register** (75 FR 19677). These rules were proposed and finalized under our authority to establish Medicare Advantage (MA) program standards at section 1856(b)(1) of the Act and are found at § 422.311 et seq. Since finalizing these rules in 2010, we conducted additional RADV audits and determined that some of the appeals

provisions finalized in the 2010 RADV Appeals final rule should be modified to strengthen and streamline the RADV appeals process and to prevent confusion. Therefore, we proposed revisions to the RADV appeals regulations on January 10, 2014. These proposed RADV provisions will apply to any RADV determinations issued on or after the effective date of this regulation.

We proposed changing certain RADV definitions at § 422.2. Specifically, we proposed removing the definition Initial Validation Contractor (IVC); removing the definition of RADV payment error calculation appeal process; and removing the definition of ''One Best Medical Record for the purposes of Medicare Advantage Risk Adjustment Data Validation (RADV)''. In addition, we proposed adding one new definition by specifically defining the RADV appeals process. We also proposed revising the definitions of ''Risk Adjustment Data Validation (RADV)'' and ''attestation process'' within the RADV appeals context. Furthermore, we proposed amending RADV definitions at § 422.2 to specify that the Secretary, along with CMS, could conduct RADV audits.

At § 422.311, we proposed to update select RADV appeals terminology. We proposed amending the RADV regulations by adopting one common term to refer to RADV audit reports: ''RADV Audit Report''. As mentioned earlier, we proposed removing from the RADV regulations the term—''Initial Validation Contractor, or IVC,'' since RADV medical record review process no longer utilizes ''initial'' and ''secondary'' validation contractors to conduct medical record review under RADV. Instead, we now utilize medical record reviewers to code medical records who may be employed by the same or different medical record review contractors.

At § 422.311(c)(1), we proposed to simplify the RADV appeals process by combining the two existing RADV appeal procedures—one for medical record review and one for payment error calculation—into one set of requirements and one process comprised of three administrative steps: Reconsideration, hearing officer review, and CMS Administrator-level review. Combining these existing RADV medical record review determination and payment error calculation appeals policies and processes improves the overall appeals process by simplifying the overall RADV appeals process and reducing burden on all parties involved in the RADV appeals process. We also believed that doing so improves overall RADV appeals procedures by providing clarity that leads to greater efficiencies in adjudicating RADV appeals. Within this overall framework, we also proposed defining issues that would be eligible for RADV appeal at § 422.311(c)(2) and issues that would not be eligible for RADV appeals under this combined-appeal process at § 422.311(c)(3). We further proposed defining the manner and timing of a request for RADV appeal at § 422.311(c)(2)(iii), a reconsideration process at § 422.311(c)(6), a hearing process at § 422.311(c)(7)(iv), and an Administrator-level review at § 422.311(c)(8).

At § 422.311(a), we proposed that the Secretary, along with CMS, be permitted to conduct RADV audits beginning with the effective date of this regulation. Because of the absence of a clearly-defined burden of proof standard for RADV medical record review determination appeals, at § 422.311(c)(4) we proposed adoption of a burden of proof standard for all RADV determinations—be they payment error calculation or RADV medical record review determinations—whereby the burden would be on MA organizations to prove, based on a preponderance of the evidence, that CMS's determination(s) was (were) erroneous. At § 422.311(b)(2) we proposed changing the compliance date for meeting RADV audit requirements for the validation of risk adjustment data to the due date when MA organizations selected for RADV audit must submit medical records to the Secretary—and not only CMS.

We received comments from health plans, managed care industry trade associations, providers, provider trade associations and other interested parties. These comments have resulted in changes to the previously described proposals, as discussed later in this section. Some of the comments we received did not apply to the proposed RADV appeals processes. However, because some of these comments apply to underlying RADV audit process, we are responding to certain comments because they appear to be relevant to the RADV appeals process. Other comments were clearly outside the scope of our proposed rule, so we have not included responses to those comments.

b. RADV Definitions

We proposed to amend the RADV definitions at § 422.2 as follows:

• Removing the following definitions:

++ ''Initial Validation Contractor (IVC)'' means the first level of medical record review under the RADV audit process.

++ ''RADV payment error calculation appeal process'' means an administrative process that enables MA organizations that have undergone RADV audit to appeal the CMS calculation of an MA organization's RADV payment error.

++ ''The one best medical record for the purposes of Medicare Advantage Risk Adjustment Validation (RADV)'' means the clinical documentation for a single encounter for care (that is, a physician office visit, an inpatient hospital stay, or an outpatient hospital visit) that occurred for one patient during the data collection period. The single encounter for care must be based on a face-to-face encounter with a provider deemed acceptable for risk adjustment and documentation of this encounter must be reflected in the medical record.

• Adding the following definition:

++ ''RADV appeal process'' means an administrative process that enables MA organizations that have undergone RADV audit to appeal the Secretary's medical record review determinations and the Secretary's calculation of an MA organization's RADV payment error.

• Revising the following definitions:

++ Risk adjustment data validation (RADV) audit means a payment audit of a Medicare Advantage (MA) organization administered by CMS or the Secretary that ensures the integrity and accuracy of risk adjustment payment data.

++ ''Attestation process'' means a CMS-developed RADV process that enables MA organizations undergoing RADV audit to submit CMS-generated attestations for eligible medical records with missing or illegible signatures or credentials. The purpose of the CMS-generated attestations is to cure signature and credential issues for eligible medical records. CMS-generated attestations do not provide an opportunity for a provider or supplier to replace a medical record or for a provider or supplier to attest that a beneficiary has the medical condition.

We received no comments specifically recommending modifications to the proposed definitions as stated, though we did receive comments regarding the policy behind some of these definition changes. The policy comments will be addressed later in this rule, though we are finalizing the specific definitions without modification.

c. Publication of RADV Methodology

In the October 22, 2009 proposed rule, and as reinforced in the April 15, 2010 final rule, we indicated that we would, ''publish its RADV methodology in some type of public document—most

likely, a Medicare Manual, so that the public can review and provide comment as it deems necessary''. We also indicated that we would provide an annual notice of RADV audit methodology. Our last RADV-related notice of methodology was published in February 2012. We will continue to publish a notice of the methodology employed, but will do so only if there is a change in the RADV methodology that would require publication. We note that these notices of RADV audit methodology updated information provided on RADV audit methodology provided in the October 22, 2009 proposed rule and April 15, 2010 final rule.

In addition, we provided in the October 22, 2009 proposed rule preamble that we would provide an expanded explanation of methodology and payment error calculation factors as a part of each audit report of findings that we send to MA organizations that undergo RADV audit. Such explanation and factors have been and will continue to be part of the RADV audit report(s) that CMS provides health plans that have undergone RADV audits.

d. Proposal To Update RADV Appeals Terminology (§ 422.311)

Current RADV regulations utilize the following terms for the CMS-issued RADV audit report: Audit report post medical record review; RADV audit report; IVC-level RADV audit report; and RADV audit report of finding. This use of multiple terms to refer to what is the same audit report (the RADV audit report that CMS issues following conclusion of the medical record review portion of the audit) is potentially confusing. Therefore, we proposed amending the RADV regulations throughout to adopt one common term to refer to RADV audit reports: ''RADV Audit Report''. By standardizing terminology throughout the RADV regulations, the proposed amendment provides clarity which may lead to increased efficiency.

As mentioned earlier in the description of RADV-related definitions that have changed, we have revised certain RADV-related definitions to accommodate changes to both the RADV audit process and the RADV appeals process. One definition that we have removed from the RADV regulations is Initial Validation Contractor, or IVC. The RADV medical record review process no longer utilizes ''initial'' and ''secondary'' validation contractors to conduct medical record review under RADV. Instead we now utilize medical record reviewers to code medical records undergoing RADV review. These reviewers may be employed by the same or different medical record review contractors. Therefore, the term ''IVC'' is no longer relevant to the RADV audit process. As a result, we proposed to remove this term from the RADV regulations at the following citations: § 422.311(c)(2)(i)(B) through (D); § 422.311(c)(2)(ii)(B), § 422.311(c)(2)(iii)(A), § 422.111(c)(2)(v), (vi), § 422.311(c)(3)(ii)(A), and § 422.311(c)(3)(iii)(A) and (B). We invited comment on this proposal.

Comment: A commenter requested that CMS verify that the medical record review error determination standard, which presently requires multiple review determinations by independent coders to confirm a CMS–HCC coding error, remains in effect and is not altered by this proposed rule.

Response: While we did not propose RADV coding changes, we believe the question merits a response. We believe that our proposal to remove the definition of ''Initial Validation Contractor'' (IVC) may have led some to believe that we were abandoning RADV audit processes that require multiple levels of independent medical record review (coding) by independent reviewers before we will confirm a CMS–HCC coding error. This standard has not changed, notwithstanding the removal of the term IVC from the RADV appeals rules. We continue to utilize medical record reviewers to code medical records undergoing RADV review, though these reviewers may now be employed by the same or different medical record review contractors. The principle of independent review and multiple confirmations of an identified CMS–HCC remain in effect.

e. Proposal To Simplify the RADV Appeals Process

Currently, there are two types of RADV-related appeals processes described in our regulations at § 422.311: Medical record review-determination appeals and RADV payment error calculation appeals. RADV medical record review-determination appeal requirements and procedures are discussed at § 422.311(b)(3) and § 422.311(c)(2). Medical record review determination appeal is a two-stage administrative appeal process—the first step is a hearing by a hearing officer, followed by a CMS Administrator—level review. This appeal procedure provides MA organizations with an opportunity to appeal RADV medical record review determinations that are made by coders reviewing the medical record documentation submitted by MA organizations undergoing RADV audit. The second type of RADV appeal, payment error calculation appeal, is discussed at § 422.311(c)(3). Payment error calculation appeal is a three-pronged appeal process: reconsideration, followed by a hearing officer review, followed by CMS Administrator—level review. This appeal process was specifically designed to afford MA organizations the opportunity to appeal CMS's contract-level RADV payment error calculation.

We proposed that the administrative appeals language described at § 422.311(b)(3) and § 422.311(c)(2) for RADV medical record review determination appeals and § 422.311(c)(3) for RADV payment error calculation appeals be replaced with new regulatory language proposed § 422.311(c)(1), that combines the two existing RADV appeal policies and procedures into one set of requirements and one process. We proposed to combine the two RADV appeals processes into one combined RADV appeals process that is comprised of three administrative steps: Reconsideration, hearing officer review, and CMS Administrator-level review. A three-step administrative appeals process comprising reconsideration, hearing officer review, and Administrator-levels of review is a common administrative appeals model used elsewhere within the Medicare managed care program, such as in appealing contract award determinations and intermediate sanctions. The combined RADV appeal process that we proposed at new § 422.311(c)(1), also has the benefit of simplifying what is today a complex two-track appeal process into one process. While both CMS and the MA industry will benefit from simplifying this process, MA organizations also obtain an additional level of review under the combined approach since MA organizations will be afforded a reconsideration appeal step for medical record review determinations that is today—not part of the existing RADV appeal process. Shortening the existing two-track appeal process should also reduce the resources and level of effort needed from both MA organizations and CMS in participating in a RADV appeal proceeding. Under this proposal, MA organizations can simply request to appeal their RADV audit findings one time and specify whether they want to appeal either their medical record review determination(s), payment error calculation, or both. The specific details regarding this proposed process follow. We proposed these changes based upon

our experience with RADV appeals and because we hope to reduce the burden associated with undertaking RADV appeals on both MA organizations and CMS. The details of the proposed policy and procedure follow.

(1) Issues Eligible for RADV Appeal

Current regulations at §§ 422.311(c)(2) et seq., and 422.311(c)(3) et seq., specify RADV-related medical record review and payment error calculation documents and issues eligible for the medical record review determination and payment error calculation appeal processes. We proposed to amend the policies and procedures around issues eligible for RADV appeals at § 422.311(c)(2) and § 422.311(c)(3) by combining proposed policies and procedures for the existing two-pronged appeal approach into one set of policies and procedures for RADV appeals at the new § part 422.311(c)(2)(iv). At § 422.311(c)(2)(i), we proposed that as a general rule, MA organizations may appeal RADV medical record review determinations and RADV payment error calculation, though in order to be eligible to pursue these appeals, we specify at proposed § 422.311(c)(2)(i)(A) and (B) that MA organizations must adhere to established RADV audit procedures and requirements and adhere to RADV appeals procedures and requirements. At § 422.311(c)(2)(ii) we proposed that failure to follow RADV audit procedures and requirements and RADV appeals procedures and requirements will render the MA organization's request for RADV appeal invalid. Furthermore, at proposed § 422.311(c)(2)(iii) we stipulate that the MA organization's written request for medical record review determination appeal must specify the audited HCC(s) that have been identified pursuant to RADV audit as being in error, and further specify that MA organizations must provide a justification in support of the audited HCC(s) that the MA organization elects to appeal. At § 422.311(c)(2)(i)(iv) we proposed that for each audited HCC, MA organizations may appeal one medical record that has undergone RADV medical record review and that if an attestation was submitted to cure a signature or credential issue, that attestation may likewise be included in the HCC appeal. For example, if an MA organization submitted a medical record that did not contain a signature and/or credential—and the MA organization submitted an attestation to cure the error that CMS subsequently failed to accept—the MA organization could choose to appeal CMS's determination to not accept the submitted attestation. We reiterate that the purpose of CMS-generated attestations is to cure signature and credential errors associated with an eligible submitted medical record and not to provide an opportunity for a provider or supplier to attest that a beneficiary has a certain medical condition. Evidence for the existence of the medical condition is found in a medical record.

We proposed to modify our language at § 422.311(c)(2)(i)(v) to clarify existing RADV appeals provisions which stipulate that MA organizations must adhere to the ''one best medical record'' policy. Under changes to the RADV audit methodology announced by CMS in February 2012, we now allow MA organizations to submit more than one medical record (that is, more than the ''one best medical record'') during the RADV audit process to validate an audited CMS–HCC. However, for purposes of appealing a CMS medical record review determination, we will not permit organizations to appeal multiple medical records but will instead—require that MA organizations identify a record from amongst those records submitted, and to submit that record for appeal. For each audited HCC, MA organizations may appeal only one medical record that has undergone RADV review. This policy was published in the February 2012 White Paper and is not included in this final rule.

At § 422.311(c)(2)(vi) we proposed that a written request for RADV payment error calculation appeal must clearly specify the MA organization's own RADV payment error calculation and must also specify where the payment error calculation was erroneous.

(2) Issues Not Eligible for RADV Appeals

At § 422.311(c)(3) we proposed documents and issues that are ineligible for RADV appeals. Consistent with the overall approach of combining into one RADV appeals process what was heretofore two separate RADV appeals processes—by way of this new proposed section, we propose to amend existing regulations at § 422.311(c)(3). At new § 422.311(c)(3), we proposed that MA organizations' request for appeal may not include HCCs, medical records or other documents beyond the audited HCC, selected medical record and any accompanying attestation that the MA organization chooses to appeal. We specify at § 422.311(c)(3)(ii) that the MA organizations may not appeal CMS's medical record review determination methodology or CMS's payment error calculation methodology. This is a clarification to existing RADV regulations at § 422.311(c)(3)(D) which specifies that MA organizations may not appeal CMS's payment error calculation methodology. At § 422.311(c)(3)(iii) we specify that MA organizations may not appeal RADV medical record review-related errors when appealing RADV error-calculation issues since medical record review determination issues must be resolved before we can calculate RADV payment errors. And at § 422.311(c)(3)(iv) we specify that RADV errors that result from an MA organization's failure to submit a medical record are not eligible for appeal.

(3) Manner and Timing of a Request for RADV Appeal

We proposed to replace existing RADV regulations at § 422.311(c)(2)(iii) et seq., and § 422.311(c)(3)(iii) et seq., regarding the manner and timing of a request for RADV appeals. Again, at § 422.311(c)(5), we proposed to combine the formerly two separate sets of requirements and procedures into one RADV appeals process addressing the request for RADV appeal. At § 422.311(c)(5)(i) we proposed that at the time the Secretary issues her RADV audit report, the Secretary notifies audited MA organizations that they may appeal RADV HCC errors that are eligible for medical record review determination appeal and may appeal the Secretary's RADV payment error calculation. At § 422.311(c)(5)(ii) we specify that MA organizations have 30 days from the date of CMS's issuance of the RADV audit report to file a written request with CMS for RADV appeal. This request for RADV appeal must specify whether the MA organization requests medical record review determination appeal, whether the MA organization requests RADV payment error calculation appeal, or whether the MA organization requests both medical record review determination appeal and RADV payment error calculation appeal—and in each instance—the issues with which the MA organization disagrees, and the reasons for the disagreements. See proposed regulations at § 422.311(c)(6).

In proposed § 422.311(c)(5)(ii), we specify that while MA organizations may now elect to appeal either medical record review determination, payment error calculation, or both—they must notify CMS which issues they will appeal at the same time. This new provision replaces existing RADV appeals requirements regarding notification at § 422.311(c)(2)(iii) and § 422.311(c)(3)(iii)(C).

For MA organizations that elect both medical record review determination appeal and RADV payment error calculation appeal, we specify at § 422.311(c)(5)(iii)(A) and (B) that the Secretary will adjudicate the request for RADV payment error calculation following conclusion of reconsideration of the MA organization's request for medical record review determination appeal. This is necessary because RADV payment error calculations are based upon the outcomes of medical record review determinations. For example, for an MA organization that appeals both medical record review determinations and payment error calculations, the reconsideration official would first adjudicate and rule on the medical record review determinations and then proceed to recalculate the RADV payment error.

(4) Reconsideration Stage

Under current RADV appeals procedures, only the RADV payment error calculation appeal process contains a reconsideration step. We proposed to amend existing regulations at § 422.311(c)(3)(iii)(C) and § 422.311(c)(3)(v), (vi), and (vii) by proposing a new reconsideration stage for RADV appeals at § 422.311(c)(6) et seq. Reconsideration is the first stage of the new RADV appeals process and will apply to both medical record review determinations and error calculation issues being appealed. Therefore, MA organizations that elect to appeal RADV audit findings de facto begin the appeal process with the reconsideration step. At proposed § 422.311(c)(6)(i) we specify that a MA organization's written request for medical record review determination reconsideration must specify the audited HCC identified as being in error that the MA organization wishes to appeal; and to provide a justification in support of the audited HCC chosen for appeal. At proposed § 422.311(c)(6)(ii) we specify that the MA organizations' written request for payment error calculation reconsideration must include the MA organization's own RADV payment error calculation that clearly indicates where the RADV payment error calculation was erroneous. The request for payment error calculation reconsideration may also include additional documentary evidence pertaining to the calculation of the error that the MA organization wishes the reconsideration official to consider.

At proposed § 422.311(c)(6)(iii) we describe the conduct of the reconsideration process that is being proposed. We specify that for medical record review determination reconsideration, a medical record review professional who was not involved in the initial medical record review determination of the disputed HCC reviews the medical record and accompanying dispute justification; and reconsiders the initial audited HCC medical record review determination. For payment error calculation reconsideration, we ensure that a third party not involved in the initial RADV payment error calculation reviews the RADV payment error calculation, reviews the MA organization's own RADV payment error calculation, and recalculates the payment error in accordance with CMS's RADV payment error calculation procedures.

At proposed § 422.311(c)(6)(iv), we specify that the reconsideration official issues a written reconsideration decision to the MA organization, and that the reconsideration official's decision is final unless the MA organization disagrees with the reconsideration official's decision. If the MA organization disagrees with the reconsideration official's decision, it may request a hearing.

(5) Hearing Stage

Existing regulations at § 422.311(c)(2)(iv) through (ix) and § 422.311(C)(4) et seq., specify the procedures under which CMS conducts hearings under the RADV appeals process for medical record review and payment error calculation. We proposed to replace these provisions with new hearing requirements and procedures at § 422.311(c)(7)(iv).

At § 422.311(c)(7)(i), we proposed that at the time the RADV appeals reconsideration official issues his/her reconsideration determination to the MA organization, the reconsideration official notifies the MA organization of any RADV audited HCC errors and or payment error calculations that are eligible for RADV hearing. At § 422.311(c)(7)(ii), we specify that a MA organization that requests a hearing officer review must do so in writing in accordance with procedures established by CMS. At § 422.311(c)(7)(iii), we specify that a written request for a hearing must be filed with the Hearing Officer within 30 days of the date the MA organization receives the reconsideration officer's written reconsideration decision. If the MA organization appeals the medical record review reconsideration determination, the written request for RADV hearing must include a copy of the written decision of the reconsideration official; must specify the audited HCCs that the reconsideration official confirmed as being in error; and must specify a justification as to why the MA organization disputes the reconsideration official's determination. If the MA organization appeals the RADV payment error calculation, the written request for RADV hearing must include a copy of the written decision of the reconsideration official and must include the MA organization's own RADV payment error calculation that clearly specifies where the CMS's payment error calculation was erroneous.

At § 422.311(c)(7)(iv), we proposed that a CMS hearing officer conduct the RADV hearing. At § 422.311(c)(7)(v), we specify terms and conditions under which a hearing officer may be disqualified. A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision. A party to the hearing who objects to the assigned hearing officer must notify that officer in writing at the earliest opportunity. The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw. If the hearing officer withdraws, another hearing officer will conduct the hearing. If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

At § 422.311(c)(7)(vi), we proposed that the hearing officer reviews the medical record and any accompanying attestation that the MA organization selected for review, the reconsideration official's payment error calculation (if appealed), the reconsideration official's written determination, and the written justification submitted by the MA organization and CMS in response to the reconsideration official's determination.

At § 422.311(c)(7)(vii), we proposed RADV appeal hearing procedures. We proposed that the hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and rulings. These powers include the authority to dismiss the appeal with prejudice and take any other action which the hearing officer considers appropriate, including for failure to comply with RADV audit and appeals rules and procedures. We proposed that the hearing be altogether on the record unless the hearing officer, at his or her full discretion, approves a parties request for a live or telephonic hearing regarding some or all of the medical records in dispute, or if the hearing office schedules a live or

telephonic hearing on its own motion. The hearing officer's review will be solely limited to the record. The record is comprised of the RADV reviewed medical record and any accompanying attestation that the MA organization selected for review, the reconsideration official's payment error calculation (if appealed), the reconsideration official's written determination, the written justification submitted by the MA organization in response to the reconsideration official's determination, and written briefs from the MA organization explaining why they believe the reconsideration official's determination was incorrect. In addition, the record will be comprised of a brief from CMS that responds to the MA organization's brief.

In terms of specifying the conduct of the hearing, we proposed at § 422.311(c)(7)(vii)(B) that the hearing officer neither receives testimony nor accepts any new evidence that is not part of the record. At § 422.311(c)(7)(vii) we proposed that the hearing officer be given the authority to decide whether to uphold or overturn the reconsideration official's decision, and pursuant to this decision—to send a written determination to CMS and the MA organization, explaining the basis for the decision.

At § 422.311(c)(7)(ix), we proposed that in accordance with the hearing officer's decision, a third party not involved in the initial RADV payment error calculation recalculate the MA organization's RADV payment error and issue a new RADV audit report to the appellant MA organization and CMS. For MA organizations appealing the RADV payment error calculation only, we proposed that a third party not involved in the initial RADV payment error calculation recalculate the MA organization's RADV payment error and issue a new RADV audit report to the appellant MA organization and CMS. At§ 422.311(c)(7)(x) we proposed that the hearing officer's decision be final unless the decision is reversed or modified by the CMS Administrator.

(6) CMS Administrator Review Stage

Existing regulations at § 422.311(c)(2)(x) et seq., and § 422.311(C)(4)(vi) et seq., specify the CMS Administrator-level review procedures that CMS adheres to under the current RADV appeals process for medical record review determinations and payment error calculation. We proposed to replace these regulations with new RADV appeal-related CMS Administrator review requirements and procedures at § 422.311(c)(8).

At § 422.311(c)(8)(i) and (ii), we proposed that a request for CMS Administrator review must be made in writing within 30 days of receipt of the hearing officer's decision; and must be filed with the CMS Administrator by CMS or an MA organization. At § 422.311(c)(8)(iii), we proposed that after receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision. At § 422.311(c)(8)(iv) we proposed that if the CMS Administrator elects to review the hearing decision—the Administrator acknowledges the decision to review the hearing decision in writing and notifies CMS and the MA organization of their right to submit comments within 15 days of the date of the notification. At § 422.311(c)(8)(iv)(B), we proposed that the CMS Administrator be limited to the review of the record and that the record be comprised of the hearing record, and written arguments from the MA organization and/or CMS explaining why either or both parties believe the hearing officer's determination was correct or incorrect.

Regarding Administrator-level review procedures at § 422.311(c)(8)(vi), we proposed that the Administrator reviews the record and determines whether the hearing officer's determination should be upheld, reversed, or modified. At § 422.311(c)(8)(v), we proposed that the Administrator render his or her final decision in writing to the parties within 60 days of acknowledging his or her decision to review the hearing officer's decision. At § 422.311(c)(8)(vi), we proposed that the decision of the hearing officer become final if the Administrator declines to review the hearing officer's decision or does not make a decision within 60 days.

Combining these existing RADV medical record review determination and payment error calculation appeals policies and processes improves the overall appeals process by strengthening the depth and integrity of these procedures. We also believe that doing so improves overall RADV appeals procedures by providing clarity that leads to greater efficiencies in adjudicating RADV appeals. We welcomed comments on these proposals.

We received the following comments and our response follows:

Comment: Several commenters agreed that combining the RADV medical record review determination and payment error calculation appeals policies and processes into one combined appeals process strengthens the overall appeals process and should reduce administrative burden. A commenter disagreed with this assessment. Another commenter indicated that appealing both a medical record review determination and the payment error calculation concurrently within a 30-day timeframe would be problematic.

Response: We continue to believe the combining two RADV appeals processes into one combined appeals process will improve efficiency and reduce administrative burden. Previously, MA organizations wishing to appeal both medical record review determinations and a RADV payment error calculation would have been required to participate in two hearings and two Administrator-level reviews. Under our proposal, these same organizations need only participate in one hearing and one Administrator review. Regarding the notion that appealing both a medical record review determination and the payment error calculation concurrently within a 30-day timeframe would be problematic, we believe the commenter misunderstood how the proposed process is intended to work. The proposed provision at § 422.311(c)(5)(ii)(c) states that for MA organizations that appeal both medical record review determination appeal and RADV payment error calculation appeal—the Secretary adjudicates the request for RADV payment error calculation appeal following conclusion of reconsideration of the MA organization's request for medical record review determination appeal and not concurrently as the commenter asserted. However, to provide additional clarity to the provision, we have amended § 422.311(c)(5)(iii)(B) to state that MA organization's request for appeal of their RADV payment error calculation will not be adjudicated until appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are final for that stage of appeal. We trust this clarifies this provision and CMS therefore finalizes this proposal.

Comment: A commenter objected to the proposed provision at § 422.311(c)(2)(ii) that failure to follow RADV audit procedures and requirements and RADV appeals procedures and requirements will render the MA organization's request for RADV appeal invalid. This commenter stated procedural issues should not render an appeal invalid unless they undermine the integrity of the audit results or are otherwise significantly prejudicial.

Response: We disagree. RADV is an inherently complex administrative

process and the appeals procedures we have proposed are likewise detailed and comprehensive. Failure by MA organizations to follow RADV audit procedures could compromise the integrity of the administrative record that will serve as the foundational document that will be considered during any appeals process. Moreover, if we were to make subjective case-by-case determinations regarding what defines ''undermining the integrity of the audit process,'' then we would compromise our ability to establish objective review standards upon which to base appeals determinations. Therefore, we are finalizing this provision as proposed.

Comment: Several commenters requested that CMS allow MA organizations to appeal determinations made on ''additional'' CMS–HCCs abstracted during the medical record review process. Some commenters asserted that these additional CMS–HCCs are underpayments for which they are entitled payment. These commenters also asserted that MA organizations that do not receive credit for what they believe to be additional CMS–HCCs present in a submitted medical record should be entitled to appeal the fact that they did not receive credit.

Response: We disagree. We note that an additional CMS–HCC is a CMS–HCC that CMS uncovers during the review of the MA organization's submitted medical record(s) for which it had not received payment. We acknowledge that in certain circumstances when CMS uncovers these additional CMS–HCCs, the MA organization can in fact receive credit for these newly-discovered diagnoses codes to offset the overpayment findings resulting from the medical record review of the audited CMS–HCC. The RADV process addresses additional CMS–HCCs, or ''additionals,'' as they are termed, through the application of rules for crediting a sampled enrollee with additional CMS–HCCs that are identified incidentally, during medical record review. We emphasize that these ''additional'' diagnoses were not submitted for payment by MA organizations during the data collection period for enrollees selected in the sample, and yet in certain instances we provide audited MA organizations credit through our RADV medical record review process. At its core, RADV is an audit process that is intended to validate the CMS–HCCs that were submitted voluntarily by MA organizations in order to determine whether the risk adjustment portion of payment were properly made. We would note that the data collection period for any given payment year provides a substantial amount of time for MA organizations to submit and/or correct enrollee diagnoses data to reflect an enrollee's health status. The RADV audit process is not intended to serve as a de facto mechanism for extending the data collection deadlines under which MA organizations operate. For these reasons, MA organizations will not be permitted to appeal additional CMS–HCC determinations found under the RADV audit for which MA organizations did not receive credit.

Comment: At § 422.311(c)(2)(i), CMS proposed that for each audited CMS–HCC, MA organizations may appeal one medical record that has undergone RADV medical record review and that if an attestation was submitted to cure a signature or credential issue, that attestation may likewise be included in the CMS–HCC appeal. In response to this proposal, a commenter requested that CMS allow MA organizations to use an attestation to replace a medical record. Another commenter recommended that CMS change the attestation process embedded in the existing RADV audit procedures so that when CMS notifies an MA organization that an audited CMS–HCC was not validated due to lack of signature or credential, CMS would likewise allow, after medical record review, submission of an attestation to cure the identified RADV error.

Response: The purpose of the CMS-generated attestations is to provide MA organizations with an opportunity to cure signature and credential CMS–HCC validation errors for eligible medical records. CMS-generated attestations are not intended to provide an opportunity for a MA organizations, provider or supplier to replace a medical record; or for a provider or supplier to attest that a beneficiary has the medical condition reflected in the CMS–HCC at issue. Risk adjustment rules require that allowable diagnoses be verified in a medical record, not attestation. Regarding the recommendation that CMS notifies an MA organization that an audited CMS–HCC was not validated due to lack of signature or credential pursuant to RADV medical record review, we believe MA organizations bear the responsibility for identifying records that do not contain signature or credentials, and should do so at the same time they submit medical records to CMS for RADV medical record review.

Comment: At § 422.311(c)(2)(iv), CMS proposed a provision which stipulates that notwithstanding these changes, for purposes of appealing a CMS medical record review determination, we will not permit MA organizations to appeal multiple medical records but will instead require MA organizations to identify one medical record from amongst the records submitted, and submit that record for appeal. For each audited CMS–HCC, MA organizations may appeal only one medical record that has undergone RADV review. Several commenters objected to CMS's proposal that RADV appeals be limited to one medical record selected by the MA organization. These commenters believe CMS should not require MA organizations to select one medical record to appeal, but should rather permit MA organizations to appeal multiple medical records as part of the proposed RADV appeal process.

Response: We believe these comments are in part responding to information that we provided in February 2012 regarding changes in RADV methodology. At that time, we announced that CMS would allow MA organizations to submit more than one medical record for CMS–HCC validation during the RADV medical record review stage of the RADV audit process. While we now permit MA organizations to submit more than one medical record during the RADV audit process to validate an audited CMS–HCC, only one medical record is required and ultimately utilized by CMS to validate an audited CMS–HCC or conversely, to make a determination that the audited CMS–HCC is not present in the submitted medical record. Since one medical record is sufficient to validate an audited CMS–HCC, we believe it is reasonable to limit MA organizations to selecting one medical record for purposes of RADV appeal. Guidelines set forth in the International Classification of Diseases, Ninth Clinical Revision (ICD–9) specify that the information necessary to abstract a code be contained in entirety in documentation for one encounter (either inpatient or outpatient). Multiple records cannot be combined to obtain sufficient documentation for a diagnosis. Furthermore, risk adjustment rules specify that only one diagnosis submission throughout the entire data collection period initiates a risk score adjustment. Given this, multiple medical record support is not required to confirm the diagnosis. Therefore, the appeal record should be carefully selected to ensure payment is validated. Therefore, we do not accept this recommendation.

Comment: Several commenters objected to CMS's proposal at § 422.311(c)(3) to not permit MA organizations to appeal either medical record review determination or payment error calculation methodology. A

commenter stated that MA organizations should be allowed to identify and explain their objections to audit and appeals procedures and requirements without losing their ability to pursue the administrative appeals process.

Response: At § 422.311(c)(3)(ii), we proposed that MA organizations would not be permitted to appeal CMS's medical record review determination methodology or CMS's payment error calculation methodology. We proposed this requirement for the same reason that we finalized the RADV appeals requirement in 2010 that MA organizations could not appeal the RADV payment error calculation methodology. The payment error calculation methodology would be known to audited MA organizations before their RADV audit began. MA organizations that questioned or did not otherwise understand the methodology would have an opportunity to seek clarification from CMS regarding the methodology at that time.

In December 2010, in response to questions from the MA industry regarding our RADV payment error calculation methodology, we published a white paper describing our RADV payment error calculation methodologies, and invited public comment. In response to comments received in February 2012, we published a RADV-related notice of methodology specifying the RADV payment error calculation methodology that the agency would utilize on a moving-forward basis.

This same principle applies to the way we conduct medical record review within the RADV audit context. We have long adhered to the International Classification of Diseases, Ninth Revision, Clinical Modification, or ICD–9–CM, system to classify and assign codes to health conditions abstracted from medical records that MA organizations submit to validate audited CMS–HCCs. ICD–9–CM standards are widely available to the public and will be available to MA organizations before RADV audits are initiated. We anticipate continuing to adhere to these standards until such time as new coding standards (for example, ICD–10) are universally adhered to in the United States. We continue to believe that it is essential that CMS adhere to a universally accepted coding classification system that is widely available in the public domain when conducting RADV audits.

We disagree that MA organizations lose their ability to pursue the administrative appeals process described at § 422.311 when they identify and explain objections to audit and appeals procedures. MA organizations can fully execute their rights to RADV administrative appeals as described at § 422.311 by following applicable regulations. Those rules clearly specify issues that are eligible for RADV appeal at § 422.311(c)(2) and § 422.311(c)(3); and issues that are ineligible for RADV appeal at § 422.311(c)(3). To the extent an MA organization appeals RADV issues that are eligible for RADV appeal that request for appeal will go forward. To the extent an MA organization appeals issues that are ineligible for RADV appeal; we will not act upon that request for RADV appeal. The act of identifying and explaining objections to audit and appeals procedures will not in and of itself nullify an MA organization's request to appeal issues that are eligible for RADV appeal.

Comment: At § 422.311(c)(5)(ii) we proposed that MA organizations have 30 days from the date of CMS's issuance of the RADV audit report to file a written request with CMS for RADV appeal. At § 422.311(c)(7)(iii), we proposed that a written request for a hearing must be filed with the Hearing Officer within 30 days of the date the MA organization receives the reconsideration officer's written reconsideration decision. At § 422.311(c)(8)(i) and (ii), we proposed that a request for CMS Administrator review must be made in writing within 30 days of receipt of the hearing officer's decision. Several commenters requested that CMS consider providing MA organizations additional time at each of these steps within the RADV appeals process to elect to pursue further appeals activity. In most instances, these commenters requested CMS provide a 60-day response time instead of the proposed 30-day response time.

Response: We agree with the commenters' recommendations and will change the proposed response times from 30 days to 60 days at § 422.311(c)(5)(ii), § 422.311(c)(7)(iii), and § 422.311(c)(8)(i) and (ii).

Comment: A commenter recommended that CMS correct a cross-reference error between preamble language and regulation text. The error pertains to language at § 422.311(c)(6)(iv)(C) which references the hearing process in accordance with paragraph (c)(8). As stated in the preamble, we believe this should be a reference to (c)(7), which sets forth the rules for requesting a hearing. Paragraph (c)(8) relates to review by the CMS administrator.

Response: We agree with commenter's recommended edit and have changed the regulation text to specify paragraph (c)(7) and not (c)(8).

Comment: A commenter recommended that CMS clarify the provision at § 422.311(c)(7)(vii)(B)(2)(i) that states that either party be allowed to request a live or telephonic hearing, still subject to the hearing officer's discretion. The commenter recommended that both CMS and the MA organization be allowed to request a live or telephonic hearing, still subject to the hearing officer's discretion.

Response: Proposed § 422.311(7)(vii)(B)(2)(i) specifies that ''the parties may request a live or telephonic hearing . . .'' The term ''the parties'' in this instance means CMS or the MA organization, and not either CMS or the hearing officer. Therefore, either organization that is a party of the hearing process may request a live or telephonic hearing. This clarification notwithstanding, the CMS Administrator nevertheless maintains the independent discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision. See § 422.311(7)(vii)(B)(2)(iii).

Comment: In proposed § 422.311(c)(8)(i) and (ii), CMS requires that a request for CMS Administrator—level review be filed with the CMS Administrator by either CMS or an MA organization. A commenter recommended that CMS accept adverse decisions by its hearing officers and not be permitted to appeal them to the CMS Administrator. Another requested clarification whether an MA organization would be given a ''meaningful opportunity'' to appeal a hearing officer's decision that is favorable to CMS (and not to the MA organization) if CMS' inaction allows the hearing officer's decision to become finalized.

Response: We disagree that only MA organizations should be provided an opportunity to appeal a hearing officer's adverse determination to the Administrator. Doing so would provide MA organizations with a level of due process not available to CMS, thus weighing the appeals process in favor of MA organizations. Consequently, we believe that both parties should be able to appeal a hearing officer's unfavorable decision to the Administrator level of review. Regarding the question of whether an MA organization would be given a meaningful opportunity to appeal a hearing officer's decision that is favorable to CMS if CMS' inaction allows the hearing officer's decision to become finalized, we reiterate that a decision that is favorable to CMS would inherently be unfavorable to the MA organization rendering them eligible to request review by the CMS Administrator so long as other appeals-

pre-requisites (for example, following of applicable rules, etc.) have been met. At proposed § 422.311(c)(8)(ii) we specify that an MA organization that has received a hearing officer's decision may request review by the CMS Administrator.

Comment: Several commenters objected to CMS's proposed RADV appeals-related documentation standards. A commenter requested that CMS reconsider its position that the medical record that they designate for RADV appeal be selected from one of the medical records that they originally submitted for medical record review under RADV audit. Another commenter requested that CMS reconsider its position that errors resulting from an outright failure by an MA organization to submit a medical record are not eligible for RADV appeal by the MA organization.

Response: Both of these recommendations suggest that CMS should extend, not have or otherwise not adhere to a medical record submission deadline when conducting RADV audits. It is our position that establishing realistic medical record submission deadlines is essential for conducting RADV audits timely. Conducting any type of audit activity absent the establishment of realistic documentation submission standards increases the burden and costs associated with completing the audit tasks on all parties involved. In fact, in response to industry concerns that we were not providing sufficient time for MA organizations to obtain and submit the medical records necessary to validate CMS–HCCs, we earlier extended the RADV audit medical record submission window from 3 months to 5 months. We believe 5 months is sufficient time for MA organizations to locate and submit medical records necessary to validate an audited CMS–HCC. Therefore, we reaffirm that the medical record that an MA organization selects to support its appeal of an adverse CMS–HCC determination must come from records that the MA organizations submitted to CMS for audit.

Comment: Several commenters objected to what they contend is a burden that RADV audits impose upon the physicians and physician practices that must produce medical records necessary to conduct audits. A provider-based trade association requests that MA organizations requesting medical records for a RADV audit be required to provide documentation on the scope of the audit from CMS, as providers believe there have been abuses in terms of the amount of requests and data demands which exceed the actual requirements. By requiring MA organizations to provide documentation of the CMS RADV audit request and the specific medical records required, this commenter contended that CMS will ensure it receives all necessary documentation, while also ensuring MA organizations are not using the RADV audit to unduly burden providers. We note that outside of the proposed rule, CMS has also received letters arguing that the burden associated with RADV audits is not limited to the CMS' audits but also extends to internal audit activity undertaken by MA organizations that mimic the RADV audits that we undertake for Medicare payment validation. These commenters raised concerns that MA organizations were misrepresenting their internal audit activity as official CMS RADV audits.

Response: In an effort to minimize the burden associated with this activity, we have developed best practices that we encourage MA organizations to employ in their efforts to gather medical records from providers and hospitals. To the extent MA organizations employ these practices; it is our belief that the impact of RADV audits on providers can be minimized. We also understand the increasing need for providers to be able to distinguish when they are being asked for medical records in association with an MA organization's own audit or in accordance with an official Medicare program RADV audit which is subject to statutory requirements. Therefore, we issue letters on our letterhead that MA organizations must use when requesting medical records from providers when the request is specifically related to an official CMS RADV audit. Providers may rely upon these letters as an indicator that a given medical record request is for CMS' RADV audit process, and providers may request this authorizing letter before responding to requests by an MA organization.

f. Proposal To Expand Scope of RADV Audits

Federal regulations at § 422.311(a) specify that RADV audits are conducted by CMS. We proposed to amend this regulation at § 422.311(a) by specifying that the Secretary of the Department of Health and Human Services, along with CMS, may conduct RADV audits beginning with the effective date of this regulation. We also proposed to amend RADV definitions at § 422.2 to specify that The Secretary of the Department of Health and Human Services, along with CMS, may conduct RADV audits. We welcomed comment on this proposal.

We received the following comments and our response follows:

Comment: Many commenters objected to proposed § 422.311(a) which specifies that the Secretary, along with CMS, could conduct RADV audits beginning with the date when CMS' proposed RADV appeals rule change became effective. Some of these commenters also objected to CMS's proposal to amend RADV definitions at § 422.2 to specify that the Secretary, along with CMS, could conduct RADV audits. Another commenter requested clarification for the rationale and mechanics of allowing HHS to conduct RADV audits, citing concerns about maintaining consistency in the audit process.

Response: We conduct RADV audits to help ensure the integrity of the Medicare program though activities aimed at determining whether certain payments should have been made by Medicare. The Secretary (including the Office of Inspector General (OIG)—pursuant to OIG's authority under the Inspector General Act of 1978, 5 U.S.C. App.) clearly has the authority to conduct RADV audit activity. Our proposing this provision and the related change in definition simply clarifies what is already an existing statutory authority. In response to the commenters requested clarification on the mechanics of how the Secretary would conduct RADV audits, we would note that the Secretary or OIG, will provide instructions regarding its RADV audit at the time the Secretary or OIG notifies selected organizations of pending RADV audit activity.

g. Proposal To Clarify the RADV Medical Record Review Determination Appeal Burden of Proof Standard

Our regulations at § 422.311(c)(3)(iv) specify that for RADV payment error calculation appeals, MA organizations bear the burden of proving that CMS failed to follow its stated RADV payment error calculation methodology. However, RADV regulations do not specify a burden of proof standard for the RADV medical record review determination appeal process. The absence of a clearly-defined burden of proof standard for RADV medical record review determination appeals creates an appeal environment where MA organizations, CMS and RADV appellate officials are free to interpret and apply different burden of proof standards when arguing or reviewing appeals cases. We proposed to amend the rule with new § 422.311(c)(4) which specifies that the burden of proof for all RADV determinations—be they payment error calculation or RADV

medical record review determinations—is on MA organizations to prove, based on a preponderance of the evidence, that CMS's determination was erroneous.

This approach would stand in contrast to a burden of proof standard in which the MA organization were to prove that a valid diagnoses exists on the record, and that therefore, the audited HCC has been validated. This proposed amendment to the rule provides the medical record review determination process a clear burden of proof standard which more aligns with the existing RADV payment error calculation appeals burden of proof standard. Doing so also improves the overall RADV appeals procedures by providing clarity that leads to greater efficiencies in adjudicating RADV appeals. We invited comment on this proposal.

We received the following comments and our response follows:

Comment: Several commenters objected to proposed § 422.311(c)(4) which specifies that the burden of proof for all RADV determinations—be they payment error calculation or medical record review determinations—resides with the MA organizations, based on a preponderance of the evidence standard, that CMS's RADV audit determination(s) was erroneous. These commenters recommended revising the regulation to place the burden of supporting an affirmative finding that a payment error has been made, on CMS. A commenter also requested that CMS more clearly define how a ''preponderance of the evidence'' burden of proof standard would be applied.

Response: In developing this proposal, we reviewed other types of burdens of persuasion, such as the burden to establish by ''clear and convincing'' evidence that a fact exists or does not exist. First, we based our decision to propose a preponderance of the evidence standard on CMS precedence in other appeals processes. Second, we determined that it may not seem fair to the MA organizations to set a high expectation for persuasion, especially for those MA organizations which have not gone through a RADV appeals process before. We determined that it would not set as high a standard as ''clear and convincing'' or ''beyond a reasonable doubt'' for these cases at this time. Proof that evidence as a whole is of a degree which is more probable than not is sufficient to overturn a CMS determination.

h. Proposal To Change RADV Audit Compliance Date

Currently, the compliance date for RADV audits is the due date when MA organizations selected for RADV audit must submit medical records to CMS or its contractors. We proposed to change the compliance date for meeting RADV audit requirements for the validation of risk adjustment data to the due date when MA organizations selected for RADV audit must submit medical records to the Secretary—and not only to CMS. See proposed regulation language at § 422.311(b)(2).

We received no comments on this proposal and therefore are finalizing this provision without modification.

B. Improving Payment Accuracy

4. Recovery Audit Contractor (RAC) Determination Appeals (Proposed Part 422 Subpart Z and Part 423 Subpart Z)

a. Background

Section 306 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) required the Secretary to conduct a demonstration to determine whether recovery auditors could be used effectively to identify improper payments paid under Medicare Part A and Part B claims. We conducted the demonstration from March 2005 to March 2008 in six states. The Recovery Audit demonstration established recovery auditors as a successful tool in the identification and prevention of improper Medicare payments.

In December 2006, the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109–432) was enacted. Section 302(a) of the TRHCA created a permanent Medicare Recovery Audit Contractor (RAC) program and added a new paragraph (h) to section 1893 of the Act that required us to establish a national recovery audit program for Medicare Part A and Part B. The national Medicare Fee-For-Service (FFS) Recovery Audit program was established on January 1, 2010.

Section 6411(b) of the Affordable Care Act amended section 1893(h)(1) of the Act by requiring the establishment of recovery audit programs for Medicare Parts C and D, in addition to the RAC program already in place for Medicare A and B.

On December 27, 2010, we published a notice in the **Federal Register** (75 FR 81278) requesting comments on how to best implement the RAC program for Parts C and D. Analysis of the comments received assisted us with implementation of the Part C and D RACs.

In January 2011, we entered into a recovery audit contract for Part D. The Part D RAC began recouping identified overpayments in 2012. On December 7, 2012, we published a Request for Quotation (RFQ) via the General Services Administration's (GSA) eBuy seeking quotations on the implementation of a Medicare Part C RAC. We anticipate the award of a Part C RAC contract in FY 2014.

Given that we began recouping overpayments determined by the Part D RAC in 2012, and we anticipate recouping overpayments in Part C after awarding a Part C RAC contract in FY 2014, it is appropriate to provide a codified administrative appeals process to allow for plans to challenge the overpayment findings generated by the RACs just as we provide for challenges to overpayment determinations elsewhere in the Medicare program. In crafting our proposed appeals process for Parts C and D RAC determinations, we reviewed existing appeals processes in other areas, including Parts A and B RAC determinations, Part C RADV Audits, Part D payments, etc.

b. Proposed RAC Appeals Process

After reviewing the agency's existing appeal processes, we determined that the general mechanisms set forth in § 422.311 and § 423.350 offered the most appropriate models for the Part C and D RAC appeals process.

The Part D RAC currently reviews PDE data to identify overpayments and underpayments that are paid back to the plans. When overpayments are identified, Part D plans are notified and funds are recovered. If a plan disagrees with the calculated overpayment amounts or whether the overpayments are proper, the plan may appeal the Part D RAC's determination directly to the CMS Center for Program Integrity.

A multilevel independent appeals process is an important component of the Part C and Part D RAC program as it allows plans to appeal determinations they contend are made in error. The administrative appeals mechanisms in this final rule would apply to all Part C and Part D RAC determinations. As we implement the Part C RAC, we would determine if additional changes to the proposed appeals process are necessary.

Based on the foregoing, we proposed to add a new subpart Z in Parts 422 and 423, respectively that would include the proposed provisions discussed in this section. In accordance with CMS direction and criteria, the Part C or Part D RAC would conduct an issue specific audit of CMS' payment(s) to plans. An independent validation of all Part C and Part D RAC-identified improper

payments would be conducted. If both the Part C or Part D RAC and the independent validation determine that an improper payment was made, the Part C or Part D RAC would send a notice of improper payment to the plan. If the Part C or Part D RAC determines an overpayment was made to the plan, it would send a demand letter requesting repayment. The demand letter would: (1) Explain the reason for the overpayment determination; (2) explain our recoupment process; and (3) contain instructions on how the plan may appeal the Part C or Part D RAC's finding. There would be no minimum monetary threshold for an appeal at any level.

The following 3-level process sets forth our proposed administrative appeals process for overpayment determinations by the Part C and Part D RACs. Please note that the appeals process set forth applies to both § 422.2600 and § 423.2600. Because the sections largely mirror one another, discussions in this preamble would apply to both programs, unless otherwise noted. (1) Reconsiderations (§ 422.2605 and § 423.2605)

At § 422.2605 and § 423.2605, we proposed that if the plan believes the part C or Part D RAC did not apply CMS' stated payment methodology correctly, a plan may appeal the determination to an independent reviewer. CMS' payment methodology itself, however, is not subject to appeal. That is, while miscalculations and factual or data errors may be appealed, the plan may not appeal the substantive basis for the overpayment determination. This is consistent with the approach to Part D reconciliation appeals at § 423.350(a)(1), which states that the Part D plan may appeal ''if CMS did not apply its stated payment methodology correctly.'' The Part D reconciliation appeals process does not permit the underlying payment methodology to be appealed.

Examples of appealable issues would include, but are not limited to: (1) A Part C or Part D RAC determination that a plan provider/pharmacy was excluded from Medicare when the service was furnished; (2) a Part C or Part D RAC determination that a payment was a duplicate payment; or (3) whether the Part C or Part D RAC miscalculated an overpayment.

In paragraph (a), we proposed that the plan's request for reconsideration must be filed with the independent reviewer within 60 calendar days from the date of the demand letter. In paragraph (b)(1), we proposed that the request for reconsideration must be in writing and must provide evidence or reasons or both to substantiate the request. In paragraph (b)(2), we proposed that the plan must include with its request all supporting documentation, evidence, and substantiation it wants the independent reviewer to consider. This material must be submitted in the format requested by CMS. Documentation, evidence, or substantiation submitted after the filing of the reconsideration request would not be considered.

In paragraph (c), we proposed that CMS may file a rebuttal to the plan's reconsideration request. The rebuttal must be submitted to the independent reviewer within 30 calendar days of the independent reviewer's notification to CMS that it has received the plan's reconsideration request. We would notify and send its rebuttal to the plan at the same time it is submitted to the independent reviewer. In paragraph (d), we proposed that the independent reviewer would conduct the reconsideration. Specifically, the independent reviewer would review the notification of improper payment, the evidence, and findings upon which it was based, and any evidence that the plan or CMS submitted in accordance with regulations. In paragraph (e), we proposed that the independent reviewer would inform CMS and the plan of its decision in writing. In paragraph (f), we proposed that a reconsideration decision would be final and binding unless the plan requests a hearing in accordance with § 422.2605 and § 423.2605. Finally, in paragraph (g), we proposed that a plan that is dissatisfied with the independent reviewer's reconsideration decision would be entitled to a review by a hearing official as provided in § 422.2610 and § 423.2610.

(2) Hearing Official Determinations (§ 422.2610 and § 423.2610)

In proposed § 422.2610 and § 423.2610, we outline the process for requesting review of the record by a CMS hearing official. In paragraph (a), we proposed that a request for review must be filed with CMS within 15 days from the date of the independent reviewer's issuance of a determination. The request must be in writing and must provide a basis for the request. In paragraph (b), we proposed that the plan must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered. Documentation, evidence, or substantiation submitted after the filing of the request would not be considered.

In paragraph (c), we proposed that a CMS-designated hearing official would conduct the review. A hearing would not be conducted, either live or via telephone, unless the hearing official, in his or her sole discretion, chooses such a mechanism. In all cases, the hearing official's review would be limited to information that: (1) The Part C or Part D RAC used in making its determinations; (2) the independent reviewer used in making its determinations; (3) the plan submits with its hearing request; and (4) CMS submits per paragraph (d). Neither the plan nor CMS would be allowed to submit new evidence.

In paragraph (d), we proposed that CMS may file a rebuttal to the plan's hearing request. The rebuttal must be submitted within 30 calendar days of the plan's submission of its hearing request. CMS would send its rebuttal to the plan at the same time it is submitted to the hearing official. In paragraph (e), we proposed that the CMS hearing official would decide the case within 60 days and send a written decision to the plan and CMS, explaining the basis for the decision. In paragraph (f), we proposed that the hearing official's decision would be final and binding, unless the decision was reversed or modified by the CMS Administrator in accordance with § 422.2615 and § 423.2615.

(3) Administrator Review (§ 422.2615 and § 423.2615)

In proposed § 422.2615 and § 423.2615, we discuss the Administrator review process. In paragraph (a), we proposed that if a plan is dissatisfied with the hearing official's decision, the plan may request that the CMS Administrator review the decision. The request must be filed with the CMS Administrator within 15 calendar days of the date of the hearing official's decision. The request must provide evidence or reasons or both to substantiate the request. In paragraph (b), we proposed that the plan must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered. Neither the plan nor CMS would be allowed to submit new evidence. Documentation, evidence or substantiation submitted after the filing of the request would not be considered.

In paragraph (c), we proposed that after receiving a request for review, the Administrator would have the discretion to review the hearing official's decision in accordance with paragraph (e) or to decline to review said decision.

In paragraph (d), we proposed that the Administrator would notify the plan of whether he or she intends to review the

hearing official's decision. If the Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding. If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan that the request for review has been accepted. CMS would send its rebuttal statement to the plan at the same time it is submitted to the Administrator. In paragraph (e), we proposed that if the Administrator agrees to review the hearing official's decision, the Administrator would determine, based upon this decision, the hearing official record, and any arguments submitted by the plan or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The Administrator would furnish a written decision to the plan and to CMS. The Administrator's decision would be final and binding.

We received the following comments and our responses follow:

Comment: Several commenters expressed concern over the proposed 15-day timeframe for plan sponsors to request review by a Hearing Official and also the proposed 15-day timeframe to request review by the Administrator. Commenters believe that a 15-day timeframe for requesting additional review may result in unnecessary appeals and that 30 days is a more appropriate timeframe for plan sponsors to evaluate if additional appeals for review are appropriate. Commenters pointed out that a 30-day timeframe is typical among other similar CMS appeals processes.

Response: We agree with commenters that a 15-day timeframe for requesting additional review by a Hearing Official or the Administrator may not provide enough time for plan sponsors to make an appropriate decision regarding additional appeals for review and we are finalizing this rule with a 30-day timeframe for such requests. This timeframe will also make the Parts C and D RAC Appeals process more structurally similar to existing appeals processes such as the RADV Appeals process.

Comment: A commenter requested that CMS clarify the distinction between ''payment methodology'' and ''findings of the applied methodology'' given that CMS proposed that ''payment methodology'' is not subject to appeal. This commenter believes that this distinction is critical to providing meaningful appeal rights to plan sponsors. The commenter provided an example such as when the RAC determines that a payment received by the Part D sponsor should have been treated as Direct and Indirect Remuneration (DIR).

Response: We agree with the commenter that this distinction is critical to providing a meaningful appeals process to plan sponsors. In the proposed rule, we indicated that miscalculations and factual or data errors may be appealed as ''findings of the applied methodology''. If a plan sponsor believes that a Part D RAC incorrectly classified a payment as DIR, for example, this would be a question of fact regarding the findings of the applied methodology that the plan sponsor is entitled to appeal.

Comment: A commenter questioned why new evidence could not be submitted at subsequent levels of appeal after the first level reconsideration and requested that CMS allow new evidence to be submitted at each level of appeal.

Response: We disagree with the commenter. We do not believe it is common for evidence relevant to a RAC determination to be unavailable to a plan sponsor 60 days after a Notice of Improper Payment is received by the plan sponsor. This is the relevant timeframe for requesting a reconsideration and submitting relevant evidence and documentation to the independent reviewer. Also, we do not believe it is generally appropriate for plan sponsors to withhold relevant evidence from the independent reviewer at the Reconsideration stage of appeal and we want to safeguard the program from this type of activity. We have modeled our proposed process after existing CMS appeals processes that do not allow the submission of new evidence at higher levels of appeal, such as the CMS RADV appeals process. We also note that in addition to the plan sponsor not being permitted to submit new evidence at subsequent levels of appeal, we are also precluded from submitting new evidence at subsequent levels of appeal.

Comment: A commenter questioned why CMS did not define ''designated independent reviewer'' and suggested that in order to ensure that the first level appeals reviewer is both qualified and independent of the RAC, the regulation should specify the necessary qualifications for this position. The commenter further suggested that the regulation contain a specific conflict of interest provision that would disallow any financial or other relationship between the RAC and the independent reviewer.

Response: We agree with the commenter that the integrity of the proposed appeals process is imperative and that the designated independent reviewer be both qualified and independent of the RAC. We decline to specify the necessary qualifications for this position in the regulation and we decline to add a specific conflict of interest provision in the regulation. We believe that the independence of the reviewer will be self-evident as the reviewer will not be affiliated with the RAC and we have no incentive to select independent reviewers who are lacking the qualifications to fulfill this task.

Comment: A commenter requested that CMS make clear that the Part D sponsor is not required to make any payment with respect to a RAC finding until the sponsor has exhausted the administrative appeals process. The commenter also requested that CMS clarify that any final and binding decision by the Administrator does not preclude judicial review.

Response: We agree that final Part D payment adjustments based on RAC findings will not be made until all administrative appeal rights are exhausted. This is our current practice under the existing appeals process and will continue to be the practice under the formal three-level appeals process being implemented in this final rule. We also agree with the commenter that any final and binding decision by the Administrator under this rule does not preclude judicial review.

After review of the public comments received on these proposals, we are finalizing our proposals with one modification. In §§ 422.2610(a) and 422.2615(a) and § 423.2610(a) and § 423.2615(a), we are revising the timeframe for MA organizations and Part D plan sponsors, respectively, to request review by a Hearing Official or the Administrator from 15 days to 30 days.

C. Implementing Other Technical Changes

1. Definition of a Part D Drug (§ 423.100)

Section 1860D–2(e) of the Act defines a covered Part D drug as a drug that may be dispensed only upon a prescription and that is described in paragraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2) of the Act; or a biological product described in clauses (i) through (iii) of paragraph (B) of such section, or insulin described in paragraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary), and such term includes a vaccine licensed under section 351 of the Public Health Service Act (and, for vaccinations administered on or after January 1, 2008, its administration), and any use of a covered Part D drug for a medically

accepted indication (as defined in paragraph (4)). We codified this definition in § 423.100.

a. Combination Products

The FDA approves and regulates many products that include drug-drug and drug-device combinations. However, for the purposes of the Part D program, only combination products approved and regulated by the FDA as drugs, vaccines, or biologics are potentially eligible for Part D coverage, in line with the Part D drug definition. We proposed to address this issue in regulation to codify and clarify policy we previously addressed through guidance.

We proposed to add paragraph (vii) under the definition of a Part D drug to further clarify that only those combination products approved and regulated in their combination form by the FDA as a drug, vaccine, insulin, or biologic, as described in paragraph (i), (ii), (iii), or (v) of the Part D drug definition, may be eligible for Part D coverage. Our proposal would make it clear that the definition of a Part D drug excludes products where a combination of items are bundled or packaged together for convenience (such as one box packaging together multiple products, each in separate bottles), where the bundle has not been evaluated and approved by the FDA. This proposal would not affect products where multiple active ingredients (including at least one Part D eligible prescription-only ingredient) are incorporated into a single pill or single injection, as such products would have had to go through FDA approval in this combined form, meeting the Part D requirement. Combination products that are FDA approved would then be treated like other Part D drugs, eligible for coverage only when being used for a medically accepted indication and not otherwise excluded from Part D coverage (for example, because it is covered as prescribed and dispensed or administered under Medicare Part B).

This proposed policy is intended to clarify that a combination product containing at least one constituent ingredient that would, if dispensed separately, meet the definition of a Part D drug is eligible for Part D coverage only if it has received FDA approval in its combined form. Combination products not FDA approved as drugs under the Federal Food, Drug, and Cosmetics Act would not satisfy section 1927(k)(2)(A)(i) of the Act, defining covered outpatient drugs as those approved for safety and effectiveness as a prescription drug. Combination vaccines not licensed as a vaccine under section 351 of the Public Health Service Act similarly would not satisfy the definition of a Part D drug as defined in section 1860D–2(e)(1) of the Act.

Our proposal would not require that all constituent ingredients of a combination product be FDA-approved prescription drugs. An example would be an FDA-approved prescription drug that combines a Part D drug with a non-Part D covered vitamin. Conversely, a product combining a Part D drug with a medical food, dietary supplement, or another Part D drug, where the combined product has not received FDA approval as a prescription drug, vaccine, or biologic would not be eligible for Part D coverage.

Comment: A commenter noted it supported the proposed policy regarding combination products.

Response: We appreciate the support for our proposal.

Comment: A commenter requested that CMS provide clarification on what constitutes a vitamin versus what constitutes a dietary supplement.

Response: In the preamble, we provided an example of a Part D drug combined with a vitamin that would be eligible for coverage, if FDA approved in the combined form. We also provided an example of a Part D drug combined with a dietary supplement that would not be eligible for coverage because the FDA had not approved that combination. We did not mean to imply that only approved combinations involving vitamins would be eligible, nor did we mean to distinguish between vitamins as opposed to dietary supplements in that paragraph. Our intent was to distinguish their eligibility for coverage by the fact that one of these combined products was approved as a combination drug product by the FDA and the other was not.

After consideration of the public comments we received, we are finalizing this provision with a technical modification to improve the clarity of the provision.

b. Barbiturates and Benzodiazepines

We also proposed to amend the definition of a Part D drug to address certain exclusions by revising paragraph (2)(ii). When the Part D benefit started in 2006, all uses of barbiturates and benzodiazepines were excluded from coverage by statute. In 2008, section 175 of the MIPPA amended section 1860D–2(e)(2)(A) of the Act to include coverage for barbiturates when used in the treatment of epilepsy, cancer, or a chronic mental health disorder and for benzodiazepines when used for any medically accepted indication, effective January 1, 2013. In 2010, section 2502 of the Affordable Care Act amended section 1927(d) of the Act, to remove barbiturates and benzodiazepines from the list of drugs subject to exclusion from coverage, effective for services provided on or after January 1, 2014. Thus, this subsequent statutory change effectively includes barbiturates as a Part D drug for all medically accepted indications. The proposed revision to § 423.100 would conform our definition of Part D drug to the new statutory requirement by removing from paragraph (2)(ii) the clause ''barbiturates when used to treat epilepsy, cancer, or a chronic mental health disorder; and benzodiazepines.''

We did not receive any comments regarding this proposal.

We note that an error appeared in the corresponding regulations text of the January 10, 2014 proposed rule. In the regulations text (79 FR 2062), we made a typographical error in an amendatory instruction and inadvertently did not remove the previously noted clause from the definition of ''Part D drug'' at § 423.100(2)(ii). Therefore, we are making the required corrections in the regulations text of this final rule.

c. Medical Foods

We proposed to add paragraph (2)(iii) to the list of exclusions from the definition of Part D drug to specify that medical foods, as defined in 21 U.S.C. 360ee, are not Part D drugs. Medical foods are not described in paragraphs A(i), A(ii) or A(iii) of section 1927(k)(2) of the Act, and therefore, do not meet the statutory definition of a covered Part D drug, nor do they fall under other categories eligible for Part D coverage listed in the Part D drug definition, such as biologics, vaccines, and insulin.

Moreover, as described previously in the section on combination products, a product with relevant components including some or all ingredients meeting the definition of a Part D drug would not be eligible for Part D coverage unless the combined product has also been approved by the FDA as a drug, vaccine, or biologic.

The proposed clarifications involving coverage for approved combination products and non-coverage of medical foods would not affect current policies surrounding Part D coverage of parenteral nutrition. (See the Part D manual guidance, Chapter 30.7 regarding the payment for parenteral and enteral nutrition items and services.) Extemporaneously compounded prescription drug products (addressed separately in Chapter 6 of the Part D manual and in § 423.120) also would not be affected by the proposed changes. Part D coverage for

extemporaneously compounded prescriptions is available for the ingredients that independently meet the definition of a Part D drug when the product needed is one requested by the provider to meet a specific medical need, where there is no commercially available alternative. The convenience packaging of unapproved combination products for broad distribution does not meet the criteria set out specifically for extemporaneously compounded prescriptions.

Comment: A commenter that strongly disagreed with the proposal stated that there are medically indicated nutritional supplements such as food thickeners, caloric supplements, and probiotics which should be covered if prescribed by a physician.

Response: The definition of a ''covered Part D drug'' found in section 1860D–2(e)(1) of the Act does not allow us to cover food thickeners, caloric supplements, and probiotics even if prescribed by a prescription. These items do not meet any of the requirements of that section.

After consideration of the public comment we received, we are finalizing this provision without modification.

2. Special Part D Access Rules During Disasters or Emergencies (§ 423.126)

Section 1860D–4(b) of the Act requires us to ensure beneficiaries have access to covered Part D drugs. When a disaster strikes or is imminent, beneficiaries may find they have trouble accessing drugs through normal channels or must move to safer locations far away from their regular pharmacies. In order to ensure that beneficiaries do not run out of their medications during or as a result of a disaster or emergency, we issued guidance on December 18, 2009, identifying when, in the course of a disaster, Part D sponsors would be expected to relax ''refill-too-soon'' (RTS) edits. We proposed to codify a revised version of that policy. Proposed § 423.126(a)(1)(i) would require Part D sponsors to relax RTS edits in the event of any imminent or occurring disaster or emergency that would hinder an enrollee's access to covered Part D drugs. By this we mean that there is an anticipated or actual disaster or emergency, as evidenced by a declaration of a disaster or emergency issued by an appropriate federal, state or local official, and it is reasonable to conclude that such disaster or emergency or preparation therefore would make it difficult for beneficiaries to obtain refills of their medications because the disaster or emergency or anticipation thereof has affected, or will affect, their ability to have timely access to their usual pharmacies. For example, if federal, state or local authorities issue mandatory evacuation orders to populations or segments of the population in a geographic area, it would be reasonable to conclude that the evacuation would hinder an LTC resident's ability to get a refill after he or she is evacuated from the facility. In such an instance, then, Part D sponsors with enrollees in the affected area would be required to relax RTS edits so that the LTC pharmacies could provide beneficiaries with refills to take with them to the location to which they are being evacuated.

Our proposed requirement would apply to one refill for each drug the beneficiary is taking for refills sought within 30 days of the date the plan sponsor began relaxing RTS edits. We believe this timeframe would be sufficient to ensure that beneficiaries who are unable to obtain refills during the emergency or disaster will be able to do so as soon as they can safely access a network pharmacy. We solicited comment as to whether 30 days after the date of the triggering declaration provides an appropriate amount of time to ensure that beneficiaries do not run out of their medications. In particular, we would be interested in learning about any situations in which a beneficiary affected by an actual or impending disaster or emergency would be likely to go to a pharmacy more than 30 days after the triggering declaration such that the resumption of RTS edits after 30 days would be problematic. We also solicited comment as to how it would be feasible for Part D sponsors to identify pharmacies or beneficiaries located in affected areas for which they would be required to relax edits and, how long it might then take to program the necessary changes.

Although we believed our proposal provides a general framework for when RTS edits must be relaxed, we solicited comment on whether we should impose more particular requirements in cases where a disaster or emergency could result in a voluntary or mandatory evacuation of an LTC facility. We are also concerned that if a disaster strikes the area in which an LTC facility is located but not the area in which its servicing LTC pharmacy is located, the appropriate edits may not be relaxed. Accordingly, we solicited comment as to whether it would be more feasible to establish beneficiary specific edits limited to residents of LTC facilities in affected areas given that evacuation decision-making is rarely a straightforward, linear process (for example, not just based on the declaration of a disaster or emergency), but rather, often involves myriad facility-specific factors. In particular, we solicited comment on the practicality of requiring Part D sponsors to relax RTS edits for residents of a particular LTC facility after that facility decides on its own initiative to evacuate through use of National Council on Prescription Drug Programs (NCPDP) Submission Clarification Code (SCC) code 13, which conveys that there is an emergency. We solicited comment as to whether use of this code number, 13, is specific enough to signal that sponsors need to loosen RTS edits and whether it would be practical for LTC facilities to request that their LTC pharmacies enter the SCC code 13. Lastly, we stated we would be interested in any other ideas on how to structure workable edits or institute manual procedures to best target only enrollees who live in LTC facilities located in areas affected by a disaster.

We also stated that we would be interested in hearing from any commenters who would recommend any other triggering events that would require Part D sponsors to relax RTS edits. In particular, we solicited comment as to whether it would be feasible to require sponsors to relax edits after the issuance by the National Weather Service (NWS) of a Hurricane or Tropical Storm watch or warning. The NWS typically issues watches 36 hours in advance of adverse weather conditions possibly hitting an area, while the NWS issues watches 48 hours (2 days) in advance of those conditions possibly hitting an area. All watches/warnings are posted on the NWS Web site immediately after their issuance. We solicited comment as to whether watch/warnings would require RTS overrides in the whole state, or just areas under the watch or warning. We also stated that we were interested in comments regarding the time generally needed to move residents of LTC facilities with their medication supplies to safety.

Lastly, we believe that sponsors are in the best position to determine how to relax the specific RTS edits when required under our proposal. However, we also wish to ensure that all sponsors relax RTS edits in a consistent manner in order that enrollees have the same critical access to drugs when disasters and emergencies are imminent or have occurred—regardless of the specific plan in which they are enrolled. Accordingly, we solicited comments on the types of situations that might arise and the extent to which sponsors should be allowed to exercise some discretion in complying with this proposed requirement.

And, as has been the case under our current guidance, Part D sponsors may consider extending the implementation of the RTS edits but are not required to do so. However, if sponsors choose to reinstate the RTS edits, they need to work closely with enrollees who indicate that they are still displaced or otherwise impacted by the disaster or emergency.

Comment: Several commenters supported CMS's proposal. A commenter commended CMS's efforts to ensuring access to critical and other drugs during times of crises.

Response: We thank the commenters for the support.

Comment: Several commenters were concerned that the policy was not clear enough to ensure that Part D sponsors would apply it consistently. A commenter suggested that requiring sponsors to ''reasonably conclude'' whether a beneficiary would have difficulty obtaining refills would result in an inconsistent relaxation of edits and suggested instead that CMS provide clear direction by exercising its section 1135 waiver authority. Another commenter requested that CMS issue HPMS alerts to advise Part D sponsors on when to relax edits every time a trigger event occurred not only because of the subjective nature of the sponsor assessment but because it also depended on whether a sponsor knew that about a declaration. A commenter requested that we make it clear sponsors would only be obligated to relax edits when operationally possible.

Response: We appreciate the suggestions and will consider them in the future.

Comment: A commenter suggested that CMS allow beneficiaries enrolled in mail order pharmacy programs to use local retail or hospital pharmacies during emergencies when disasters or other emergencies interfere with their receipt of drugs through the mail.

Response: While we appreciate the concerns, we did not propose any changes with respect to mail order during disasters and emergencies and we are not adopting this recommendation at this time.

Comment: Several commenters responded to our request for comment by agreeing that it was appropriate to limit the window for relaxed edits to 30 days after the date of declaration. Another commenter suggested that the 30 day period should start running when the emergency actually occurred because declarations often do not take place until later—in which case the proposed timeframe might actually exceed 30 days.

Response: We appreciate the comments, and will use them to inform possible future rulemaking.

Comment: Several commenters believed use of the NCPDP submission code appropriate, while another concluded it would not work because it was beneficiary specific and not specific to LTC facilities. A commenter stated it was difficult to operationalize RTS overrides by areas and that it was typically done by state. Comments on the feasibility of relying on NWS watches and warnings ranged from several commenters who thought it inappropriate to ever relax edits on account of such warnings because they might never occur, to a commenter who thought it appropriate to limit such application solely to hurricane and tropical storm warnings, to another commenter who thought both types of warnings appropriate triggers and suggested that CMS also rely on advisories from NWS. However, not all commenters discussed warnings and watches in the context of LTC facilities and, in fact, a commenter questioned whether our proposal even applied to non-LTC situations.

Response: We appreciate the comments and will use them to inform possible future rulemaking.

Comment: A few commenters requested that we broaden our policy by allowing sponsors to relax edits more often than proposed. A commenter suggested we allow sponsors make determinations regarding whether to relax edits ''well before'' declarations were issued rather than wait for their issuance, and other commenters identified specific situations that they felt should prompt such a determination such as local challenges and severe weather (such as tornadoes) and accompanying difficulties (such as power outages extending for multiple days). Another commenter requested that CMS automatically grant special access rules when a state of emergency is declared in a state or region thereof rather than leave the discretion to apply those rules to sponsors.

In contrast, several commenters requested that we revise the regulation so that sponsors would be able to relax edits less often than proposed. Observing that many anticipated snow storms that did not actually take place last winter, a commenter requested that CMS not allow Part D sponsors to relax edits for government declarations that merely announced the possibility, rather than the occurrence, of disasters or emergencies. Another commenter suggested that we limit application of the policy to declarations only from federal and state authorities because it was difficult for Part D sponsors with large service areas to track declarations by local authorities.

Another commenter recommended that we retain the current guidance.

Response: As a result of the comments we received on this issue, we are not finalizing this proposal. We have concluded that we need to carefully consider our options and consequently have decided to leave in place current guidance. There was simply not a consensus regarding any aspect of the proposed regulation to sufficiently inform a decision to finalize. For instance, a number of commenters expressed opposing views: Some requested that we broaden our policy by allowing sponsors to relax edits more often than proposed, while others suggested that we curtail the circumstances under which sponsors would be permitted to relax edits. Some contractors liked the discretionary aspects of the proposal and the existing guidance while others sought bright line indicators—although sometimes just to trigger the times when discretion might be applied. Several commenters appear to have misunderstood our proposal.

We believe it is important to ensure that beneficiaries receive drugs in the event of disasters or anticipated disasters that might hinder their access to such drugs for a period of time. But we are concerned that if sponsors do not uniformly relax edits under similar circumstances, beneficiaries in different plans will be treated disparately. We hope to prevent situations in which, for instance, two beneficiaries living in the same area are affected by the same disaster, but one beneficiary is able refill a prescription that otherwise would been subject by RTS edits, while the other, who is enrolled in a different plan, is not. The variety of comments and responses suggests that resolving these issues may require more focused inquiry. In the meantime, the current guidance will remain in place (found in Prescription Drug Benefit Manual, Chapter 5, Benefits and Beneficiary Protections, Section 50.12). We again thank all the commenters including those that took the time to respond to our specific solicitations. We will keep their suggestions in mind as we carefully consider our options for the future, including whether to address our regulatory proposals in future rulemaking.

3. Termination of a Contract Under Parts C and D (§§ 422.510 and 423.509)

a. Cross-Reference Change (§ 423.509(d))

Section 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act describes the

procedures for termination for both Part C and Part D plan sponsors respectively. We codified organizations' appeal rights under subpart N of parts 422 and 423. Under the Part C § 422.510(d), a reference to the appeal rights ''in accordance with subpart N'' is made. However, in the corresponding section for Part D Plan sponsors at § 423.509(d), the reference to the appeal rights reads ''in accordance with § 423.642.'' The Part C and Part D references should be the same.

We proposed to align the Part C and Part D appeal rights language under §§ 422.510(d) and 423.509(d) by replacing the inconsistent language at § 423.509(d) to now read ''in accordance with subpart N of this part.''

b. Terminology Changes (§§ 422.510 and 423.509)

Sections 1857(c) and 1860D–12(b)(3)(B) of the Act authorize CMS to terminate contracts with MA organizations and Part D plan sponsors respectively. In the current termination regulations at §§ 422.510 and 423.509, there is inconsistent use of the terms ''days'' and ''calendar days''. Therefore, we proposed to replace the word ''days'' with ''calendar days'' in both §§ 422.510 and 423.509.

c. Technical Change To Align Paragraph Headings (§ 422.510(b)(2))

Sections 1857(c)(2) and 1860D–12(b)(3)(B) of the Act provide CMS with the authority to terminate contracts, for Part C and Part D sponsors respectively. The Part C paragraph heading at § 422.510(b)(2) incorrectly reads ''Expedited termination of contract by CMS.'' Therefore, we proposed to revise the paragraph heading of § 422.510(b)(2) to read ''Immediate termination of contract by CMS''. This change will also make it consistent with the corresponding heading for Part D, in § 423.509(b)(2).

d. Terminology Change (§ 423.509(b)(2)(C)(ii))

Sections 1857(c)(2) and 1860D–12(d)(3)(B) of the Act provide CMS with the authority to terminate contracts, for Part C and Part D sponsors respectively. In § 423.509(b)(2)(C)(ii) the regulation incorrectly references ''MA organization.'' This section concerns Part D, so the correct reference is ''Part D Plan Sponsor''. Therefore, we proposed to change § 423.509(b)(2)(C)(ii) to appropriately reference Part D plan sponsor; not MA organization, as it currently states.

We received no comments on these proposals and are therefore finalizing these provisions without modification.

4. Technical Changes Regarding Intermediate Sanctions and Civil Money Penalties

Sections 1857(g) and 1860D–12(b)(3)(E) of the Act provide us with the authority to impose intermediate sanctions (sanctions) and CMPs on Part C and Part D sponsors, respectively.

a. Technical Changes to Intermediate Sanctions Notice Receipt Provisions (§§ 422.756(a)(2) and 423.756(a)(2))

Under §§ 422.756(a)(2) and 423.756(a)(2) the current language states that written requests for rebuttal by the MA organization or Part D plan sponsor must be received within ''10 calendar days from the receipt of notice''. The language in other sections of this subpart refers to receipt of a notice as ''days after receipt of this notice.'' All sections should be consistent. Therefore, we proposed to modify the language at §§ 422.756(a)(2) and 423.756(a)(2) to state ''10 calendar days after receipt of the notice''. In addition, we proposed to correct grammatical errors in current §§ 422.756(a)(2) and 423.756(a)(2) by revising the language in both §§ 422.756(a)(2) and 423.756(a)(2) [2] to add the word ''the'' before notice; as proposed, the second sentence in each paragraph (a)(2) would read ''CMS considers receipt of the notice as the day after the notice is sent by fax, email, or submitted for overnight mail.''

b. Cross-Reference Changes (§ 422.756(b)(4) and § 423.756(b)(4))

Under § 422.756(b)(4) and § 423.756(b)(4), we reference the procedures MA organizations and Part D plan sponsors must follow for requesting a hearing to appeal the imposition of intermediate sanctions and civil money penalties. MA organizations and Part D sponsors must adhere to hearing procedures promulgated within subpart N of the regulations, not just §§ 422.660 through 422.684 and §§ 423.650 through 423.662, respectively, as currently cited in §§ 422.756(b)(4) and 423.756(b)(4). Therefore, we proposed to modify the language at §§ 422.756(b)(4) and 423.756(b)(4) so that it would read that MA organizations and Part D sponsors ''must follow the right to a hearing procedures as specified in subpart N''.

c. Technical Changes (§§ 422.756(d) and 423.756(d))

In §§ 422.756(d) and 423.756(d) we provide alternatives to sanctions, including non-renewal or termination of the organizations contract. However, the paragraph heading of both §§ 422.756(d) and 423.756(d) only refers to terminations by CMS. Therefore, we proposed to revise the paragraph heading to ''Non-renewal or termination by CMS'' in both sections to reflect the content specified within the provision.

Within §§ 422.756(d) and 423.756(d), we state that we may decline to authorize the renewal of an organization's contract in accordance with § 422.506(b)(2) and (b)(3) for MA organizations and in accordance with § 423.507(b)(2) and (b)(3) for Part D plan sponsors. However, all of paragraph (b) in §§ 422.506 and 423.507 applies to §§ 422.756(d) and 423.756(d), respectively. Therefore, we proposed to change both provisions §§ 422.756(d) and 423.756(d) to read ''§ 422.506(b)'' and ''§ 423.507(b)'', respectively.[3]

Within §§ 422.756(d) and423.756(d), we refer to the ''sanctions described in paragraph (c)'' but in each section, paragraph (c) refers to the effective date and duration of sanctions, rather than sanctions which are actually described in §§ 422.750 and 423.750, respectively. Therefore, we proposed to change the current language at § 422.756(d) to read ''In addition to or as an alternative to the sanctions described in § 422.750 . . .'' and change the language at § 423.756(d) to read ''In addition to or as an alternative to the sanctions described in § 423.750.'' to correct this mistake.

d. Technical Changes To Align the Civil Money Penalty Provision With the Authorizing Statute (§§ 422.760(a)(3) and 423.760(a)(3))

The provisions at §§ 422.760(a)(3) and 423.760(a)(3) state, ''the harm which resulted or could have resulted from conduct of an MA organization'' and ''the harm which resulted or could have resulted from conduct of a Part D plan sponsor'', respectively. However, this language is not consistent with the authorizing statutory provisions, nor is it consistent with other provisions in corresponding sections.

Therefore, we proposed to align the language with that used in paragraphs (b)(1) and (2) from that same section in both §§ 422.760(a)(3) and 423.760(a)(3). The language would be revised to state ''The adverse effect to enrollees which resulted or could have resulted . . .'' in both §§ 422.760(a)(3) and 423.760(a)(3) to track the statutory language.

[2] We note that although the preamble accurately reflected this proposal, the regulation text for § 423.756(a)(2), (79 FR 2070), erroneously did not reflect the proposed grammatical correction.

[3] In the preamble to our proposal, we mistakenly referred to the language as being deleted by using ''and'' instead of ''through''.

e. Technical Changes To Align the Civil Money Penalty Hearing Notice Receipt Provisions (§§ 422.1020(a)(2), 423.1020(a)(2), 422.1016(b)(1), and 423.1016(b)(1))

Sections 1857(g)(4) and 1860D–12(b)(3)(E) of the Act provides us with the authority to impose civil money penalties on MA organizations and Part D plan sponsors, respectively. Under §§ 422.1020(a)(2) and 423.1020(a)(2), we discuss our procedures for requesting an appeal of a CMP. The current language in both sections state written requests for appeal ''must be filed within 60 calendar days from the receipt of notice of initial determination.'' However, this language does not align with the appeal language in subpart N for requesting a hearing.

Therefore, we proposed to change the language at §§ 422.1020(a)(2) and § 423.1020(a)(2) to align it with the language within subpart N for appeals. Specifically, we proposed to change the language in both §§ 422.1020(a)(2) and 423.1020(a)(2) to read ''after receipt'' instead of ''from the receipt'', so it reads ''within 60 calendar days after receipt of the notice of initial determination''.

In addition, under §§ 422.1016 and 423.1016, we furnish our procedures for filing briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal. The provisions at §§ 422.1016(b)(1) and 423.1016(b)(1) state, ''the other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence''. However, this language is not consistent with provisions in other corresponding sections. Therefore, we proposed to revise the language at §§ 422.1016(b)(1) and 423.1016(b)(1) to state ''The other party will have 20 days from the date of mailing or in person filing . . .'' to maintain consistency.

We received no comments on these proposals and therefore are finalizing these provisions without modification.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICRs Related to Improper Prescribing Practices and Patterns

Our additions of §§ 424.530(a)(11), 424.535(a)(13), and 424.535(a)(14) will likely result in an increase in denials, revocations, and associated appeals. However, we are unable to estimate the number of denials, revocations, and appeals. We do not have data available that can be used to make such projections, as each situation would have to be carefully reviewed and addressed on a case-by-case basis. Therefore, we cannot estimate the potential concomitant increase in the ICR burden, though, as we stated in the proposed rule, we believe any such increase will be minimal.

We received no comments on the potential ICR burden of §§ 424.530(a)(11), 424.535(a)(13), and 424.535(a)(14).

B. ICRs Related to Applicants or Their Contracted First Tier, Downstream, or Related Entities To Have Experience in the Part D Program Providing Key Part D Functions (§ 423.504(b)(8)(i) Through (iii))

Proposed § 423.504(b)(8)(i) through (iii) would require that Part D organizations seeking a new Medicare contract must have arrangements in place such that either the applicant or a contracted entity that will be performing certain key Part D functions has at least 1 full benefit year of experience providing the function or providing the function for another Part D plan sponsor. The burden associated with this requirement is the time and effort put forth by Part D applicants to answer questions about such experience as part of the Part D application process. For entities that hold an existing Part D contract, or whose parent or another subsidiary of that parent has already held a Part D sponsor contract for at least a year, it is estimated that it will take each Part D applicant for a new contract 2 minutes to provide 1 or 2 new sentences in the organizational history section of the application, and 1 minute to respond to yes-no questions about experience with the 3 functions for which experience is required, for a total of 3 minutes per applicant. For entities new to Part D, it is estimated that it will take each Part D applicant for a new contract 2 minutes to provide 1 or 2 new sentences in the organizational history section of the application, 1 minute to respond to yes-no questions about experience with the 3 functions for which experience is required, and 1 additional minute to provide at least 1 contract number of an existing or recent Part D sponsor under which the entity to provide the key function obtained its experience, for a total of 4 minutes. Based on the number of Part D applications we receive each year, we would anticipate no more than 60 Part D applications for a new contract, of which no more than 15 would be entities new to Part D. Thus, the burden for the 45 existing entities at 3 minutes each, plus the burden for the 15 new entities at 4 minutes each, brings the total burden hours to approximately 3.25 hours. If approved, the new application questions would be addressed under currently approved OMB control number (OCN) 0938–0936.

We received no comments on this proposal and therefore are finalizing this provision without modification.

C. ICRs Related to Eligibility of Enrollment for Incarcerated Individuals (§ § 417.460, 422.734, and 423.44)

We proposed to amend §§ 417.460(b)(2)(i), 417.460(f)(1)(i), 422.74(d)(4)(i)(A), 422.74(d)(4)(v), and 423.44(d)(5) to clarify the eligibility requirement for residing in the plan's service area related to incarceration for the purposes of enrolling into and remaining enrolled in MA, Part D, and Medicare cost plans. To implement these regulations, we would relay data to plans regarding an individual's incarceration through the MARx system so that the plans would be aware of the individual's eligibility when requesting enrollment and notify the plans of loss of eligibility for current members. This data is already available to us. Thus no new data would be collected, and there is no new information collection or burden on organizations.

We received no comments on the ICRs for this proposal and therefore are finalizing the ICR assessment without modification.

D. ICRs Related to Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134)

This requirement does not impose any new information collection

requirements. This is an existing recordkeeping requirement in which MA organizations must retain information pertaining to any rewards and incentives programs in accordance with our regulations at 42 CFR 422.118. We believe the burden associated with this requirement is exempt from the PRA under 5 CFR 1320.3(b)(2) as we believe this is a usual and customary business practice. Furthermore, any requests to furnish the information in a form and manner we designate are unique, that is, non-standardized and specific to each individual MA organization.

We received no comments on the ICR assessment for this proposal and therefore are finalizing this assessment without modification.

E. ICR Related To Recovery Audit Contractor Determinations (Part 422, Subpart Z and Part 423, Subpart Z)

The information collection burden associated with our proposed requirements consists of the submission of requests for: (1) Reconsiderations; (2) CMS hearing official determinations; and (3) CMS Administrator reviews. Based on existing Part D appeals data, we estimate that plans will file the following numbers of requests on an annual basis:

TABLE 4—ESTIMATED NUMBER OF PART C & D RAC APPEAL REQUESTS

Type of request	Number of requests per year
Reconsideration	104
CMS Hearing Official	10
Administrator Review	2
Total	116

The reasons for the decrease in requests at higher appeal levels are that: (1) The plan may succeed in its appeal and thus have no need to appeal to the next level; and (2) the plan may simply wish to forgo further appeals. We stress that the figures in Table 4 are mere projections, though, again, they are based on the number of Part D appeals that have been submitted to date.

We estimate that it would take a plan 5 hours to prepare and file an appeal request. In terms of cost, it has been our experience that most appeals have been prepared by high-level officials of the plan. According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2012, the mean hourly wage for the category of ''General and Operations Managers''—which we believe, considering the variety of officials who have submitted appeals, is the most appropriate category—is $55.22. With fringe benefits and overhead, the per hour rate is $83.35. Multiplying this figure by 580 hours (or 116 submissions × 5 hours) results in a projected annual cost burden of $48,343, as outlined in Table 5.

TABLE 5—ESTIMATED ANNUAL REPORTING/RECORDKEEPING BURDEN

Regulation section(s)	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance costs ($)	Total cost ($)
§ 422.2605	N/A	52	52	5	260	83.35	83.35	0	21,671.00
§ 422.2610	N/A	5	5	5	25	83.35	83.35	0	2083.75
§ 422.2615	N/A	1	1	5	5	83.35	83.35	0	416.75
§ 423.2605	N/A	52	52	5	260	83.35	83.35	0	21,671.00
§ 423.2610	N/A	5	5	5	25	83.35	83.35	0	2083.75
§ 423.2615	N/A	1	1	5	5	83.35	83.35	0	416.75
Total	N/A	116	116	N/A	580			0	48,343

We received no comments on the ICR assessment for this proposal and therefore are finalizing this assessment without modification.

V. Regulatory Impact Analysis

A. Statement of Need

The purpose of this final rule is to make revisions to the MA program (Part C) and Prescription Drug Benefit Program (Part D), implement provisions specified in the Affordable Care Act, and make other changes to the regulations based on our continued experience in the administration of the Part C and Part D programs. This final rule makes changes that are necessary to: Clarify various program participation requirements and make other clarifications and technical changes.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule has been designated an ''economically significant'' rule under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis that details the anticipated effects (costs, savings, and expected benefits), and alternatives considered. Finally, in accordance with the provision of the Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.0 million to $35.5 million in any 1 year). Individuals

and states are not included in the definition of a small entity. This final rule primarily affects the federal government, Medicare Advantage plans, and Part D Sponsors.

Part D sponsors and MA plans, entities that will be affected by the provisions of this rule, are not generally considered small business entities. We determined that there were very few MA plans and Part D sponsors that fell below the size thresholds for ''small'' businesses established by the Small Business Administration (SBA). Currently, the SBA size threshold is $35.5 million in total annual receipts for health insurers (North American Industry Classification System, or NAICS, Code 524114) and we have confirmed that most Part D sponsors have Part D receipts above the $35.5 million threshold.

While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans. A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. HHS uses as its measure of significant economic impact on a substantial number of small entities, a change in revenue of more than 3 to 5 percent. Consequently, we do not believe that this threshold will be reached by the requirements in this final rule because this final rule will have minimal impact on small entities. Therefore, an analysis for the RFA will not be prepared because the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by state, local, or tribal governments, in the aggregate, or by the private sector of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. This final rule is not expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Based on CMS Office of the Actuary estimates, we do not believe that this final rule imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications.

Table 10 details the final rule's impacts by entity, including the federal government and MA organizations and Part D sponsors. We note that the estimated savings do not represent net social benefits because they consist of transfers of value from drug manufacturers, pharmacies, and incarcerated individuals to the federal government, MA organizations, Part D sponsors and beneficiaries who continue in the programs.

C. Anticipated Effects

1. Effects of Closing Cost Contract Plans to New Enrollment

We proposed to ensure that organizations do not move enrollees from one of their cost or MA plan types to another based on financial or some other interest, and to revise § 422.503(b)(5) so that an entity seeking to contract as an MA organization must ''not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan if the MA organization and reasonable cost contract are offered by the same parent organization.'' We believe this provision will have minimal or no financial impact as only a handful of parent organizations currently offer MA and cost plans in the same service area. In addition, as the regulation requires that affected cost plans close to new enrollment, not that they terminate operations, we believe that there will be little or no impact to beneficiaries. We are finalizing the provision as proposed, with the revisions specified in our response to public comments earlier in this document.

2. Effects of Authority To Impose Intermediate Sanctions and Civil Money Penalties

We proposed to make two changes to existing authority for the imposition of intermediate sanctions and civil money penalties (CMPs). First, under the Affordable Care Act, new authority was provided to the Secretary, which now permits CMS to impose intermediate sanctions for additional contract violations in the areas of marketing and enrollment. This new authority further permits CMS to impose intermediate sanctions on contracting organizations' that employ or contract with organizations, agents, and suppliers who commit any of the contract violations contained in §§ 422.752 and 423.752.

Second, we are clarifying our authority to impose CMPs for the aforementioned contract violations. Current regulations designate the OIG as the sole government agency with the authority to impose CMPs for the contract violations contained in §§ 422.752 and/or 423.752. We are modifying the language of these provisions to clarify that CMS or the OIG may impose CMPs for these contract violations except the provision that relates to the misrepresentation of falsification of information furnished to CMS, an individual or entity.

We believe these provisions will not result in additional burden to sponsors nor will they have a financial impact on sponsors.

3. Effects of Contract Termination Notification Requirements and Contract Termination Basis

In current regulations, we are required to provide 90-day notice to organizations whose contracts are being terminated by CMS. The authorizing statute at section 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act states that the Secretary must provide reasonable notice and opportunity for hearing (including the right to appeal the initial determination) before terminating a contract (except under certain circumstances). We proposed to modify the notice timeframe from 90 days to 45 days. We believe these provisions will not result in additional burden to sponsors nor will it have a financial impact on sponsors.

4. Effects of Reducing the Burden of the Compliance Program Training Requirements

We proposed to lessen the burden placed on contracting organizations and their first tier, downstream and related entities (FDRs). Current regulations specify that contracting organizations are required to provide general compliance program training for their FDRs upon initial contracting and annually thereafter. To lessen this burden, we will require all contracting organizations to accept a certificate of completion of the CMS Standardized General Compliance Program Training and Education Module as evidence of

satisfaction of this program requirement. Under this program change, contracting organizations will not be permitted (or required) to develop or implement organization specific training for FDRs. We anticipate that this will greatly reduce the burden on various sectors of the industry including, but not limited to, insurance providers, hospitals, suppliers, pharmacists and physicians. We anticipate that this change will actually provide savings for sponsors and the FDRs since FDRs will only have to take one training as opposed to the possible numerous trainings they may take under current requirements. Additionally, sponsors will save because they will not be required to provide training materials to each FDR with which they contract.

We believe these provisions will not result in additional burden to sponsors nor will they have a financial impact on sponsors.

5. Effects of Procedures for Imposing Intermediate Sanctions and Civil Money Penalties Under Part C and D

We proposed to make changes to our authority for imposing intermediate sanctions and for determining when such sanctions will be lifted. Sections 1857(g) and 1860D–12(b)(3)(E) of the Act provide the Secretary the ability to impose intermediate sanctions on MA organizations and PDP sponsors. Intermediate sanctions consist of suspension of enrollment, suspension of marketing and suspension of payment. Current regulations governing intermediate sanctions are contained in subparts O of part 422 and Part 423. Sections 422.756 and 423.756 provide specific procedures for imposing intermediate sanctions and include provisions, which address: The duration of the sanction; and the standard that we apply when determining if a sanction should be lifted. As specified in the Act and regulations, when intermediate sanctions are imposed on contracting organizations, the sanctions remain in place until the Secretary/CMS is satisfied that the basis for the sanction determination has been corrected and is not likely to recur.

In the October 2009 proposed rule (74 FR 54634), we proposed a change that included a rule that allows us to require a plan under a marketing and/or enrollment sanction to market or accept enrollments or both for a limited period of time. As we explained in that proposed rule, the purpose of the test period is to assist us in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur. The test period provides us with the opportunity to observe a sanctioned plans ability to enroll or market to Medicare beneficiaries prior to lifting the sanction.

We proposed to extend the applicability of such a test period to include all intermediate sanctions and to clarify that while we may require a sponsor to receive enrollments during this test period, the sponsor will not receive any LIS annual or auto facilitated reassignments.

We believe these provisions will not result in additional burden to sponsors nor will they have a financial impact on sponsors.

6. Effects on Timely Access to Mail Order Services

We proposed to establish a fulfillment requirement for mail order prescriptions. We believed it was necessary and appropriate to establish mail order fulfillment requirements defining maximum turnaround times from when the pharmacy receives the prescription order to when it is shipped. This would underscore the importance of consistent and reliable access to medications, protecting beneficiaries from inconsistent or unreliable practices that may otherwise jeopardize timely access to prescriptions.

Comments persuaded us that we had not considered all relevant implications of this proposal and we decided not to finalize this provision. This in turn means that there will be no financial impact.

7. Effects of the Modification of the Agent/Broker Compensation Requirements

The current independent agent compensation structure (as originally published as CMS–4138–IFC2 in November 2008) is comprised of a 6-year cycle which ended December 31, 2013. MA organizations and Part D sponsors provide an initial compensation payment to independent agents for new enrollees or unlike plan changes (Year 1), and pay a renewal rate (equal to 50 percent of the initial year compensation) for Years 2 through 6. We proposed revising this existing compensation structure. MA organizations and Part D sponsors will have the discretion to decide, on an annual basis, whether to pay initial and/or renewal compensation payments to their independent agents. For new or unlike plan change enrollments, MA organizations and Part D sponsors could make an initial payment that is no greater than the fair market value (FMV) amount for such services, set annually by CMS in guidance interpreting these regulations. For renewals in Year 2 and subsequent years, the MA organization or Part D sponsor could pay up to 35 percent of the FMV amount for that year. We are finalizing the provision with an up to 50 percent payment for renewals, instead of the proposed 35 percent. We also proposed that plans not recover compensation when the disenrollment is not a result of the agent's behavior. We are not implementing the changes with respect to the recovery of compensation, but will finalize language to keep the existing situation, which requires full recoupment if a member disenrolls within the first 3 months of enrollment except in limited circumstances. In addition to the agent and broker compensation structures, we are setting limits on referral fees for agents and brokers.

We do not believe that any of these revisions will have a significant increase in burden or financial impact. Our existing compensation rules require that MA organizations and Part D sponsors pay on a calendar year basis, not a rolling year basis. Our regulations are restating existing requirements, to ensure consistency. While some MA organizations and Part D sponsors may have to make significant systems changes to ensure compliance, these changes are not based on this final rule but are required to meet existing requirements. MA organizations and Part D sponsors will likely have to make some systems modifications, such as paying between January 1 and December 31 of each year. However, we do not believe these will be of significant impact. Although some changes will be necessary, we believe the small cost and burden of the changes will outweigh the cost and burden of the existing multi-tier approach by simplifying the compensation structure for independent agent brokers.

8. Effects of Drug Categories or Classes of Clinical Concern

We are not finalizing the proposed criteria or their application to the categories and classes of clinical concern.

9. Effects of Medication Therapy Management Program (MTMP) under Part D

Current regulations require that Part D sponsors must have established a Medication Therapy Management Program that targets beneficiaries who: (1) Have multiple chronic diseases with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment; (2) are taking multiple Part D drugs, with

eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and (3) are likely to incur costs for covered Part D drugs in an amount greater than or equal to $3000, as increased by an annual percentage. We specified in guidance that while Part D sponsors are permitted to target beneficiaries with select chronic diseases, they must include at least five of nine core chronic diseases in their criteria. These provisions have generated wide variability in MTM programs. Moreover, despite opt-out enrollment, completion rates for comprehensive medication reviews (CMR) remain very low.

We proposed to broaden the MTM criteria to require that Part D sponsors target beneficiaries who have two or more chronic diseases and are taking two or more covered Part D drugs. We proposed to set the annual cost threshold at an amount commensurate with the annual amount of Part D costs incurred by individuals that meet the first two criteria regarding multiple chronic conditions and use of multiple covered Part D drugs. Applying this methodology, we would have set the cost threshold at $620 which is the approximate cost of filling two generic prescriptions. We proposed to revise this number periodically to reflect more up-to-date information regarding the drug spending of beneficiaries that have two or more chronic conditions and use two covered Part D drugs. We estimated that 2.5 million beneficiaries are currently eligible for MTM services, 13 percent opt-out of the MTM program, and 10 percent of participating beneficiaries will receive an annual CMR. We also estimated that an average CMR requires 35 minutes to complete and the average hourly compensation (including fringe benefits, overhead, general, and administrative expenses and fee) of the MTM provider is $120 (labor cost per CMR is $70), and that it costs $0.91 to print and mail a CMR summary in CMS' standardized format. Therefore, the estimated total annual cost of providing CMRs in all settings is $15,422,925 ($70.91/CMR x 217,500 CMRs). Previously, prior to the availability of more precise opt-out and CMR rates, we estimated that the total burden associated with conducting CMRs and delivering the CMR written summary in CMS' standardized format was 1,192,429 hours with a cost of $143,363,555, including delivery of 1,896,500 CMRs in all settings under the current eligibility criteria, and implementation and mailing costs for the CMR summary in standardized format (see OMB Control No. 0938–1154). We do not currently have data or estimates to determine the costs associated with quarterly targeted medication reviews and follow-up interventions, if necessary.

In the proposed rule, we estimated that 18 million beneficiaries would be eligible for MTM services based on the proposed criteria. Using the same opt-out, CMR, and expense rates as before, the estimated total annual cost of providing CMRs in all settings would be $111,045,060 ($70.91/CMR × 1,566,000 CMRs). This was below previous estimates.

We were unable to definitively score the proposed changes to the eligibility criteria because the portion of the administrative costs attributable to MTM is not a specific line item that can be easily extracted from the bid. Although the increase in the number of CMRs was estimated to cost $111 million, we cited evidence in the proposed rule that showed that MTM services may generate overall medical savings.

We are not finalizing these proposals. Therefore, the increased burden estimates associated with increasing eligibility from 2.5 million beneficiaries to 18 million beneficiaries are removed.

10. Effects of Requirement for Applicants or Their Contracted First Tier, Downstream, or Related Entities to Have Experience in the Part D Program Providing Key Part D Functions

Based on CMS' authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, not inconsistent with the Part C and D statutes, that are necessary and appropriate to administer the Part D program, we proposed at § 423.504(b)(8)(i) through (iii) that Part D organizations seeking a new Medicare contract must have arrangements in place such that either the applicant, or a contracted entity that will be performing certain key Part D functions, has at least one full benefit year of experience providing key Part D functions. This proposal ensures that applicants take advantage of the abundant Part D industry expertise and experience that exists today in the development of their Part D program operations, rather than relying on technical assistance from CMS and having their inexperience place beneficiaries' access to prescription drugs at risk. We believe this provision will have a very minor savings impact on the federal budget, based on savings of time and effort (staff time and contracted auditor time and resources) that the government would spend on overseeing the disproportionate level of problems experienced by organizations operating Part D plans without prior Part D experience. For each inexperienced organization allowed into the program in the absence of this proposal, we would anticipate a savings of 1,000 staff hours at an average rate of $50 per hour, for a total of $50,000 in employee time, plus an additional savings of $200,000 in contractor dollars to conduct an emergency audit, for a total of $250,000. In the absence of this proposal, we would anticipate no more than two such inexperienced entities beginning Part D operations per year, for a total annual savings of $500,000.

The burden associated with this proposal on industry will be minimal, with a total estimated number of labor hours of 3.25 to submit information during the Part D application process. Using the same average hourly salary as previously mentioned, the total cost to Part D applicants will be $162.50. We do not believe there are any non-administrative costs to industry associated with this proposal, as Part D applicants are already required to have arrangements in place to perform the key Part D functions discussed in our proposal.

The main anticipated effect from this proposal is ensuring that only entities with some experience with Part D in critically important functional areas are permitted to offer new Part D contracts, thus strengthening the Part D program by enhancing the qualification criteria. We considered the alternate proposal of requiring the prior Part D experience to be tied to specific quality outcomes. We rejected the alternative because we believed it added unnecessary complexity and burden to the process, and we believe a simple experience requirement is currently sufficient.

11. Effects of Requirement for Applicants for Stand Alone Part D Plan Sponsor Contracts To Be Actively Engaged in the Business of the Administration of Health Insurance Benefits

Based on CMS' authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, not inconsistent with the Part C and D statutes, that are necessary and appropriate to administer the Part D program, we proposed at § 423.504(b)(9)(i) through (ii) that organizations seeking to offer a stand-alone prescription drug plans (PDP) for the first time must have either: (i) Actively offered health insurance or health benefits coverage for 2 continuous years immediately prior to submitting an application, or (ii) actively managed prescription drug

benefits for a company offering health insurance or health benefits coverage for 5 continuous years immediately prior to submitting an application. This proposal will ensure that applicants have substantial experience in administering health insurance benefits prior to becoming a Part D sponsor. We believe this provision will have a very minor savings impact on the federal budget, based on savings of time and effort (staff time and contracted auditor time and resources) that the government would spend on overseeing the disproportionate level of problems experienced by organizations operating stand-alone PDPs without prior health insurance administration experience. For each inexperienced organization not allowed into the program in the absence of this proposal, we would anticipate a savings of 1,000 staff hours at an average rate of $50 per hour, for a total of $50,000 in employee time, plus an additional savings of $200,000 in contractor dollars to conduct an emergency audit, for a total of $250,000. In the absence of this proposal, we would anticipate no more than two such inexperienced entities beginning Part D operations per year, for a total annual savings of $500,000.

The burden associated with this proposal on industry will be minimal, with a total estimated number of labor hours of 3.25 to submit information during the Part D application process. Using the same average hourly salary as previously mentioned, the total cost to Part D applicants will be $162.50. We do not believe there are any non-administrative costs to industry associated with this proposal, as Part D applicants are already required to be licensed in at least one state prior to offering Part D benefits.

The main anticipated effect from this proposal is ensuring that only entities with some experience administering health insurance benefits will be permitted to offer new stand-alone PDPs, thus strengthening the Part D program by enhancing the qualification criteria. CMS considered the alternate proposal of requiring the prior health insurance benefit administration experience to be tied to specific quality outcomes. We rejected this alternative because we believed it added unnecessary complexity and burden to the process, and we believe a simple experience requirement is currently sufficient.

12. Effects of Limit Parent Organizations To One Prescription Drug Plan (PDP) Sponsor Contract per PDP Region

This provision has no quantifiable impact because the savings that might be achieved likely will be offset by the burden necessary with the consolidation activities and legal work necessary to implement these changes.

13. Effects of Limit Stand-Alone Prescription Drug Plan Sponsors To Offering No More Than Two Plans per PDP Region

As this proposal is not being finalized, there will be no financial impact.

14. Effects of Applicable Cost-Sharing for Transition Supplies: Transition Process Under Part D

We proposed to add at § 423.120(b)(3)(vi) a paragraph clarifying that a Part D sponsor must charge cost sharing as follows: (a) For low-income subsidy (LIS) enrollees, a sponsor must not charge higher cost sharing for transition supplies than the statutory maximum copayment amounts; (b) for non-LIS enrollees, a sponsor must charge: (1) The same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved under a coverage exception; and (2) the same cost sharing for formulary drugs subject to utilization management edits provided (for example, prior authorization and step therapy) during the transition that would apply once the utilization management criteria are met.

Because increases or decreases in cost sharing during transition supplies under the various circumstances are likely to offset one another, we anticipate that there will be no cost impact on plans.

15. Effects of Interpreting the Non-Interference Provision

We proposed to formally interpret section 1860D–11(i) of the Act, referred to as the non-interference provision. This provision prohibits CMS from interfering with the negotiations between drug manufacturers and pharmacies and Part D sponsors, and requiring a particular formulary or instituting a price structure for the reimbursement of covered part D drugs. We have not formally interpreted the statutory provision, which has resulted in different stakeholders having different views about its scope. Consequently, we believe that a clear interpretation of the statutory provision will remove ambiguity. As we are not finalizing this proposal, there is no change in regulatory impact.

16. Effects of Pharmacy Price Concessions in Negotiated Prices

We proposed to revise the definition of negotiated prices at § 423.100 to specify that all pharmacy price concessions must be included in the negotiated price. This will preclude the differential reporting that is taking place today in the realm of reporting drug costs and price concessions from network pharmacies. The rule will change current policy that permits sponsors to elect which price concessions from pharmacies to report outside the PDE. This practice currently allows price concessions to be applied disproportionately to costs that plans are liable for, and thus may shift more low-income cost-sharing subsidy and reinsurance costs to the government, as well as to manufacturers in the calculation of coverage gap discount payments. A sponsor that engages in this practice can reduce its bid and achieve a competitive advantage relative to a sponsor that applies all price concessions to the negotiated price—a competitive advantage stemming not from greater efficiency, but from a technical difference in how costs are reported to CMS. Meanwhile, the higher the negotiated price, the higher beneficiary coinsurance will be, the faster the beneficiary is moved through the benefit, and the higher government subsidies for low-income cost sharing (LICS) and reinsurance subsidies will be. Our proposal will impose consistent treatment of drug price reporting.

Our proposal to require all price concessions to be reflected in the negotiated price received by the pharmacy would not necessarily change the level of price concessions received from network pharmacies, but will impose a single consistent price concession reporting process on all Part D sponsors. Therefore, it is not clear that any contractual arrangements between a subset of sponsors and network pharmacies will require renegotiation, since only the form of the price concession, rather than its level, will be affected by this proposal.

In addition, when price concessions from pharmacies are in forms other than the negotiated price, the degree of price concession that the pharmacy has agreed is no longer reflected in the negotiated prices available at point of sale or reflected on the Medicare Prescription Drug Plan Finder (Plan Finder) tool. Thus, the true price of drugs at individual pharmacies is no longer transparent to the market. Consequently, consumers cannot efficiently minimize both their costs (cost sharing) and costs to the taxpayers by seeking and finding the lowest-cost drug/pharmacy combination. This proposal will ensure that the actual level of price competition is transparent to the Part D market.

Under current policy, a sponsor may be able to offer a lower bid than its competitors and may achieve a competitive advantage stemming not from greater efficiency, but from a technical difference in how costs are reported to CMS. When this happens, such differential reporting may result in bids that are no longer comparable, and in premiums that are no longer valid indicators of relative plan efficiency. The changes we proposed will lend to Part D bids being more accurately comparable and premiums more accurately reflecting relative plan efficiencies. The lowest premiums will more accurately direct beneficiaries to the plans that have the lowest costs to the program overall.

We do not collect sufficient detail in price concession data reported to CMS to quantify the impact of this change to standardize price concession reporting. We believe that only certain sponsors are engaging in the differential reporting practices today, and these sponsors face close competition from larger competitors that do not appear to be employing the same strategies. Consequently, if the sponsors employing these tactics increase their bids to maintain margin, they could likely risk losing market share. Therefore, we would expect these sponsors to carefully consider the risk of losing market share before raising their bids in response to our regulatory proposals, particularly those that are committed to the LIS market.

We are finalizing the provision with modification to require that negotiated prices be inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point of sale. We expect that the effect of regulation to require consistent and transparent pricing will not only provide higher-quality information to the Part D market, but also promote increased price competition among network pharmacies. This expectation is consistent with economic theory that holds that increased price transparency will increase price competition. We believe pharmacies will support including the full price concession in the point-of-sale price, and fully transparent price competition will align beneficiary and taxpayer interests in minimizing costs. Our rule will not change the level of price concessions and therefore costs under the program as a whole, but will apply consistency to how these are reported to CMS and treated in bidding and payment processes. Therefore, we anticipate that there will be no cost impact on plans.

17. Effects of Preferred Cost Sharing

We proposed to require that sponsors may offer reduced copayments or coinsurance for covered Part D drugs obtained through a subset of network pharmacies, as long as such preferred cost sharing is in return for consistently lower negotiated prices relative to the same drugs when obtained in the rest of the pharmacy network. Therefore, we intended to clarify that preferred cost sharing should consistently be aligned with and accurately signal lower costs. We proposed that by ''consistently lower'' we meant that sponsors must offer better prices on all drugs in return for the lower cost sharing. In practice we believe this would mean that whatever pricing standard is used to reimburse drugs purchased from network pharmacies in general, a lower pricing standard must be applied to drugs offered at the preferred level of cost sharing. Our analysis shows that most sponsors offering preferred cost sharing are currently achieving these levels of savings, and therefore our proposed policy would only require a change in price concession levels or reporting for a limited number of sponsors. Our proposal would apply a consistent expectation across all sponsors to compete on the same basis on negotiated prices, including in related-party pharmacy operations.

After considering the public comments, we are not finalizing the proposal to revise § 423.120(a)(9) to require consistently lower negotiated prices for Part D drugs obtained through pharmacies offering preferred cost sharing than the same Part D drugs when obtained in the rest of the pharmacy.

This proposal will not be finalized and we will not engage in further rulemaking without re-proposing in a future rule, eliminating any estimated costs for implementation at this time.

18. Effects of Maximum Allowable Cost Pricing Standard

We proposed a change to the regulations at §§ 423.501, 423.505(b)(21) and 423.505(i)(3)(vii) governing the disclosure and updating of prescription drug pricing standards used by Part D sponsors to reimburse network pharmacies to make clear that drug pricing based on maximum allowable cost (MAC) is subject to these regulations. In the final rule at 76 FR 54600 (September 1, 2011), we did not estimate a regulatory impact for Part D sponsors to comply with the prescription drug pricing standard requirements, and we do not believe these changes would result in any regulatory impact. Read together, the new provisions in §§ 423.501, 423.505(b)(21), and 423.505(i)(3)(viii) require sponsors, when applicable, to include provisions in network pharmacy contracts, to address the disclosure of MAC prices themselves to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, because the source of the MAC prices is not publicly available. Addressing prices that will be paid to a subcontractor is an activity undertaken in the normal course of business. Also, whether to use MAC prices is voluntary for Part D sponsors. Finally, sponsors must have procedures, systems, and technology currently in place to use these prices for reimbursement of pharmacy claims in the normal course of business. These systems will have to be adapted to also disclose the prices to pharmacies in advance of their use, which we believe will involve negligible effort for Part D sponsors' existing employees and/or subcontractors. Therefore, we estimate the impact of these provisions to be negligible.

19. Effects of Any Willing Pharmacy Standard Terms & Conditions

Proposed changes to § 423.120(a)(8) would require Part D sponsors to offer the contract terms and conditions (T&C) for every level of cost sharing offered under a Part D plan (preferred, standard retail, mail order, etc.) to any willing pharmacy. We expected the burden for Part D sponsors to amend contracts, where necessary, to offer every level of cost sharing would be negligible. Sponsors already must meet any willing pharmacy requirements for retail and mail order cost sharing. In 2013, nearly half of non-employer group Part D sponsors were designing and marketing plans with T&C for preferred cost sharing levels. For these sponsors, the only change associated with this proposal would have been to ensure that now T&C for all levels of cost sharing, including preferred, are being offered (if they are not already) to all interested pharmacies. For the other half of Part D sponsors not currently offering preferred cost sharing options, this proposal did not require them to start.

Part D sponsors already negotiate contracts regularly with pharmacies in order to meet network access requirements. We estimated that for sponsors who currently offer benefit packages with a preferred cost sharing level (approximately 500 plans), an estimated new burden of 5,000 legal hours (500 plans x 10 hours) for revising contract language and 2,000 hours (500 plans x 4 hours) for additional contract

support staff time negotiating with and assisting pharmacies contracting at the preferred cost sharing level for the first time. The estimated cost associated with this change is the estimated number of hours multiplied by available average hourly rates ($62.93 per hour for a lawyer, $32.22 per hour for a financial specialist [May 2012 wage data from Bureau of Labor Statistics Occupational Employment Statistics]), plus 48 percent for fringe benefits and overhead, which equals a first year cost of $561,053.20. Once a sponsor had revised contracts to meet the proposed requirement, no extraordinary additional expenses were anticipated for subsequent years. For a plan not currently offering preferred cost sharing levels, it was expected that preferred cost sharing terms and conditions would be offered to any willing pharmacy if they ever decide to offer them.

Any new burden on pharmacies was similarly expected to be negligible, as they are already reviewing and implementing terms from contracts, often annually. Pharmacies were not being directed to choose one set of T&C over another, but rather would have gained the option to review and implement terms for preferred cost sharing, if they so choose to accept the applicable negotiated pricing terms. Beneficiaries were expected to benefit from an increased number of pharmacies offering preferred cost sharing levels.

We received the following comments and our response follows:

Comment: Some commenters believed that there would be additional costs not reflected in the impact analysis, resulting from the proposed change to pharmacy contracts. One commenter believed that the estimates provided for revising contract language and especially negotiating new contracts with pharmacies were too low, and a few commenters stated that it would take more than 6 months to implement these changes.

Response: We appreciate the comments. However, this proposal will not be finalized and we will not engage in further rulemaking without re-proposing in a future rule, eliminating any estimated costs for implementation at this time.

20. Effects of Enrollment Requirements for Prescribers of Part D Covered Drugs

We proposed that prescribers must either be enrolled in Medicare or have validly opted-out in order for their prescriptions to be covered under the Part D program. This will entail Part D sponsors or their designated PBMs checking the prescriber's individual NPI to determine whether the prescriber is enrolled or in a valid opt-out status in Medicare before paying a claim from a network pharmacy or a request for reimbursement from a beneficiary.

When we promulgated the NPI PDE requirement in a final regulation published on April 12, 2012 (77 FR 22072), we estimated the impact for PBMs and plan organizations to contract for or build prescriber ID validation services. Thus, while § 423.120(c)(6) entails a new requirement for Part D sponsors, we do not believe it will have any new or additional impact because Part D sponsors must already have prescriber validation capabilities to meet the NPI PDE requirement.

We presume that if a beneficiary's prescriber is not enrolled or does not enroll in Medicare, the beneficiary will find a new prescriber who is enrolled, rather than go without needed medications. Solely from this perspective, we do not project any savings from this provision. We believe there will be savings, though, from the fact that certain unqualified individuals will no longer be able to prescribe Part D drugs, for they will be unable to meet Medicare requirements. However, we are unable to estimate a particular savings figure because we do not know how many such individuals there will be.

21. Effects of Improper Prescribing Practices and Patterns

Our additions of §§ 424.530(a)(11) and 424.535(a)(13) will likely result in additional application denials, revocations, and associated appeals. The DEA Web site found at *http://www.deadiversion.usdoj.gov/crim_admin_actions/index.html* contains a list of physicians, eligible professionals, and pharmacies that have had their DEA Certificate of Registration suspended or revoked since 2000. However, we do not have data available to assist us in calculating the possible costs to physicians and eligible professionals in lost potential billings or the possible costs or savings to the government arising from these two provisions.

Section 424.535(a)(14) will result in an increase in the total number of revocations and associated appeals. Yet we are unable to project the number of providers and suppliers that will be revoked under § 424.535(a)(14) because we do not have data available that can be used to make such an estimate. Thus, we cannot project: (1) The potential costs to providers and suppliers in lost billings, or (2) the possible costs or savings to the government arising from this provision.

We received the following comments regarding the impact of proposed §§ 424.530(a)(11), 424.535(a)(13), and 424.535(a)(14).

Comment: A commenter disagreed with CMS' determination that §§ 424.530(a)(11), 424.535(a)(13), and 424.535(a)(14) do not have federalism implications, contending that these provisions usurp the role of state licensing boards. The commenter recommended that CMS explain: (1) the federalism impacts of these provisions; and (2) the steps that it took to consult with state and local officials early in the process of developing the proposed rule.

Response: We maintain that these three provisions have no federalism implications, for CMS is not usurping the authority of states to take action against a physician or practitioner with respect to his or her licensure status. Moreover, as stated earlier, CMS (not state licensing boards) is the agency responsible for administering the Medicare program. Therefore, we must have the ability to independently take steps to protect Medicare beneficiaries and the Trust Funds.

Comment: One commenter stated that CMS did not furnish reasonable alternatives to the establishment of § 424.535(a)(14).

Response: In light of the very serious problem of abusive prescribing, as outlined by the OIG, CMS did not believe there were any reasonable alternatives to its proposal. Prompt action was necessary to protect Medicare beneficiaries and the Trust Funds.

No modifications are being made to §§ 424.530(a)(11), 424.535(a)(13), and 424.535(a)(14) as a result of these comments.

22. Effects of Broadening the Release of Part D Data

We proposed to revise our regulations governing the release of Part D data to expand the release of unencrypted prescriber, plan, and pharmacy identifiers contained in prescription drug event (PDE) records to external entities, as well as to make other changes to our policies regarding the use and release of PDE data, as currently codified at § 423.505 (f)(3), (l) and (m). These proposals would not impose any new costs on any stakeholders. Medicare Part D plan sponsors are already required to, and do, submit the information that may be used or released in accordance with these proposals. Therefore, although we are finalizing the revisions to the Part D data regulations as proposed, we are not including any assessment of this final

policy for the regulatory impact statement.

23. Effects of Establish Authority To Directly Request Information From First Tier, Downstream, and Related Entities

Pursuant to sections 1857(d)(2) and 1860D 12(b)(3)(c) of the Act, we are now proposing to specify at §§ 422.504(i)(2)(ii) and 423.505(i)(2)(ii) that HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records directly from any first tier, downstream, or related entity. This regulatory change would not grant CMS (or the MEDIC, the contractor that conducts fraud investigations on our behalf) any oversight authority beyond what we already possess.

In enabling CMS or its designee(s) to directly request information from a first tier, downstream, or related entity, we would provide a more efficient avenue to obtain necessary information. This proposal would change the current policy, which requires going through the plan sponsor in order to collect information. Our proposal would save money and time for CMS as well as the plan sponsor.

We anticipate that adoption of this proposal would result in cost savings for plan sponsors. Under the current regulatory structure, assuming that the MEDIC (the CMS contractor that typically would put forth such requests) puts forth 1000 requests per year to Part C and D sponsors, each request requires the plan sponsor to spend 5 hours developing and making the request for information from its first tier, downstream, or related entity, and communicating the results of that request back to CMS. At a rate of $55 per hour, plan sponsors may save a total of $275,000 in employee costs in the aggregate. Additionally, we believe this provision will have a very minor savings impact on the federal budget. This calculation is based on the savings in time and effort the MEDIC will experience (2 hours per information request) resulting from the ability to request information directly from first tier, downstream, and related entities. The 2 hours reflects the time the MEDIC currently spends resolving ambiguities in the request or in the information provided in response that are created by the presence of an intermediary (that is, the plan sponsor) between the requestor (MEDIC) and the custodian of the information (that is; first tier, downstream, or related entity).

In addition to cost savings, this regulatory change will reduce the administrative burden on plan sponsors. The plan sponsor will no longer have to act as the gatekeeper between the MEDIC and its first tier, downstream, or related entity.

We do not anticipate any additional burden relating to the requirement that we alert the plan sponsor that we are contacting its first tier, downstream or related entity since CMS will be merely copying the plan sponsor on the request.

24. Effects of Eligibility of Enrollment for Incarcerated Individuals

We proposed to amend §§ 417.460(b)(2)(i), 417.460(f)(1)(i), 422.2, 422.74(d)(4)(i)(A), 422.74(d)(4)(v), 423.4, and 423.44(d)(5) to clarify the eligibility requirement for residing in the plan's service area related to incarceration for the purposes of enrolling into and remaining enrolled in MA, Part D, and Medicare cost plans. We expect the impact of this change to be primarily that of savings to the MA and Part D programs. In CY 2012, there were close to 50 million Medicare beneficiaries. Approximately 34.4 million of those beneficiaries were enrolled in MA plans, PDPs, or cost plans which accounts for 68.8 percent of the total Medicare population. In the same year, an average of 21,329 Medicare beneficiaries enrolled in MA or Part D plans were identified by SSA as being incarcerated.

We issued guidance to MA plans and PDPs to investigate each individual's incarcerated status and disenroll the individual for no longer residing in the plan's service area if the plan confirmed incarcerated status. If the MA plan or PDP could not confirm the incarcerated status, those plans were to continue to investigate each instance of incarceration for up to 6 or 12 months and disenroll the individuals at the end of that time following §§ 422.74(b)(4)(ii)/423.44(b)(5)(ii) if they could not verify the incarcerated status sooner. As a result, plans received capitated payments when individuals were ineligible to receive payment of Medicare benefits. Section 1876 Cost contracts had no such instructions to disenroll individuals who are incarcerated. By directing MA plans, PDPs, and cost plans to disenroll incarcerated individuals at the time of notification from CMS, we intend to prevent improper payment for these individuals to MA plans, PDPs, and cost plans for periods when they were ineligible to receive such services. Based on the data for capitation payments for MA and PDPs, as well as the prepayments provided to cost plans, we estimate that the disenrollment of incarcerated individuals would result in a decrease in improper payments made by CMS and would result in a cost savings of $73 million in 2015.

We estimate, based on the numbers mentioned previously, that this change could save the MA program approximately $27 million in 2015, increasing to $103 million in 2024, and could save the Part D program (includes the Part D portion of MA PD plans) approximately $46 million in 2015, increasing to $153 million in 2024. As cost plans are paid based on the reasonable costs of delivering Medicare covered services to their enrollees, instead of the fixed capitation amounts paid to MA and PDPs, we believe the impact to cost plans associated with this provision to be negligible.

TABLE 6—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO INCARCERATION AND ESTIMATED SAVINGS TO THE MEDICARE ADVANTAGE PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2024

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Totals (CYs 2015–2024)
Projected number of incarcerated beneficiaries enrolled in MA plans	6,280	7,750	9,221	10,691	12,162	13,234	13,969	14,704	15,440	16,175	.....
Projected federal impact due to incarcerated individuals disenrolled 6 months sooner	−$27 million	−$35 million	−$43 million	−$52 million	−$62 million	−$70 million	−$78 million	−$86 million	−$94 million	−$103 million	−$650 million

Note: Estimates reflect scoring by the CMS, Office of the Actuary, and 2012 incarceration data provided by the SSA.

TABLE 7—PROJECTED NUMBER OF INDIVIDUALS DISENROLLED DUE TO INCARCERATION AND ESTIMATED SAVINGS TO THE MEDICARE PART D PROGRAM BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2024

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Totals (CYs 2015–2024)
Projected number of incarcerated beneficiaries enrolled in MA plans	52,605	60,076	67,547	75,018	82,489	87,937	91,672	95,408	99,144	102,879	.....
Projected federal impact due to incarcerated individuals disenrolled 6 months sooner	−$46 million	−$55 million	−$65 million	−$77 million	−$90 million	−$102 million	−$113 million	−$125 million	−$138 million	−$153 million	−$965 million

Note: Estimates reflect scoring by the CMS, Office of the Actuary, and 2012 incarceration data provided by the SSA.

We received the following comment:

Comment: One commenter requested additional information on the assumptions used to calculate the savings related to our proposal to disenroll incarcerated individuals, such as the percentage of membership of incarcerated beneficiaries.

Response: The following chart provides the assumptions used to calculate the savings previously outlined:

TABLE 8—ASSUMPTIONS FOR ELIGIBILITY OF ENROLLMENT FOR INCARCERATED INDIVIDUALS

	2015	2024
Expected MAPD Enrollment due to be disenrolled (A)	6,280	16,175
Average Part C per Capita Costs ($) (B)*	10,024	14,845
Average Length of Stay (years) (C)	0.5	0.5
Gross Savings ($millions) (A x B x C)	31.5	120.1
Savings from Part A Trust Fund ($millions) (D)	14.7	53.1
Savings from Part B Trust Fund ($millions) (E)	16.8	67.0
Savings Net of Member Premium ($millions) (D + 0.75 x E)	27.3	103.3

* Note: Part C per Capita Costs are derived from the 2014 mid-session review.

After consideration of the public comment received, we are finalizing the policy without modification.

25. Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134)

This provision permits plans to provide limited rewards and incentives to enrollees who participate in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources. While there would be a cost associated with providing rewards and incentives there may be savings as a result of healthier behavior. Because plans are not required to provide rewards and incentives and CMS does not have a means of calculating the costs and benefits of rewards/incentives at this time, we are not providing an impact analysis for this provision.

26. Effects of Improving Payment Accuracy: Reporting Overpayments, RADV Appeals, and LIS Cost Sharing

This section proposes only technical changes for overpayment reporting, RADV appeals, and CMS' treatment of diagnoses for additional payment after the final risk adjustment data submission deadline. These technical changes will not result in costs to MA organizations and Part D sponsors, nor do we expect the impact of these technical changes to result in savings.

27. Effects of Part C and Part D RAC Determination Appeals

In section III.B.4. of this final rule, to establish an administrative appeals process for overpayment determinations by the Part C and Part D RACs. The cost associated with these provisions involves the preparation and submission of appeal requests by plans. We estimate this cost to be $48,343 as summarized in the following Table 9.

TABLE 9—SUMMARY OF RAC DETERMINATION APPEALS

Provision description	Costs (in $millions)	Benefits
Submission of MA plans' first level Request for Reconsideration.	0.02167	Administrative appeal rights and accuracy in recovery demands.
Submission of Part D plans' first level Request for Reconsideration.	0.02167	Administrative appeal rights and accuracy in recovery demands.
Submission of MA plans' second level Request for Review	0.00208	Administrative appeal rights and accuracy in recovery demands.
Submission of Part D plans' second level Request for Review	0.00208	Administrative appeal rights and accuracy in recovery demands.
Submission of MA plans' third level Request for Review by the CMS Administrator.	0.0004	Administrative appeal rights and accuracy in recovery demands.
Submission of Part D plans' third level Request for Review by the CMS Administrator.	0.0004	Administrative appeal rights and accuracy in recovery demands.

28. Effects of the Technical Changes to the Definition of Part D Drug

There is no impact associated with this provision as it is a technical change to regulation language.

29. Effects of Special Part D Access Rules During Disasters

In § 423.126(a), we proposed to codify requirements similar to existing guidance that pertains to relaxing ''refill-too-soon'' (RTS) edits to permit one refill in the event of any imminent or occurring disaster or emergency that would hinder an enrollee's access to covered Part D drugs.

The proposed changes would not have resulted in any additional costs. For one, we currently expect through guidance that sponsors will relax edits after the issuance of certain federal declarations. We also do not anticipate that providing a general framework for when sponsors must relax RTS edits would necessitate an increase in resources because it is currently not uncommon for Part D sponsors to relax edits for particular individuals under certain circumstances.

The provisions would have required Part D sponsors to relax ''refill-too-soon'' (RTS) edits when, as evidenced by a declaration of a disaster or emergency or its imminence by an appropriate federal, state, or local official, it is reasonable to conclude that an occurring or imminent disaster or emergency would make it difficult for beneficiaries to obtain refills of their medications. Relaxing RTS edits in these circumstances would benefit beneficiaries by better ensuring that they do not run out of their medications

when a disaster is imminent or after it strikes.

As this proposal is not being finalized, there will be no financial impact.

30. Effects of Termination of a Contract Under Parts C and D

The changes to §§ 422.510 and 423.509 are minor technical and clarifying revisions and include making language consistent, aligning titles and correcting references. These technical and clarifying changes will not result in additional burden to MA organizations or Part D sponsors nor will they have a financial impact on such entities.

31. Effects of Technical Changes Regarding Intermediate Sanctions and Civil Money Penalties

The changes to §§ 422.756 and 423.756 are minor technical and clarifying revisions and include making language consistent, aligning titles and correcting references. These technical and clarifying changes will not result in additional burden to MA organizations or Part D sponsors nor will they have a financial impact on such entities.

TABLE 10—ESTIMATED [1] AGGREGATE SAVINGS TO THE HEALTH CARE SECTOR BY PROVISION FOR CALENDAR YEARS 2015 THROUGH 2024

Provision	Regulation section(s)	Calendar year ($ in millions)										Total ($ in millions) CYs 2015–2019
		2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	
												Federal Government (Medicare) Impacts
A.24. Eligibility of Enrollment for Incarcerated Individuals [2].	§ 417.460(b)(2)(i), § 417.460(f)(1)(i), § 422.2, § 422.74(d)(4)(i)(A), § 422.74(d)(4)(v), § 423.4, and § 423.44(d)(5).	−73	−90	−108	−129	−152	−172	−191	−211	−232	−256	−1615
Total ($ in millions)	.....	−73	−90	−108	−129	−152	−172	−191	−211	−232	−256	−1615

Notes:

[1] Estimates of savings reflect scoring by the CMS, Office of the Actuary. Also, only provisions that are being finalized with savings or cost exceeding $1,000,000 are listed. Other provisions either have no expected savings or cost, have a savings or cost that is difficult to score, have a cost that is expected to be counterbalanced by savings, have a savings or cost under $1,000,000, or, were not finalized.

[2] Supporting 2012 incarceration data provided by the SSA.

D. Expected Benefits

1. Drug Categories or Classes of Clinical Concerns (§ 423.102(b)(2)(v))

Proposed codification of the categories or classes of clinical concern provisions would assist PBMs in applying the Part D plans and managing the Part D sponsor's benefit packages more efficiently.

However, we are not codifying the propose criteria or applying them to the drug categories and classes of clinical concern. Thus, this does not apply.

2. Medication Therapy Management Program Under Part D

We anticipated that many more beneficiaries would have access to MTM services and believed that the proposed changes would have simplified the MTM criteria and minimized beneficiary confusion when choosing or transitioning between plans. Moreover, we believed the proposed changes would have reduced disparity and allowed more beneficiaries with drug therapy problems to receive MTM services.

However, we are not finalizing these proposals, so these expected benefits are no longer applicable.

E. Alternatives Considered

1. Modifying the Agent/Broker Compensation Requirements

In the preamble of this final rule, we outlined a few alternative compensation schedules. Ultimately we determined that the best approach was a two-tiered payment schedule, incorporating an initial payment and a continuous renewal payment.

2. Any Willing Pharmacy Standard Terms & Conditions

We considered the alternative of maintaining the current process where Part D plans can limit pharmacy access to preferred cost-sharing contracts. We have observed this in practice to be limiting market competition, creating a barrier to entry, and further, not producing the savings to the program that were initially anticipated.

We are not finalizing this proposal.

3. Pharmacy Price Concessions in Negotiated Prices

We did not identify any alternatives that both maintained consistent reporting among sponsors leading to comparable bids, and maximized price competition.

4. Special Part D Access Rules During Disasters or Emergencies

We did not consider alternatives to requiring Part D sponsors to lift ''refill too soon'' (RTS) edits in the event of any imminent or occurring disaster or emergency that would hinder an enrollee's access to covered Part D drugs. It is important for the well-being and health of beneficiaries that they be able to obtain their medications after disasters strike. Furthermore, given the complexities of moving large numbers of people with different health conditions to safer locations, we also believed we had no alternative but to require Part D sponsors to relax RTS edits when a disaster is imminent and access to services might be jeopardized rather than waiting for it to strike.

We are not finalizing this proposal.

5. Drug Categories or Classes of Clinical Concerns

The critical policy decision was how broadly or narrowly to establish criteria and exceptions to those criteria pursuant to Affordable Care Act provisions. Broad criteria might easily encompass many classes of drugs and significantly increase costs to the Part D program by eliminating the need for manufacturers to aggressively rebate their products for formulary placement.

Only narrow criteria would limit the number of categories or classes of clinical concern receiving additional protections under the Affordable Care Act. Similarly, broad exceptions further limit the products within those categories or classes of clinical concern that would receive additional protection under the Affordable Care Act.

However, we are not codifying the propose criteria or applying them to the drug categories and classes of clinical concern. Thus, this does not apply.

6. Medication Therapy Management Program (MTM) Under Part D

In the proposed rule, we considered leaving the maximum number of multiple chronic diseases a plan may require for targeted enrollment at three, but believed this threshold significantly limited the number of beneficiaries who qualified for MTM services and was inconsistent with literature concerning the relative risk of the combination of multiple disease states and the need for access to MTM interventions. Similarly, we considered other numbers of Part D drugs less than eight, but again believed these thresholds decreased access to MTM services, contributed to beneficiary confusion, and led to racial disparities in access to MTM services. We also considered other cost thresholds less than $3,000, for example, $900 or $1,200, which roughly coincide with cost thresholds achieved by taking 3 or 4 generic drugs, and we solicited stakeholder comment on where the threshold might alternatively be set.

7. Requirement for Applicants or Their Contracted First Tier, Downstream, or Related Entities To Have Experience in the Part D Program Providing Key Part D Functions

Based on our authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms that are necessary and appropriate to administer the Part D program, we proposed changes at § 423.504(b)(8)(i) through (iii) that Part D organizations seeking a new Medicare contract must have arrangements in place such that either the applicant or a contracted entity that will be performing certain key Part D functions has at least 1 full benefit year of experience providing the function for another Part D plan sponsor. This proposal ensures that applicants take advantage of the abundant Part D industry expertise and experience that exists today in the development of their Part D program operations, rather than relying on technical assistance from CMS and having their inexperience place beneficiaries' access to prescription drugs at risk. We believe this provision will have a very minor savings impact on the federal budget, based on savings of time and effort (staff time and contracted auditor time and resources) that the government would spend on overseeing the disproportionate level of problems experienced by organizations operating Part D plans without prior Part D experience. For each inexperienced organization allowed into the program in the absence of this proposal, we would anticipate a savings of 1,000 staff hours at an average rate of $50 per hour, for a total of $50,000 in employee time, plus an additional savings of $200,000 in contractor dollars to conduct an emergency audit, for a total of $250,000. In the absence of this proposal, we would anticipate no more than two such inexperienced entities beginning Part D operations per year, for a total annual savings of $500,000.

The burden associated with this proposal on industry would be minimal, with a total estimated number of labor hours of 3.25 to submit information during the Part D application process. Using the same average hourly salary as previously mentioned, the total cost to Part D applicants would be $162.50. We do not believe there are any non-administrative costs to industry associated with this proposal, as Part D applicants are already required to have arrangements in place to perform the key Part D functions discussed in our proposal.

The main anticipated effect from this proposal is ensuring that only entities with some experience with Part D in critically important functional areas are permitted to offer new Part D contracts, thus strengthening the Part D program by enhancing the qualification criteria. We considered the alternate proposal of requiring the prior Part D experience to be tied to specific quality outcomes. We rejected the alternative because we believed it added unnecessary complexity and burden to the process, and we believe a simple experience requirement is currently sufficient.

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a0004/a-4/pdf*), in Table 11 we have prepared an accounting statement showing the transfers associated with the provisions of this final rule for CYs 2015 through 2019.

TABLE 11—ACCOUNTING STATEMENT: CLASSIFICATIONS OF ESTIMATED TRANSFERS FROM CALENDAR YEARS 2015 TO 2024

[$ in millions]

Category	Transfers		
	Discount rate		Period covered
	7%	3%	
Annualized Monetized Transfers (Federal)	−$150.27	−156.27	CYs 2015–2024
Whom to Whom?	Federal Government to MA Organizations and Part D Sponsors		

Note: Monetized figures in 2014 Dollars.

G. Conclusion

We estimate the savings to the federal government from implementing these provisions will be $73 million in CY 2015. The savings will increase annually. In CY 2024, the federal government savings from implementing these provisions will be $256 million. For the entire estimated period, CYs 2015 through 2024, we estimate the total federal government (Medicare) impact to result in savings of approximately $1.615 billion. We note that these savings do not represent net social benefits because they consist of transfers

of value from drug manufacturers, pharmacies, and incarcerated individuals to the federal government, MA organizations, Part D sponsors and beneficiaries who continue in the programs

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

PART 417—HEALTH MAINTENANCE ORGANIZATION, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

■ 2. Section 417.1 is amended by revising the definition of ''service area'' to read as follows:

§ 417.1 Definitions.

* * * * *

Service area means a geographic area, defined through zip codes, census tracts, or other geographic measurements, that is the area, as determined by CMS, within which the HMO furnishes basic and supplemental health services and makes them available and accessible to all its enrollees in accordance with § 417.106(b). Facilities in which individuals are incarcerated are not included in the geographic service area of an HMO or CMP plan.

* * * * *

■ 3. Section 417.460 is amended by revising paragraph (b)(2)(i) and adding paragraphs (f)(1)(i)(A) through (C) to read as follows:

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

* * * * *

(b) * * *

(2) * * *

(i) Moves out of the HMO's or CMP's geographic service area or is incarcerated.

* * * * *

(f) * * *

(1) * * *

(i) * * *

(A) *Incarceration.* The HMO or CMP must disenroll an individual if the HMO or CMP establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated and does not reside in the geographic service area of the HMO or CMP per § 417.1.

(B) *Notification by CMS of incarceration.* When CMS notifies an HMO or CMP of disenrollment due to the individual being incarcerated and not residing in the geographic service area of the HMO or CMP, as per § 417.1, the disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

(C) *Exception.* The exception in paragraph (f)(2) of this section does not apply to individuals who are incarcerated.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 4. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 5. Section 422.2 is amended by—

■ A. Revising the definition of ''Attestation process''.

■ B. Removing the definition of ''Initial Validation Contractor (IVC)''.

■ C. Adding the definition of ''RADV appeal process''.

■ D. Removing the definition of ''RADV payment error calculation appeal process''.

■ E. Revising the definition of ''Risk adjustment data validation (RADV) audit''.

■ F. Removing the definition of ''The one best medical record for the purposes of Medicare Advantage Risk Adjustment Validation (RADV)''.

The revisions and additions read as follows:

§ 422.2 Definitions.

* * * * *

Attestation process means a CMS-developed RADV audit-related process that is part of the medical record review process that enables MA organizations undergoing RADV audit to submit CMS-generated attestations for eligible medical records with missing or illegible signatures or credentials. The purpose of the CMS-generated attestations is to cure signature and credential issues. CMS-generated attestations do not provide an opportunity for a provider or supplier to replace a medical record or for a provider or supplier to attest that a beneficiary has the medical condition

* * * * *

RADV appeal process means an administrative process that enables MA organizations that have undergone RADV audit to appeal the Secretary's medical record review determinations and the Secretary's calculation of an MA organization's RADV payment error.

* * * * *

Risk adjustment data validation (RADV) audit means a payment audit of a MA organization administered by the Secretary that ensures the integrity and accuracy of risk adjustment payment data.

* * * * *

■ 6. Section 422.74 is amended by revising paragraph (d)(4)(i)(A) and adding paragraph (d)(4)(v) to read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(d) * * *

(4) * * *

(i) * * *

(A) Out of the MA plan's service area or is incarcerated as specified in paragraph (d)(4)(v) of this section.

* * * * *

(v) *Incarceration.* (A) The MA organization must disenroll an individual if the MA organization establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated and does not reside in the service area of the MA plan as specified at § 422.2 or when notified of the incarceration by CMS as specified in paragraph (d)(4)(v)(B) of this section.

(B) *Notification by CMS of incarceration.* When CMS notifies the MA organization of the disenrollment due to the individual being incarcerated and not residing in the service area of the MA plan as per § 422.2, disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

* * * * *

■ 7. Section 422.134 is added to subpart C to read as follows:

§ 422.134 Reward and incentive programs.

(a) *General rule.* The MA organization may create one or more programs consistent with the standards of this section that provide rewards and incentives to enrollees in connection with participation in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources.

(b) *Non-discrimination.* Reward and incentive programs—

(1) Must not discriminate against enrollees based on race, national origin, including limited English proficiency, gender, disability, chronic disease, whether a person resides or receives services in an institutional setting, frailty, health status or other prohibited basis;

(2) Must be designed so that all enrollees are able to earn rewards; and

(3) Are subject to sanctions at § 422.752(a)(4).

(c) *Requirements.* (1) A rewards and incentives program must —

(i) Be offered in connection with the entire service or activity;

(ii) Be offered to all eligible members without discrimination;

(iii) Have a monetary cap as determined by CMS of a value that may be expected to impact enrollee behavior but not exceed the value of the health related service or activity itself; and

(iv) Otherwise comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries.

(2) Reward and incentive items may not—

(i) Be offered in the form of cash or other monetary rebates; or

(ii) Be used to target potential enrollees.

(3) The MA organization must make information available to CMS upon request about the form and manner of any rewards and incentives programs it offers and any evaluations of the effectiveness of such programs.

§ 422.300 [Amended]

■ 8. Section 422.300 is amended by removing the phrase ''and 1858 of the Act.'' and adding in its place the phrase ''1858, and 1128J(d) of the Act.''

■ 9. Section 422.310 is amended by revising paragraph (g)(2) and adding paragraph (g)(3) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(g) * * *

(2) After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary.

(i) Prior to calculation of final risk factors for a payment year, CMS allows a reconciliation process to account for risk adjustment data submitted after the March deadline until the final risk adjustment data submission deadline in the year following the payment year.

(ii) After the final risk adjustment data submission deadline, which is January 31 of the year following the payment year, an MA organization can submit data to correct overpayments but cannot submit diagnoses for additional payment.

(3) Submission of corrected risk adjustment data in accordance with overpayments after the final risk adjustment data submission deadline, as described in paragraph (g)(2) of this section, must be made as provided in § 422.326.

■ 10. Section 422.311 is amended as follows:

■ A. In paragraph (a), by removing the phrase ''CMS annually'' and adding in its place the phrase ''the Secretary annually''.

■ B. In paragraph (b)(2), by removing the phrase ''to CMS or its contractors'' and adding in its place the phrase ''to the Secretary''.

■ C. By removing paragraph (b)(3).

■ D. By revising paragraph (c).

The revision reads as follows:

§ 422.311 RADV audit dispute and appeal processes.

* * * * *

(c) *RADV audit appeals.* (1) *Appeal rights.* MA organizations that do not agree with their RADV audit results may appeal.

(2) *Issues eligible for RADV appeals.* (i) *General rules.* MA organizations may appeal RADV medical record review determinations and the Secretary's RADV payment error calculation. In order to be eligible for RADV appeal, MA organizations must adhere to the following:

(A) Established RADV audit procedures and requirements.

(B) RADV appeals procedures and requirements.

(ii) *Failure to follow RADV rules.* Failure to follow the Secretary's RADV audit procedures and requirements and the Secretary's RADV appeals procedures and requirements will render the MA organization's request for appeal invalid.

(iii) *RADV appeal rules.* The MA organization's written request for medical record review determination appeal must specify the following:

(A) The audited HCC(s) that the Secretary identified as being in error.

(B) A justification in support of the audited HCC selected for appeal.

(iv) *Number of medical records eligible for appeal.* For each audited HCC, MA organizations may appeal one medical record that has undergone RADV review. If an attestation was submitted to cure a signature or credential-related error, the attestation may be included in the HCC appeal.

(v) *Selection of medical record for appeal.* The MA organization must select the medical record that undergoes appeal.

(vi) *Written request for RADV payment error calculation appeal.* The written request for RADV payment error calculation appeal must clearly specify the following:

(A) The MA organization's own RADV payment error calculation.

(B) Where the Secretary's RADV payment error calculation was erroneous.

(3) *Issues ineligible for RADV appeals.* (i) MA organizations' request for appeal may not include HCCs, medical records or other documents beyond the audited HCC, RADV-reviewed medical record, and any accompanying attestation that the MA organization chooses for appeal.

(ii) MA organizations may not appeal the Secretary's medical record review determination methodology or RADV payment error calculation methodology.

(iii) As part of the RADV payment error calculation appeal— MA organizations may not appeal RADV medical record review-related errors.

(iv) MA organizations may not appeal RADV errors that result from an MA organization's failure to submit a medical record.

(4) *Burden of proof.* The MA organization bears the burden of proof by a preponderance of the evidence in demonstrating that the Secretary's medical record review determination(s) or payment error calculation was incorrect.

(5) *Manner and timing of a request for RADV appeal.* (i) At the time the Secretary issues its RADV audit report,

the Secretary notifies audited MA organizations of the following:

(A) That they may appeal RADV HCC errors that are eligible for medical record review determination appeal.

(B) That they may appeal the Secretary's RADV payment error calculation.

(ii) MA organizations have 60 days from date of issuance of the RADV audit report to file a written request with CMS for RADV appeal. This request for RADV appeal must specify one of the following:

(A) Whether the MA organization requests medical record review determination appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(B) Whether the MA organization requests RADV payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(C) Whether the MA organization requests both medical record review determination appeal and RADV payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(iii) For MA organizations that appeal both medical record review determination appeal and RADV payment error calculation appeal:

(A) The Secretary adjudicates the request for RADV payment error calculation following conclusion of reconsideration of the MA organization's request for medical record review determination appeal.

(B) An MA organization's request for appeal of its RADV payment error calculation will not be adjudicated until appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are final for that stage of appeal.

(6) *Reconsideration stage.* (i) *Written request for medical record review reconsideration.* A MA organization's written request for medical record review determination reconsideration must specify the following:

(A) The audited HCC that the Secretary identified as being in error that the MA organization wishes to appeal.

(B) A justification in support of the audited HCC chosen for appeal.

(ii) *Written request for payment error calculation.* The MA organization's written request for payment error calculation reconsideration—

(A) Must include the MA organization's own RADV payment error calculation that clearly specifies where the Secretary's RADV payment error calculation was erroneous; and

(B) May include additional documentary evidence pertaining to the calculation of the payment error that the MA organization wishes the reconsideration official to consider.

(iii) *Conduct of the reconsideration.* (A) For medical record review determination reconsideration, a medical record review professional who was not involved in the initial medical record review determination of the disputed audited HCCs does the following:

(*1*) Reviews the medical record and accompanying dispute justification.

(*2*) Reconsiders the initial audited medical record review determination.

(B) For payment error calculation reconsideration, CMS ensures that a third party not involved in the initial RADV payment error calculation does the following:

(*1*) Reviews the Secretary's RADV payment error calculation.

(*2*) Reviews the MA organization's RADV payment error calculation;

(*3*) Recalculates the payment error in accordance with CMS's RADV payment error calculation procedures.

(iv) *Effect of the reconsideration official's decision.* (A) The reconsideration official issues a written reconsideration decision to the MA organization.

(B) The reconsideration official's decision is final unless the MA organization disagrees with the reconsideration official's decision.

(C) If the MA organization disagrees with the reconsideration official's decision, they may request a hearing in accordance with paragraph (c)(7) of this section.

(7) *Hearing stage.* (i) *Errors eligible for hearing.* At the time the reconsideration official issues his or her reconsideration determination to the MA organization, the reconsideration official notifies the MA organization of any RADV HCC errors or payment error-calculations that are eligible for RADV hearing.

(ii) *General hearing rules.* A MA organization that requests a RADV hearing must do so in writing in accordance with procedures established by CMS.

(iii) *Written request for hearing.* The written request for a hearing must be filed with the Hearing Officer within 60 days of the date the MA organization receives the reconsideration officer's written reconsideration decision.

(A) If the MA organization appeals medical record review reconsideration determination, the written request for RADV hearing must—

(*1*) Include a copy of the written decision of the reconsideration official;

(*2*) Specify the audited HCCs that the reconsideration official confirmed as being in error; and

(*3*) Specify a justification why the MA organization disputes the reconsideration official's determination.

(B) If the MA organization appeals the RADV payment error calculation reconsideration determination, the written request for RADV hearing must include the following:

(*1*) A copy of the written decision of the reconsideration official.

(*2*) The MA organization's own RADV payment error calculation that clearly specifies where the Secretary's payment error calculation was erroneous.

(iv) *Designation of hearing officer.* A hearing officer will conduct the RADV hearing.

(v) *Disqualification of the hearing officer.* (A) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(B) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(C) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(D) If the hearing officer withdraws, another hearing officer conducts the hearing.

(E) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to the Secretary.

(vi) *Hearing Officer review.* The hearing officer reviews the following:

(A) For a medical record review determination appeal, the hearing officer reviews all of the following:

(*1*) The RADV-reviewed medical record and any accompanying attestation that the MA organization selected for review.

(*2*) The reconsideration official's written determination.

(*3*) The written brief submitted by the MA organization or the Secretary in response to the reconsideration official's determination.

(B) For a payment error calculation appeal, the hearing officer reviews all of the following:

(*1*) The reconsideration official's written determination.

(*2*) Briefs addressing the reconsideration decision.

(vii) *Hearing procedures.* (A) *Authority of the Hearing Officer.* The

hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and the Secretary rulings. These powers include the authority to dismiss the appeal with prejudice and take any other action which the hearing officer considers appropriate, including for failure to comply with such rules and procedures.

(B) *The hearing is on the record.* (*1*) Except as specified in paragraph (c)(viii)(B)(*2*) of this section, the hearing officer is limited to the review of the record.

(*2*)(*i*) Subject to the hearing officer's full discretion, the parties may request a live or telephonic hearing regarding some or all of the disputed medical records.

(*ii*) The hearing officer may, on his or her own-motion, schedule a live or telephonic hearing.

(*3*) The record is comprised of the following:

(*i*) *Written decisions* described at paragraphs (c)(6)(iv) and (7)(vi) of this section.

(*ii*) Written briefs from the MA organization explaining why they believe the reconsideration official's determination was incorrect.

(*iii*) The Secretary's optional brief that responds to the MA organization's brief—

(*4*) The hearing officer neither receives testimony nor accepts any new evidence that is not part of the record.

(*5*) Either the MA organization or the Secretary may ask the hearing officer to rule on a motion for summary judgment.

(viii) *Hearing Officer decision.* The hearing officer decides whether to uphold or overturn the reconsideration official's decision, and sends a written determination to CMS and the MA organization, explaining the basis for the decision.

(ix) *Computations based on hearing decision.* (A) Once the hearing officer's decision is considered final in accordance with paragraph (c)(7)(x) of this section, a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization and CMS.

(B) For MA organizations appealing the RADV error calculation only, a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization and CMS.

(x) *Effect of the Hearing Officer's decision.* The hearing officer's decision is final unless the decision is reversed or modified by the CMS Administrator.

(8) *CMS Administrator review stage.* (i) A request for CMS Administrator review must be made in writing and filed with the CMS Administrator.

(ii) CMS or a MA organization that has received a hearing officer's decision and requests review by the CMS Administrator must do so within 60 days of receipt of the hearing officer's decision.

(iii) After receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision.

(iv) If the CMS Administrator elects to review the hearing decision—

(A) The CMS Administrator acknowledges the decision to review the hearing decision in writing and notifies CMS and the MA organization of their right to submit comments within 15 days of the date of the notification; and

(B) The CMS Administrator is limited to the review of the record. The record is comprised of the following:

(*1*) The record is comprised of documents described at paragraph (c)(7)(vii)(B)(3) of this section.

(*2*) The hearing record.

(*3*) Written arguments from the MA organization or CMS explaining why either or both parties believe the hearing officer's determination was correct or incorrect.

(C) The CMS Administrator reviews the record and determines whether the hearing officer's determination should be upheld, reversed, or modified.

(v) The CMS Administrator renders his or her final decision in writing to the parties within 60 days of acknowledging his or her decision to review the hearing officer's decision.

(vi) The decision of the hearing officer is final if the CMS Administrator—

(A) Declines to review the hearing officer's decision; or

(B) Does not make a decision within 60 days.

■ 11. Section 422.326 is added to subpart G to read as follows:

§ 422.326 Reporting and returning of overpayments.

(a) *Terminology.* For purposes of this section—

Applicable reconciliation occurs on the date of the annual final deadline for risk adjustment data submission described at § 422.310(g), which is announced by CMS each year.

Funds means any payment that an MA organization has received that is based on data submitted by the MA organization to CMS for payment purposes, including § 422.308(f) and § 422.310.

Overpayment means any funds that an MA organization has received or retained under title XVIII of the Act to which the MA organization, after applicable reconciliation, is not entitled under such title.

(b) *General rule.* If an MA organization has identified that it has received an overpayment, the MA organization must report and return that overpayment in the form and manner set forth in this section.

(c) *Identified overpayment.* The MA organization has identified an overpayment when the MA organization has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment.

(d) *Reporting and returning of an overpayment.* An MA organization must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment, unless otherwise directed by CMS for purposes of § 422.311.

(1) *Reporting.* An MA organization must notify CMS, of the amount and reason for the overpayment, using a notification process determined by CMS.

(2) *Returning.* An MA organization must return identified overpayments in a manner specified by CMS.

(e) *Enforcement.* Any overpayment retained by an MA organization is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) of this section.

(f) *Look-back period.* An MA organization must report and return any overpayment identified for the 6 most recent completed payment years.

■ 12. Section 422.503 is amended by –

■ A. Adding paragraph (b)(4)(vi)(C)(*3*).

■ B. Adding reserved paragraph (b)(4)(vi)(G)(*4*).

■ C. Revising paragraph (b)(4)(vi)(G)(*5*).

The revisions and additions are as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(C) * * *

(*3*) An MA organization must require all of its first tier, downstream, and related entities to take the CMS training and accept the certificate of completion of the CMS training as satisfaction of this requirement. MA organizations are prohibited from developing and implementing their own training or

providing supplemental training materials to fulfill this requirement.

* * * * *

(G) * * *

(5)(i) Not accept, or share, a corporate parent organization owning a controlling interest in an entity that accepts new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(ii) Not accept, as either the parent organization owning a controlling interest of, or subsidiary of, an entity that accepts new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

* * * * *

■ 13. Amend § 422.504 by:

■ A. Revising paragraph (i)(2)(i).

■ B. Redesignating paragraph (i)(2)(ii) as (i)(2)(iv).

■ C. Adding new paragraph (i)(2)(ii) and paragraphs (i)(2)(iii) and (1)(5).

The revisions and additions read as follows:

§ 422.504 Contract provisions.

* * * * *

(i)* * *

(2)* * *

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and entities related to CMS' contract with the MA organization.

(ii) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records under paragraph (i)(2)(i) of this section directly from any first tier, downstream, or related entity.

(iii) For records subject to review under paragraph (i)(2)(ii) of this section, except in exceptional circumstances, CMS will provide notification to the MA organization that a direct request for information has been initiated.

* * * * *

(l) * * *

(5) *Certification of accuracy of data for overpayments.* The CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that the information provided for purposes of reporting and returning of overpayments under § 422.326 is accurate, complete, and truthful.

* * * * *

■ 14. Amend § 422.510 as follows;

■ A. By redesigating paragraphs (a)(4) through (15) as paragraphs (a)(4)(i) through (xii).

■ B. By adding new paragraph (a)(4) introductory text.

■ C. In newly redesignated paragraphs (a)(4)(ii), (v), (vi), and (viii) by removing the term ''fails'' and adding in its place the term ''failed''.

■ D. In newly redesignated paragraphs (a)(4)(iii), (iv), (vii), (ix), and (x), by removing the term ''Fails'' and adding in its place the term ''Failed''.

■ E. By revising newly redesignated paragraph (a)(4)(xii).

■ F. By revising paragraph (b)(1)(i) through (iii) and the heading for paragraph (b)(2).

■ G. In paragraph (b)(2)(i)(C), by removing the cross-reference ''(a)(4) of this section'' and adding in its place the cross reference ''(a)(4)(i) of this section''.

■ H. In paragraph (c)(2)(iii), by removing the cross reference ''(a)(4) of this section'' and adding in its place the cross reference ''(a)(4)(i) of this section''.

The additions and revisions read as follows:

§ 422.510 Termination of contract by CMS.

* * * * *

(a) * * *

(4) CMS may make a determination under paragraph (a)(1), (2), or (3) of this section if the MA organization has had one or more of the following occur:

* * * * *

(xii) Has failed to report MLR data in a timely and accurate manner in accordance with § 422.2460 or that any MLR data required by this subpart is found to be materially incorrect or fraudulent.

* * * * *

(b) * * *

(1) * * *

(i) CMS notifies the MA organization in writing at least 45 calendar days before the intended date of the termination.

(ii) The MA organization notifies its Medicare enrollees of the termination by mail at least 30 calendar days before the effective date of the termination.

(iii) The MA organization notifies the general public of the termination at least 30 calendar days before the effective date of the termination by releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site.

(2) *Immediate termination of contract by CMS.** * *

* * * * *

■ 15. Amend § 422.752 by adding paragraphs (a)(9) through (12) and revising paragraphs (c)(1) and (c)(2)(ii) to read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) * * *

(9) Except as provided under § 423.34 of this chapter, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual.

(10) Transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission.

(11) Fails to comply with marketing restrictions described in subpart V or applicable implementing guidance.

(12) Employs or contracts with any individual, agent, provider, supplier or entity who engages in the conduct described in paragraphs (a)(1) through (11) of this section.

* * * * *

(c) * * *

(1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in the following:

(i) Section 422.760(b) for any of the determinations at § 422.510(a), except § 422.510(a)(4)(i).

(ii) Section 422.760(c) for any of the determinations at § 422.752(a) except § 422.752(a)(5).

(2) * * *

(ii) Determinations made under § 422.510(a)(4)(i).

■ 16. Amend § 422.756 as follows:

■ A. In paragraph (a)(2), by removing the phrase ''days from receipt'' and adding in its place ''days after receipt'' and by removing the phrase ''considers receipt of notice'' and adding in its place ''considers receipt of the notice''.

■ B. In paragraph (b)(4), by removing the cross-reference ''§ 423.660 through § 423.684 of this part.'' and adding in its place ''Subpart N of this part.''.

■ C. In paragraph (c)(3)(ii) introductory text, by removing the phrase ''In instances where marketing or enrollment or both intermediate sanctions have been imposed,'' and adding in its place the phrase ''In instances where intermediate sanctions have been imposed,''.

■ D. Adding paragraph (c)(3)(ii)(C).

■ E. Revising paragraph (d).

The addition and revision read as follows:

§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.

(c) * * *

(3) * * *

(ii) * * *

(C) During the limited time period, sanctioned sponsoring organizations

offering Part D plans under the benchmark that would normally participate in the annual and monthly auto enrollment process for enrollees receiving the low income subsidy will not be allowed to receive or process these types of enrollments.

* * * * *

(d) *Non-renewal or termination by CMS.* In addition to or as an alternative to the sanctions described in § 422.750, CMS may—

(1) Decline to authorize the renewal of an organization's contract in accordance with § 422.506(b); or

(2) Terminate the contract in accordance with § 422.510.

* * * * *

■ 17. Amend § 422.760 by revising paragraph (a)(3) and the heading of paragraph (b) and adding paragraph (c) to read as follows:

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) * * *

(3) The adverse effect to enrollees which resulted or could have resulted from the conduct of MA organization;

* * * * *

(b) *Amount of penalty imposed by CMS.* * * *

* * * * *

(c) *Amount of penalty imposed by CMS or OIG.* CMS or the OIG may impose civil money penalties in the following amounts for a determination made under § 422.752(a):

(1) Civil money penalties of not more than $25,000 for each determination made.

(2) With respect to a determination made under § 422.752(a)(4) or (a)(5)(i), not more than $100,000 for each such determination, except with respect to a determination made under § 422.752(a)(5), an assessment of not more than the amount claimed by such plan or MA organization based upon the misrepresentation or falsified information involved.

(3) Plus with respect to a determination made under § 422.752(a)(2), double the excess amount charged in violation of such paragraph (and the excess amount charged must be deducted from the penalty and returned to the individual concerned).

(4) Plus with respect to a determination made under § 422.752(a)(4), $15,000 for each individual not enrolled as a result of the practice involved.

■ 18. Amend § 422.1016 by revising the first sentence of paragraph (b)(1) to read as follows:

§ 422.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

* * * * *

(b) * * *

(1) The other party will have 20 calendar days from the date of mailing or in person filing to submit any rebuttal statement or additional evidence.* * *

* * * * *

■ 19. Amend § 422.1020 by revising paragraph (a)(2) to read as follows:

§ 422.1020 Request for hearing.

(a) * * *

(2) The MA organization or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days after receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

* * * * *

■ 20. Amend § 422.2274 by:

■ A. Revising the introductory text.

■ B. Redesignating paragraphs (a) through (f) as (b) through (g).

■ C. Adding new paragraph (a).

■ D. Revising newly redesignated paragraph (b).

■ E. Adding paragraph (h).

The revisions and addition read as follows:

§ 422.2274 Broker and agent requirements.

If an MA organization uses agents and brokers to sell its Medicare plans, the following requirements in this section are applicable.

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

Compensation (1) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to—

(i) Commissions;

(ii) Bonuses;

(iii) Gifts;

(iv) Prizes or Awards; or

(v) Referral or Finder fees.

(2) Does not include—

(i) Payment of fees to comply with State appointment laws, training, certification, and testing costs;

(ii) Reimbursement for mileage to, and from, appointments with beneficiaries; or

(iii) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Like plan type means one of the following:

(1) PDP replaced with another PDP.

(2) MA or MA–PD replaced with another MA or MA–PD.

(3) Cost plan replaced with another cost plan.

Unlike plan type means one of the following:

(1) PDP replaced with an MA–PD or an MA–PD replaced with a PDP.

(2) PDP replaced with a cost plan or a cost plan replaced with a PDP.

(3) MA–PD replaced with a cost plan or a cost plan replaced with an MA–PD.

Plan year means the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in a like plan type.

(b) *Compensation rules.* An MA organization must compensate independent brokers and agents, if compensation is paid, only according to the following rules in this section.

(1) *Compensation amounts.* (i) For an initial year enrollment of a Medicare beneficiary into an MA plan, the compensation must be at or below the fair market value of such services, published annually as a cut-off amount by CMS.

(ii) For renewal years, compensation may be up to 50 percent of the current fair market value cut-off amounts published annually by CMS.

(iii) If the MA organization contracts with a third party entity such as a Field Marketing Organization or similar type entity to sell its insurance products, or perform services (for example, training, customer service, or agent recruitment)—

(A) The total amount paid by the MA organization to the third party and its agents for enrollment of a beneficiary into a plan, if any, must be made in accordance with paragraph (b)(1) of this section; and

(B) The amount paid to the third party for services other than selling insurance products, if any, must be fair-market value and must not exceed an amount that is commensurate with the amounts paid by the MA organization to a third party for similar services during each of the previous 2 years.

(2) *Aggregate compensation.* (i) An entity must not provide aggregate compensation to its agents or brokers greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan at any time.

(ii) An agent or broker must not receive aggregate compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type at any time.

(iii) The initial compensation is paid for replacements between unlike plan types.

(3) *Compensation payment and payment recovery.* (i) Compensation may only be paid for the enrollee's months of enrollment during a plan year.

(ii)(A) Subject to paragraph (b)(3)(iii) of this section, compensation payments may be made at one time for the entire current plan year or in installments throughout the year.

(B) Compensation may not be paid until January 1 of the enrollment year and, if paid at all, must be paid in full by December 31 of the enrollment year.

(iii) When a beneficiary disenrolls from an MA plan, compensation paid to agents and brokers must be recovered for those months of the plan year for which the beneficiary is not enrolled. For disenrollments occurring within the first 3 months, the entire compensation must be recovered unless CMS determines that recoupment is not in the best interests of the Medicare program.

(4) *Compensation structure.* (i) The MA organization must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the plan marketing period, October 1.

(ii) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

* * * * *

(h) *Finder's (referral) fees.* Finder's (referral) fees paid to all agents and brokers—

(1) May not exceed an amount that CMS determines could reasonably be expected to provide financial incentive for an agent or broker to recommend or enroll a beneficiary into a plan that is not the most appropriate to meet his or her needs; and

(2) Must be included in the total compensation not to exceed the fair market value for that calendar year.

Subpart Y—[Reserved]

■ 21. Part 422 is amended by adding reserved subpart Y.

■ 22. Part 422 is amended by adding subpart Z to read as follows:

Subpart Z—Part C Recovery Audit Contractor Appeals Process

Sec.

422.2600 Payment appeals.
422.2605 Request for reconsideration.
422.2610 Hearing official review.
422.2615 Review by the Administrator.

Subpart Z—Part C Recovery Audit Contractor Appeals Process

§ 422.2600 Payment appeals.

If the Part C RAC did not apply its stated payment methodology correctly, an MA organization may appeal the findings of the applied methodology. The payment methodology itself is not subject to appeal.

§ 422.2605 Request for reconsideration.

(a) *Time for filing a request.* The request for reconsideration must be filed with the designated independent reviewer within 60 calendar days from the date of the demand letter received by the MA organization.

(b) *Content of request.* (1) The request for reconsideration must be in writing and specify the findings or issues with which the MA organization disagrees.

(2) The MA organization must include with its request all supporting documentary evidence it wishes the independent reviewer to consider.

(i) This material must be submitted in the format requested by CMS.

(ii) Documentation, evidence, or substantiation submitted after the filing of the reconsideration request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the MA organization's reconsideration request.

(1) The rebuttal must be submitted within 30 calendar days of the review entity's notification to CMS that it has received the MA organization's reconsideration request.

(2) CMS sends its rebuttal to the MA organization at the same time it is submitted to the independent reviewer.

(d) *Review entity.* An independent reviewer conducts the reconsideration. The independent reviewer reviews the demand for repayment, the evidence and findings upon which it was based and any supporting documentation that the MA organization or CMS submitted in accordance with this section.

(e) *Notification of decision.* The independent reviewer informs the CMS and the MA organization of its decision in writing.

(f) *Effect of decision.* A reconsideration decision is final and binding unless the MA organization requests a hearing official review in accordance with § 422.2610.

(g) *Right to hearing official review.* An MA organization that is dissatisfied with the independent reviewer's reconsideration decision is entitled to a hearing official review as provided in § 422.2610.

§ 422.2610 Hearing official review.

(a) *Time for filing a request.* A MA organization must file with CMS a request for a hearing official review within 30 calendar days from the date of the independent reviewer's issuance of a reconsideration determination.

(b) *Content of the request.* (1) The request must be in writing and must specify the findings or issues in the reconsideration decision with which the MA organization disagrees and the reasons for the disagreements.

(2) The MA organization must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(3) No new evidence may be submitted.

(4) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the MA organization's hearing official review request.

(1) The rebuttal must be submitted within 30 calendar days of the MA organization's submission of its hearing official review request.

(2) CMS sends its rebuttal to the MA organization at the same time it is submitted to the hearing official.

(d) *Conducting a review.* A CMS-designated hearing official conducts the hearing on the record.

(1) The hearing is not to be conducted live or via telephone unless the hearing official, in his or her sole discretion, requests a live or telephonic hearing.

(2) In all cases, the hearing official's review is limited to information that meets one or more of the following:

(i) The Part C RAC used in making its determinations.

(ii) The independent reviewer used in making its determinations.

(iii) The MA organization submits with its hearing request.

(iv) CMS submits in accordance with paragraph (c) of this section.

(3) Neither the MA organization nor CMS may submit new evidence.

(e) *Hearing official decision.* The CMS hearing official decides the case within 60 days and sends a written decision to the MA organization and CMS, explaining the basis for the decision.

(f) *Effect of hearing official decision.* The hearing official's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 422.2615.

§ 422.2615 Review by the Administrator.

(a) *Request for review by Administrator.* If an MA organization is dissatisfied with the hearing official's decision, it may request that the CMS Administrator review the decision.

(1) The request must be filed with the CMS Administrator within 30 calendar

days of the date of the hearing official's decision.

(2) The request must provide evidence or reasons to substantiate the request.

(b) *Content of request.* The MA organization must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(1) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(2) Neither the MA organization, nor CMS may submit new evidence.

(c) *Discretionary review.* After receiving a request for review, the CMS Administrator has the discretion to review the hearing official's decision in accordance with paragraph (e) of this section or to decline to review said decision.

(d) *Notification of decision whether to review.* The Administrator notifies the MA organization within 45 days of receiving the MA organization's hearing request of whether he or she intends to review the hearing official's decision.

(1) If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan that the request for review has been accepted. CMS sends its rebuttal statement to the plan at the same time it is submitted to the Administrator.

(2) If the CMS Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding.

(e) *CMS Administrator's review.* If the CMS Administrator agrees to review the hearing official's decision, he or she determines, based upon this decision, the hearing record, and any arguments submitted by the MA organization or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The Administrator furnishes a written decision, which is final and binding, to the MA organization and to CMS.

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 23. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

■ 24. Amend § 423.1 by adding new references in numerical order to paragraph (a)(1) to read as follows:

§ 423.1 Basis and scope.

(a) * * *

(1) * * *

1128J(d). Reporting and Returning of Overpayments.

* * * * *

1860D–14A. Medicare coverage gap discount program.

* * * * *

1860D–43. Condition for coverage of drugs under this part.

* * * * *

■ 25. Amend § 423.44 by adding paragraphs (d)(5)(iii) and (iv) to read as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(d) * * *

(5) * * *

(iii) *Incarceration.* The PDP must disenroll an individual if the PDP establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated and does not reside in the service area of the PDP as specified at § 423.4 or when notified of an incarceration by CMS as specified in paragraph (d)(5)(iv) of this section.

(iv) *Notification by CMS of incarceration.* When CMS notifies the PDP of the disenrollment due to the individual being incarcerated and not residing in the service area of the PDP as per § 423.4, disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

* * * * *

■ 26. In § 423.100, amend the definition of ''Part D drug'' as follows:

■ A. By adding paragraph (1)(vii).

■ B. By revising paragraph (2) introductory text.

■ C. In paragraph (2)(i), by removing ''; and'' and adding in its place ''.''.

■ D. In paragraph (2)(ii), by removing the phrase ''; barbiturates when used to treat epilepsy, cancer, or a chronic mental health disorder; and benzodiazepines.'' and adding in its place ''.''

■ E. By adding paragraph (2)(iii).

The additions read as follows:

§ 423.100 Definitions

* * * * *

Part D drug * * *

(1) * * *

(vii) A combination product approved and regulated by the FDA as a drug, vaccine, or biologic described in paragraphs (1)(i), (ii), (iii), or (v) of this definition.

(2) Does not include any of the following:

* * * * *

(iii) Medical foods, defined as a food that is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation, and that are not regulated as drugs under section 505 of the Federal Food, Drug, and Cosmetic Act.

* * * * *

■ 27. Section 423.100 is further amended, effective January 1, 2016, by revising the definition of ''Negotiated prices'' to read as follows:

§ 423.100 Definitions

* * * * *

Negotiated prices means prices for covered Part D drugs that meet all of the following:

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug.

(2) Are inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale; and

(3) Include any dispensing fees; but

(4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale.

(5) Must not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part.

* * * * *

■ 28. Amend 423.120 by:

■ A. Revising paragraph (b)(2)(v).

■ B. Adding paragraph (b)(3)(vi).

■ C. Adding paragraph (c)(5) introductory text.

■ D. Adding paragraph (c)(6).

The revisions and additions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(2) * * *

(v) Until such time as there are established, through notice and comment rulemaking, criteria to identify, as appropriate, categories and classes of clinical concern, the categories and classes of clinical concern are as specified in section 1860D–4(b)(3)(G)(iv) of the Act.

* * * * *

(3) * * *

(vi) A Part D sponsor must charge cost sharing for a temporary supply of drugs provided under its transition process such that the following conditions are met:

(A) For low-income subsidy (LIS) enrollees, a sponsor must not charge higher cost sharing for transition supplies than the statutory maximum copayment amounts.

(B) For non-LIS enrollees, a sponsor must charge—

(*1*) The same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with § 423.578(b); and

(*2*) The same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met.

* * * * *

(c) * * *

(5) Before June 1, 2015, the following are applicable:

* * * * *

(6) Beginning June 1, 2015, the following are applicable: —

(i) A Part D sponsor must deny, or must require its pharmaceutical benefit manager (PBM) to deny, a pharmacy claim for a Part D drug if an active and valid physician or eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) National Provider Identifier (NPI) is not contained on the claim.

(ii) A Part D sponsor must deny, or must require its PBM to deny, a pharmacy claim for a Part D drug if the physician or eligible professional (when permitted to write prescriptions by applicable State law)—

(A) Is not enrolled in the Medicare program in an approved status; and

(B) Does not have a valid opt-out affidavit on file with an A/B Medicare Administrative Contractor (MAC).

(iii) A Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary for a drug if the request is not for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted by applicable State law, other eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who—

(A) Is identified by his or her legal name in the request; and

(B)(*1*) Is enrolled in Medicare in an approved status; or

(*2*) Has a valid opt-out affidavit on file with an A/B MAC.

(iv) In order for a Part D sponsor to submit to CMS a prescription drug event record (PDE), the PDE must contain an active and valid individual prescriber NPI and must pertain to a claim for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted by applicable State law, an eligible professional (as defined in section 1848(k)(3)(B)(i) or (ii) of the Act) who—

(A) Is enrolled in Medicare in an approved status, or

(B) Has a valid opt-out affidavit on file with an A/B MAC.

* * * * *

■ 29. Section 423.360 is added to subpart G to read as follows:

§ 423.360 Reporting and returning of overpayments.

(a) *Definitions.* For the purposes of this section the following definitions are applicable:

Applicable reconciliation means the later of either the annual deadline for submitting—

(i) PDE data for the annual Part D payment reconciliations referred to in § 423.343(c) and (d); or

(ii) Direct and indirect remuneration data.

Funds for purposes of this section, means any payment that a Part D sponsor has received that is based on data submitted by the Part D sponsor to CMS for payment purposes, including data submitted under § 423.329(b)(3), § 423.336(c)(1), § 423.343, and data provided for purposes of supporting allowable costs as defined in § 423.308 which includes data submitted to CMS regarding direct or indirect remuneration.

Overpayment means funds that a Part D sponsor has received or retained under title XVIII of the Act to which the Part D sponsor, after applicable reconciliation, is not entitled under such title.

(b) *General rule.* If a Part D sponsor has identified that it has received an overpayment, the Part D sponsor must report and return that overpayment in the form and manner set forth in this section.

(c) *Identified overpayment.* The Part D sponsor has identified an overpayment when the Part D sponsor has determined, or should have determined through the exercise of reasonable diligence, that the Part D sponsor has received an overpayment.

(d) *Reporting and returning of an overpayment.* A Part D sponsor must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment.

(1) *Reporting.* A Part D sponsor must notify CMS of the amount and reason for the overpayment, using the notification process determined by CMS.

(2) *Returning.* A Part D sponsor must return identified overpayments in a manner specified by CMS.

(e) *Enforcement.* Any overpayment retained by a Part D sponsor is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) of this section.

(f) *Look-back period.* A Part D sponsor must report and return any overpayment identified within the 6 most recent completed payment years.

§ 423.464 [Amended]

■ 35. Amend § 423.464 as follows:

■ A. In paragraph (f)(2)(i) introductory text, by removing the phrase ''a Part D plan must—'' and adding in its place ''a Part D plan must do all of the following:''.

■ B. In paragraph (f)(2)(i)(A), by removing ''; and'' and adding in its place ''.''.

■ 30. Amend § 423.501, effective January 1, 2016, by a adding a definition for ''prescription drug pricing standard'' to read as follows:

§ 423.501 Definitions.

* * * * *

Prescription drug pricing standard means any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts based on any of the following:

(1) Average wholesale price.

(2) Wholesale acquisition cost.

(3) Average manufacturer price.

(4) Average sales price.

(5) Maximum allowable cost.

(6) Other cost, whether publicly available or not.

* * * * *

■ 31. Amend § 423.503 by adding paragraphs (a)(3) to read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) * * *

(3) CMS does not approve an application when it would result in the applicant's parent organization, directly or through its subsidiaries, holding more than one PDP sponsor contract in the PDP Region for which the applicant is seeking qualification as a PDP sponsor. A parent organization is an entity that exercises a controlling interest in the applicant.

* * * * *

■ 32. Amend § 423.504 by adding paragraphs (b)(4)(vi)(C)(*4*) and (b)(8) and (9) to read as follows:

§ 423.504 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(C) * * *

(*4*) A Part D plan sponsor must require all of its first tier, downstream and related entities to take the CMS training and accept the certificate of completion of the CMS training as satisfaction of this requirement. Part D plan sponsors are prohibited from developing and implementing their own training or providing supplemental training materials to fulfill this requirement.

* * * * *

(8) If neither the applicant, nor its parent or another subsidiary of the same parent, holds a Part D sponsor contract that has been in effect for at least 1 year at the time it submits an application, the applicant must have arrangements in place such that the applicant and its contracted first tier, downstream, or related entities, in combination, have at least 1 full-benefit year of experience within the 2 years preceding the application submission performing at a minimum all of the following functions in support of the operation of another Part D contract:

(i) Authorization, adjudication, and processing of prescription drug claims at the point of sale.

(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers.

(iii) Operation of an enrollee appeals and grievance process.

(9) For organizations applying to offer stand-alone prescription drug plans, the organization, its parent, or a subsidiary of the organization or its parent, must have either of the following:

(i) For 2 continuous years immediately prior to submitting an application, actively offered health insurance or health benefits coverage, including prescription drug coverage, as a risk-bearing entity in at least one State.

(ii) For 5 continuous years immediately prior to submitting an application, actively managed prescription drug benefits for an organization that offers health insurance or health benefits coverage, including at a minimum, all of the services listed in paragraph (b)(8) of this section.

* * * * *

■ 33. Amend § 423.505 as follows:

■ A. In paragraph (f)(3)(v), by removing ''.'' and adding in its place ''.''.

■ B. In paragraph (f)(3)(vi), by removing ''; and'' and adding in its place ''.''.

■ C. By adding paragraph (f)(3)(viii).

■ D. In paragraph (i)(2)(i), by removing the phrase ''audit, evaluate and inspect'' and adding in its place ''audit, evaluate, collect, and inspect''.

■ E. By redesignating paragraph (i)(2)(ii) as paragraph (i)(2)(iv).

■ F. By adding new paragraphs (i)(2)(ii)and (i)(2)(iii).

■ G. By removing paragraph (i)(3)(iv).

■ H. By redesignating (i)(3)(v) through (viii) as (i)(3)(iv) through (vii).

■ I. By adding paragraph (k)(7).

■ J. By adding a paragraph (m) heading.

■ K. By revising paragraphs (m)(1)(iii).L. By revising paragraph (m)(3).

The revisions and additions read as follows:

§ 423.505 Contract provisions.

* * * * *

(f) * * *

(3) * * *

(viii) Supporting program integrity purposes, including coordination with the States.

* * * * *

(i) * * *

(2) * * *

(ii) HHS, the Comptroller General or their designees have the right to audit, evaluate, collect, and inspect any records under paragraph (i)(2)(i) of this section directly from any first tier, downstream, or related entity.

(iii) For records subject to review under paragraph (i)(2)(ii) of this section, except in exceptional circumstances, CMS will provide notification to the Part D sponsor that a direct request for information has been initiated.

* * * * *

(k) * * *

(7) *Certification of accuracy of data for overpayments.* The CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that the information provided for purposes of reporting and returning of overpayments under § 423.360 is accurate, complete, and truthful.

* * * * *

(m) *Release of data.*

(1) * * *

(iii) Subject, in certain cases, to encryption of beneficiary identifiers and aggregation of cost data to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors, in accordance with all of the following principles:

(A) Subject to the restrictions in this paragraph, all elements on the claim are available to HHS, other executive branch agencies, and the States.

(B) Cost data elements on the claim generally are aggregated for releases to other executive branch agencies, States, and external entities. Upon request, CMS excludes sales tax from the aggregation at the individual level if necessary for the project.

(C) Beneficiary identifier elements on the claim generally are encrypted for release, except in limited circumstances, such as the following:

(*1*) If needed, in the case of release to other HHS entities, Congressional oversight agencies, non-HHS executive agencies and the States.

(*2*) If needed to link to another dataset, in the case of release to external entities. Public disclosure of research results will not include beneficiary identifying information.

* * * * *

(3)(i) CMS must make available to Congressional support agencies (the Congressional Budget Office, the Government Accountability Office, the Medicare Payment Advisory Commission, and the Congressional Research Service when it is acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1)) all information collected under paragraph (f)(3) of this section for the purposes of conducting congressional oversight, monitoring, making recommendations, and analysis of the Medicare program.

(ii) The Congressional Research Service is considered an external entity when it is not acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1) for the purposes of paragraph (m)(1) of this section.

* * * * *

■ 34. Section 423.505 is further amended, effective January 1, 2016, by revising paragraphs (b)(21) and (i)(3)(vii) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(21)(i) Update any prescription drug pricing standard (as defined in § 423.501) based on the cost of the drug used for reimbursement of network pharmacies by the Part D sponsor on January 1 of each contract year and not less frequently than once every 7 days thereafter;

(ii) Indicate the source used for making any such updates; and

(iii) Disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for any prescription drug pricing standard is not publicly available.

* * * * *

(i) * * *

(3) * * *

(vii) If applicable, provisions addressing the drug pricing standard requirements of § 423.505(b)(21).

* * * * *

■ 35. Amend § 423.509 as follows:

■ A. By redesignating paragraphs (a)(4), through (7), (a)(8) introductory text, (a)(8)(i) and (ii), and (a)(9) through (14) as paragraphs (a)(4)(i) through (iv), (a)(4)(v) introductory text, (a)(4)(v)(A) and (B), and (a)(4)(vi) through (xi), respectively.

■ B. By adding paragraph (a)(4) introductory text.

■ C. In newly redesignated paragraphs (a)(4)(ii), (iv), (v) introductory text, (vi), and (vii), by removing the term ''fails'' and adding in its place the term ''failed''.

■ D. In newly redesignated paragraphs (a)(4)(iii), (viii), and (ix), by removing the term ''fails'' and adding in its place the term ''failed''.

■ E. By revising newly redesignated paragraphs (a)(4)(x) and (xi).

■ G. By revising paragraphs (b)(1)(i) through (iv) and (b)(2)(i)(C).

■ H. In paragraph (b)(2)(ii), by removing the phrase ''MA organization'' and adding in its place the phrase ''Part D plan sponsor''.

■ I. In paragraph (c)(2)(iii), by removing the cross-reference ''(a)(4) of this section'' and adding in its place the cross-reference ''(a)(4)(i) of this section''.

■ J. In paragraph (d), by removing the cross-reference ''§ 423.642'' and adding in its place the cross-reference ''subpart N of this part''.

The additions and revisions read as follows:

§ 423.509 Termination of a contract by CMS.

(a) * * *

(4) CMS may make a determination under paragraph (a)(1), (2) or (3) of this section if the Part D Plan sponsor has had one or more of the following occur:

* * * * *

(x) Achieves a Part D summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

(xi)(A) Has failed to report MLR data in a timely and accurate manner in accordance with § 423.2460; or

(B) That any MLR data required by this subpart is found to be materially incorrect or fraudulent.

* * * * *

(b) * * *

(1) * * *

(i) CMS notifies the Part D plan sponsor in writing at least 45 calendar days before the intended date of the termination.

(ii) The Part D plan sponsor notifies its Medicare enrollees of the termination by mail at least 30 calendar days before the effective date of the termination.

(iii) The Part D plan sponsor notifies the general public of the termination at least 30 calendar days before the effective date of the termination by releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site.

(iv) CMS notifies the general public of the termination no later than 30 calendar days after notifying the plan of CMS's decision to terminate the Part D plan sponsor's contract by releasing a press statement.

(2) * * *

(i) * * *

(C) The contract is being terminated based on the grounds specified in paragraphs (a)(4)(i) and (xi) of this section.

* * * * *

§ 423.642 [Amended]

■ 36. Amend § 423.642(c)(1) by removing the phrase ''90 calendar days'' and adding in its place ''45 calendar days''.

■ 37. Amend § 423.752 as follows:

■ A. By adding paragraphs (a)(7) through (10).

■ B. By revising paragraph (c)(1).

■ C. In paragraph (c)(2)(ii), by removing the phrase ''pursuant to 423.509(a)(4)'' and adding in its place the phrase ''pursuant to § 422.510(a)(4)(i) of this chapter''.

The additions and revision read as follows:

§ 423.752 Basis for imposing intermediate sanctions and civil money penalties.

* * * * *

(a) * * *

(7) Except as provided under § 423.34, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual.

(8) Transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission.

(9) Fails to comply with marketing restrictions described in subpart V or applicable implementing guidance.

(10) Employs or contracts with any individual, agent, provider, supplier or entity who engages in the conduct described in paragraphs (a)(1) through (9) of this section.

* * * * *

(c) * * *

(1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in either of the following:

(i) Section 423.760(b) for any of the determinations at § 423.509(a), except § 423.509(a)(4)(i).

(ii) Section 423.760(c) for any of the determinations in paragraph (a) of this section except § 422.752(a)(5) of this chapter.

* * * * *

■ 38. Amend § 423.756 as follows:

■ A. In paragraph (a)(2), by removing the phrase ''days from receipt'' and adding in its place ''days after receipt'' and by removing the phrase ''considers receipt of notice'' and adding in its place the phrase ''considers receipt of the notice''.

■ B. In paragraph (b)(4), by removing the cross-reference ''§ 423.650 through § 423.662 of this part.'' and adding in its place ''Subpart N of this part.''.

■ C. In paragraph (c)(3)(ii) introductory text, by removing the phrase ''In instances where marketing or enrollment or both intermediate sanctions have been imposed,'' and adding in its place the phrase ''In instances where intermediate sanctions have been imposed,''.

■ D. Adding paragraph (c)(3)(ii)(C).

■ E. Revising paragraph (d).

The addition and revision read as follows:

§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.

* * * * *

(c) * * *

(3) * * *

(ii) * * *

(C) During the limited time period, sanctioned Part D plan sponsors under the benchmark that would normally participate in the annual and monthly auto enrollment process for enrollees receiving the low income subsidy will not be allowed to receive or process these types of enrollments.

(d) *Non-renewal or termination by CMS.* In addition to or as an alternative to the sanctions described in § 423.750, CMS may decline to authorize the renewal of an organization's contract in accordance with § 423.507(b), or terminate the contract in accordance with § 423.509.

(1) Decline to authorize the renewal of an organization's contract in accordance with § 423.507(b); or

(2) Terminate the contract in accordance with § 423.509.

* * * * *

■ 39. Amend § 423.760 as follows:
■ A. In paragraph (a) introductory text, by removing the phrase ''under 423.752(c)(1), CMS will consider as appropriate:'' and adding in its place the phrase ''under § 423.752(c)(1), CMS considers the following as appropriate:''.
■ B. In paragraphs (a)(1) and (2), by removing ''; '' and adding in its place ''.''.
■ C. Revising paragraph (a)(3).
■ D. In paragraph (a)(4) by removing ''; '' and adding in its place ''.''.
■ E. In paragraph (a)(5), by removing ''; and'' and adding in its place ''.''.
■ F. Adding paragraph (c).

The revision and addition read as follows:

§ 423.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) * * *

(3) The adverse effect to enrollees which resulted or could have resulted from the conduct of the Part D sponsor.

* * * * *

(c) *Amount of penalty imposed by CMS or OIG.* CMS or the OIG may impose civil money penalties in the following amounts for a determination made under § 423.752(a):

(1) Civil money penalties of not more than $25,000 for each determination made.

(2) With respect to a determination made under § 423.752(a)(4) or (a)(5)(i), not more than $100,000 for each such determination except with respect to a determination made under § 423.752(a)(5), an assessment of not more than the amount claimed by such plan or PDP sponsor based upon the misrepresentation or falsified information involved.

(3) Plus with respect to a determination made under § 423.752(a)(2), double the excess amount charged in violation of such paragraph (and the excess amount charged must be deducted from the penalty and returned to the individual concerned).

(4) Plus with respect to a determination made under § 423.752(a)(4), $15,000 for each individual not enrolled as a result of the practice involved.

■ 40. Amend § 423.1016 by revising the first sentence in paragraph (b)(1) to read as follows:

§ 423.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

* * * * *

(b) * * *

(1) The other party will have 20 calendar days from the date of mailing or in person filing to submit any rebuttal statement or additional evidence. * * *

* * * * *

■ 41. Amend § 423.1020 by revising paragraph (a)(2) to read as follows:

§ 423.1020 Request for hearing.

(a) * * *

(2) The Part D sponsor or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days after receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

* * * * *

■ 42. Amend § 423.2274 by:
■ A. Revising the introductory text.
■ B. Redesignating paragraphs (a) through (f) as (b) through (g).
■ C. Adding new paragraph (a).
■ D. Revising newly redesignated paragraph (b).
■ E. Adding paragraph (h).

The revisions and additions read as follows:

§ 423.2274 Broker and agent requirements.

If a Part D sponsor uses agents and brokers to sell its Part D plans, the following requirements in this section are applicable.

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

Compensation—(1) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to—

(i) Commissions;

(ii) Bonuses;

(iii) Gifts;

(iv) Prizes or Awards; or

(v) Referral or Finder fees.

(2) Does not include—

(i) Payment of fees to comply with State appointment laws, training, certification, and testing costs;

(ii) Reimbursement for mileage to, and from, appointments with beneficiaries; or

(iii) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Like plan type means one of the following:

(1) PDP replaced with another PDP.

(2) MA or MA–PD replaced with another MA or MA–PD.

(3) Cost plan replaced with another cost plan.

Unlike plan type means one of the following:

(1) PDP replaced with an MA–PD or an MA–PD replaced with a PDP.

(2) PDP replaced with a cost plan or a cost plan replaced with a PDP.

(3) MA–PD replaced with a cost plan or a cost plan replaced with an MA–PD.

Plan year means the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in a like plan type.

(b) *Compensation rules.* A Part D sponsor must compensate independent brokers and agents, if compensation is paid, only according to the following rules in this section.

(1) *Compensation amounts.* (i) For an initial year enrollment of a Medicare beneficiary into a Part D plan, the compensation must be at or below the fair market value of such services, published annually as a cut-off amount by CMS.

(ii) For renewal years, compensation may be up to 50 percent of the current fair market value cut-off amounts published annually by CMS.

(iii) If the Part D sponsor contracts with a third party entity such as a Field Marketing Organization or similar type entity to sell its insurance products, or perform services (for example, training, customer service, or agent recruitment)—

(A) The total amount paid by the Part D sponsor to the third party and its agents for enrollment of a beneficiary into a plan, if any, must be made in accordance with paragraph (b)(1) of this section; and

(B) The amount paid to the third party for services other than selling insurance products, if any, must be fair-market value and must not exceed an amount that is commensurate with the amounts paid by the Part D sponsor to a third party for similar services during each of the previous 2 years.

(2) *Aggregate compensation.* (i) An entity must not provide aggregate compensation to its agents or brokers greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan at any time.

(ii) An agent or broker must not receive aggregate compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type at any time.

(iii) The initial compensation is paid for replacements between unlike plan types.

(3) *Compensation payment and payment recovery.* (i) Compensation may only be paid for the enrollee's

months of enrollment during a plan year.

(ii)(A) Subject to paragraph (b)(3)(iii) of this section, compensation payments may be made at one time for the entire current plan year or in installments throughout the year.

(B) Compensation may not be paid until January 1 of the enrollment year and, if paid at all, must be paid in full by December 31 of the enrollment year.

(iii) When a beneficiary disenrolls from an MA plan, compensation paid to agents and brokers must be recovered for those months of the plan year for which the beneficiary is not enrolled. For disenrollments occurring within the first 3 months, the entire compensation must be recovered unless CMS determines that recoupment is not in the best interests of the Medicare program.

(4) *Compensation structure.* (i) A Part D sponsor must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the plan marketing period, October 1.

(ii) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

* * * * *

(h) Finder's (referral) fees. Finder's (referral) fees paid to all agents and brokers—

(1) May not exceed an amount that CMS determines could reasonably be expected to provide financial incentive for an agent or broker to recommend or enroll a beneficiary into a plan that is not the most appropriate to meet his or her needs; and

(2) Must be included in the total compensation not to exceed the fair market value for that calendar year.

Subpart Y—[Reserved]

■ 43. Part 423 is amended by adding reserved subpart Y.

■ 44. Part 423 is amended by adding subpart Z to read as follows:

Subpart Z—Recovery Audit Contractor Part D Appeals Process

Sec.

423.2600 Payment appeals.
423.2605 Request for reconsideration.
423.2610 Hearing official review.
423.2615 Review by the Administrator.

Subpart Z—Recovery Audit Contractor Part C Appeals Process

§ 423.2600 Payment appeals.

If the Part D RAC did not apply its stated payment methodology correctly, a Part D plan sponsor may appeal the findings of the applied methodology. The payment methodology itself is not subject to appeal.

§ 423.2605 Request for reconsideration.

(a) *Time for filing a request.* The request for reconsideration must be filed with the designated independent reviewer within 60 calendar days from the date of the demand letter received by the Part D plan sponsor.

(b) *Content of request.* (1) The request for reconsideration must be in writing and specify the findings or issues with which the Part D plan sponsor disagrees.

(2) The Part D plan sponsor must include with its request all supporting documentary evidence it wishes the independent reviewer to consider.

(i) This material must be submitted in the format requested by CMS.

(ii) Documentation, evidence, or substantiation submitted after the filing of the reconsideration request will not be considered.

(c) *CMS Rebuttal.* CMS may file a rebuttal to the Part D plan sponsor's reconsideration request.

(1) The rebuttal must be submitted within 30 calendar days of the review entity's notification to CMS that it has received the Part D plan sponsor's reconsideration request.

(2) CMS sends its rebuttal to the Part D plan sponsor at the same time it is submitted to the independent reviewer.

(d) *Review entity.* An independent reviewer conducts the reconsideration. The independent reviewer reviews the demand for repayment, the evidence and findings upon which it was based, and any evidence that the Part D plan sponsor or CMS submitted in accordance with this section.

(e) *Notification of decision.* The independent reviewer informs CMS and the Part D plan sponsor of its decision in writing.

(f) *Effect of decision.* A reconsideration decision is final and binding unless the Part D plan sponsor requests a hearing official review in accordance with § 423.2610.

(g) *Right to hearing official review.* A Part D plan sponsor that is dissatisfied with the independent reviewer's reconsideration decision is entitled to a hearing official review as provided in § 423.2610.

§ 423.2610 Hearing official review.

(a) *Time for filing a request.* A Part D plan sponsor must file with CMS a request for a hearing official review within 30 calendar days from the date of the independent reviewer's issuance of a determination.

(b) *Content of the request.* (1) The request must be in writing and must provide evidence or reasons or both to substantiate the request.

(2) The Part D plan sponsor must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(3) No new evidence may be submitted.

(4) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the Part D plan sponsor's hearing official review request.

(1) The rebuttal must be submitted within 30 calendar days of the Part D plan sponsor's submission of its hearing official review request.

(2) CMS sends its rebuttal to the Part D plan sponsor at the same time it is submitted to the hearing official.

(d) *Conducting a review.* A CMS-designated hearing official conducts the hearing on the record.

(1) The hearing is not to be conducted live or via telephone unless the hearing official, in his or her sole discretion, requests a live or telephonic hearing.

(2) In all cases, the hearing official's review is limited to information that meets one or more of the following:

(i) The Part D RAC used in making its determinations.

(ii) The independent reviewer used in making its determinations.

(iii) The Part D plan sponsor submits with its hearing request.

(iv) CMS submits in accordance with paragraph (c) of this section.

(3) Neither the Part D plan sponsor nor CMS may submit new evidence.

(e) *Hearing official decision.* The CMS hearing official decides the case within 60 days and sends a written decision to the Part D plan sponsor and CMS, explaining the basis for the decision.

(f) *Effect of hearing official decision.* The hearing official's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 423.2610.

§ 423.2615 Review by the Administrator.

(a) *Request for review by Administrator.* If a Part D plan sponsor is dissatisfied with the hearing official's decision, it may request that the CMS Administrator review the decision.

(1) The request must be filed with the CMS Administrator within 30 calendar days of the date of the hearing official's decision.

(2) The request must provide evidence or reasons to substantiate the request.

(b) *Content of request.* The Part D plan sponsor must submit with its request all

supporting documentation, evidence, and substantiation that it wants to be considered.

(1) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(2) Neither the Part D plan sponsor nor CMS may submit new evidence.

(c) *Discretionary review.* After receiving a request for review, the CMS Administrator has the discretion to review the hearing official's decision in accordance with paragraph (e) of this section or to decline to review said decision.

(d) *Notification of decision whether to review.* The CMS Administrator notifies the Part D plan sponsor within 45 days of receiving the Part D plan sponsor's hearing request of whether he or she intends to review the hearing official's decision. If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan sponsor that the request for review has been accepted. CMS sends its rebuttal statement to the plan sponsor at the same time it is submitted to the Administrator. If the CMS Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding.

(e) *Administrator review.* If the CMS Administrator agrees to review the hearing official's decision, he or she determines, based upon this decision, the hearing record, and any arguments submitted by the Part D plan sponsor or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The CMS Administrator furnishes a written decision, which is final and binding, to the Part D plan sponsor and to CMS.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 45. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 46. Amend § 424.530 by adding paragraph (a)(11) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(11) *Prescribing authority.* (i) A physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked; or

(ii) The applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs, and such suspension or revocation is in effect on the date the physician or eligible professional submits his or her enrollment application to the Medicare contractor.

* * * * *

■ 44. Amend § 424.535 by revising the section heading and adding paragraphs (a)(13) and (14) to read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(13) *Prescribing authority.* (i) The physician or eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked; or

(ii) The applicable licensing or administrative body for any state in which the physician or eligible professional practices suspends or revokes the physician or eligible professional's ability to prescribe drugs.

(14) *Improper prescribing practices.* CMS determines that the physician or eligible professional has a pattern or practice of prescribing Part D drugs that falls into one of the following categories:

(i) The pattern or practice is abusive or represents a threat to the health and safety of Medicare beneficiaries or both. In making this determination, CMS considers the following factors:

(A) Whether there are diagnoses to support the indications for which the drugs were prescribed.

(B) Whether there are instances when the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit).

(C) Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses.

(D) The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the State or States in which he or she practices, and the reason(s) for the action(s).

(E) Whether the physician or eligible professional has any history of ''final adverse actions'' (as that term is defined in § 424.502).

(F) The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined).

(G) Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe medications, and the reason(s) for any such restriction, suspension, revocation, or termination.

(H) Any other relevant information provided to CMS.

(ii) The pattern or practice of prescribing fails to meet Medicare requirements. In making this determination, CMS considers the following factors:

(A) Whether the physician or eligible professional has a pattern or practice of prescribing without valid prescribing authority.

(B) Whether the physician or eligible professional has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber's DEA registration.

(C) Whether the physician or eligible professional has a pattern or practice of prescribing drugs for indications that were not medically accepted—that is, for indications neither approved by the FDA nor medically accepted under section 1860D–2(e)(4) of the Act—and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient.

* * * * *

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

Dated: April 30, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: May 1, 2014.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2014–11734 Filed 5–19–14; 2:56 pm]

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Part III

Department of Transportation

14 CFR Parts 234, 244, *et al.*

Transparency of Airline Ancillary Fees and Other Consumer Protection Issues; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Parts 234, 244, 250, 255, 256, 257, 259, and 399

[Docket No. DOT–OST–2014–0056]

RIN 2105–AE11

Transparency of Airline Ancillary Fees and Other Consumer Protection Issues

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department is seeking comment on a number of proposals to enhance protections for air travelers and to improve the air travel environment, including a proposal to clarify and codify the Department's interpretation of the statutory definition of ''ticket agent.'' By codifying the Department's interpretation, the Department intends to ensure that all entities that manipulate fare, schedule, and availability information in response to consumer inquiries and receive a form of compensation are adhering to all of the Department's consumer protection requirements that are applicable to ticket agents such as the full-fare advertising rule and the code-share disclosure rule.

This NPRM also proposes to require airlines and ticket agents to disclose at all points of sale the fees for certain basic ancillary services associated with the air transportation consumers are buying or considering buying. Currently, some consumers may be unable to understand the true cost of travel while searching for airfares, due to insufficient information concerning fees for ancillary services. The Department is addressing this problem by proposing that carriers share real-time, accurate fee information for certain optional services with ticket agents.

Other proposals in this NPRM to enhance airline passenger protections include: Expanding the pool of ''reporting'' carriers; requiring enhanced reporting by mainline carriers for their domestic code-share partner operations; requiring large travel agents to adopt minimum customer service standards; codifying the statutory requirement that carriers and ticket agents disclose any airline code-share arrangements on their Web sites; and prohibiting unfair and deceptive practices such as undisclosed biasing in schedule and fare displays and post-purchase price increases. The Department is also considering whether to require ticket agents to disclose the carriers whose tickets they sell in order to avoid having consumers mistakenly believe they are searching all possible flight options for a particular city-pair market when in fact there may be other options available. Additionally, this NPRM would correct drafting errors and make minor changes to the Department's second Enhancing Airline Passenger Protections rule to conform to guidance issued by the Department's Office of Aviation Enforcement and Proceedings (Enforcement Office) regarding its interpretation of the rule.

DATES: Comments must be received by August 21, 2014. Comments received after this date will be considered to the extent practicable.

ADDRESSES: You may file comments identified by the docket number DOT–OST–2014–0056 by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave., SE., Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* The Docket Management Facility is located on the West Building, Ground Floor, of the U.S. Department of Transportation,1200 New Jersey Ave. SE., Room W12–140, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

Instructions: You must include the agency name and the Docket Number DOT–OST–2014–0056 or the Regulatory Identification Number (RIN) for the rulemaking at the beginning of your comment. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment if submitted on behalf of an association, a business, a labor union, etc.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://DocketsInfo.dot.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Kimberly Graber or Blane A. Workie, Office of the Assistant General Counsel for Aviation Enforcement and Proceedings, U.S. Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590, 202–366–9342 (phone), 202–366–7152 (fax), *kimberly.graber@dot.gov* or *blane.workie@dot.gov* (email).

SUPPLEMENTARY INFORMATION:

Executive Summary

1. Purpose of the Regulatory Action

The U.S. Department of Transportation (DOT) is issuing this notice of proposed rulemaking (NPRM) to improve the air travel environment of consumers based on its statutory authority to prohibit unfair or deceptive practices in air transportation, 49 U.S.C. 41712. The Department is taking action to strengthen the rights of air travelers when purchasing airline tickets from ticket agents, ensure that passengers have adequate information about regional carriers' operations to make informed decisions when selecting flights, increase notice to consumers of some of the fees carriers charge for optional or ancillary services, and prohibit unfair and deceptive practices such as post-purchase price increases and undisclosed biasing in fare and schedule displays.

2. Summary of Regulatory Provisions

	Subject	Proposed rule
1	Codification of the Department's Interpretation of ''Ticket Agent''.	Codifies the Department's broad interpretation of the statutory definition of the term ''ticket agent'' to include Global Distribution Systems (GDS), websites with flight metasearch engines, and similar intermediaries in the sale of air transportation, if the intermediary is compensated in connection with the sale of air transportation.
2	Disclosure of Certain Ancillary Fee Information to Consumers (''GDS Issue'').	Two alternative proposals regarding disclosure of fee information for basic ancillary services. • Proposal #1: Requires carriers to disclose fee information for basic ancillary services to all ticket agents to which a carrier provides its fare information, including GDSs.

	Subject	Proposed rule
		• Proposal #2: Requires carriers to disclose fee information for basic ancillary services to all ticket agents to which a carrier provides its fare information and which sell air transportation directly to consumers; this would exclude ticket agents that arrange but don't sell air transportation, such as GDSs. Both proposals would: • Define basic ancillary services as first checked bag, second checked bag, one carry-on item, and advance seat selection, to the extent these options are offered by the carrier. • Not require a carrier to allow ticket agents to sell these services; or if a carrier permits ticket agents to sell those services, it would not require carriers to charge the same fee for the service as the agents. If a carrier is not selling the service through a ticket agent, the carrier and ticket agent are responsible for disclosing to consumers when and how fees should be paid, and for baggage fees, must honor the fee quoted at the time of purchase. • Require all ticket agents and airlines that provide fare information to consumers to also provide fee information for basic ancillary services to consumers. This information should be made available to the consumer at the point in which fares are being compared. • Prohibit ticket agents with existing contractual agreements with a carrier for the distribution of the carrier's fare and schedule information from charging additional or separate fees for distribution of information about basic ancillary services—i.e., a ticket agent cannot unilaterally change contract terms to require additional payments to upload and disseminate the required ancillary service fee information. Existing contracts should be honored until the contract expires unless mutually renegotiated by the parties.
3	Expansion of Reporting Carriers for Service Quality Data.	Expands the pool of reporting carriers from any carrier that accounts for at least 1% of domestic scheduled passenger revenue to any carrier that accounts for at least 0.5% of domestic scheduled passenger revenue. (This definition would cover carriers such as Spirit Airlines, Allegiant Airlines, and Republic Airlines.)
4	Data Reporting for Domestic Code-Share Partner Operations.	Requires reporting carriers to include data for their domestic scheduled flights operated by their code-share partners: • On-time Performance • Mishandled Baggage • Oversales
5	Customer Service Commitments (Large Ticket Agents).	Requires large ticket agents (those with annual revenue of $100 million or more) to adopt certain customer service commitments, including a commitment to: • Provide prompt refunds where ticket refunds are due, including fees for optional services that consumers purchased from them but were not able to use due to flight cancellation or oversale situation; • Provide an option to hold a reservation at the quoted fare without payment, or to cancel without penalty, for 24 hours; • Disclose cancellation policies, seating configurations, and lavatory availability on flights; • Notify customers in a timely manner of itinerary changes; and • Respond promptly to customer complaints.
6	Transparency in Display of Code-Share Operations as Required by 49 U.S.C. 41712(c).	Amends the Department's code-share disclosure regulation to codify the statutory requirement that carriers and ticket agents must disclose any code-share arrangements on their Web sites. Requires disclosure on the first display presented in response to a search of a requested itinerary for each itinerary involving a code-share operation. Disclosure must be in a format that is easily visible to a viewer.
7	Disclosure of the Carriers Marketed (Applies to Large Travel Agents Only).	Seeks comments regarding whether: • To require large ticket agents to maintain and display lists of carriers whose tickets they market and sell; and if required, how to disclose the carriers that are marketed and sold by the ticket agent.
8	Prohibition of Display Bias	Prohibits undisclosed biasing by carriers and ticket agents in any Internet displays of the fare and schedule information of multiple carriers.
9	Prohibition on Post-Purchase Price Increases For Ancillary Services.	Revises the existing prohibition on post-purchase increases with respect to the price of ancillary services that are not purchased with the air transportation so carriers and other sellers of air transportation are only prohibited from increasing the price for the carriage of baggage. The price for other ancillary services not purchased at the time of ticket purchase may be increased until the consumer purchases the service itself.

3. Summary of Preliminary Regulatory Analysis

SUMMARY OF MONETIZED COSTS AND MONETIZED BENEFITS OVER 10 YEARS, DISCOUNTED AT 7 PERCENT

[Millions $]

Provisions	Costs	Benefits
1: Definition of ticket agent	N/A	N/A
2: Disclosure of certain ancillary fees information to consumers	$ 46.15	$ 25.1
3 & 4: Reduce reporting threshold to 0.50% and submit additional set of reports that includes code-share partners	29.75	N/A
5: Minimum customer service standards for ticket agents	2.97	N/A
6: Display bias prohibition	N/A	N/A
7: Disclosure of code-share segments in schedules, advertisements and communications with consumers	N/A	N/A
8: Disclosure of carriers marketed	N/A	N/A
9: Prohibition of post-purchase price increase for ancillary services	N/A	N/A
Total (Proposed Provisions)	80.51	25.1

The quantifiable costs of this rulemaking exceed the quantifiable benefits. However, when unquantified costs and benefits are taken into account, we anticipate that the benefits of this rulemaking would justify the costs. It was not possible to measure the benefits of the proposals in this rulemaking, except for the benefits for provision 2. For example, there are a number of unquantified benefits for the proposals such as improved on time performance for newly reporting carriers and code-share flights of reporting carriers, improved customer goodwill towards ticket agents, and greater competition and lower overall prices for ancillary services and products. There are also some unquantified costs such as increased management costs to improve carrier performance, increased staff time to address consumer complaints, and decreased carrier flexibility to customize services, though we believe these costs would be minimal. If the value of the unquantified benefits, per passenger, is any amount greater than one cent and the unquantified costs are minimal as anticipated, then the entire rule is expected to be net beneficial.

Background

This NPRM addresses several recommendations to the Department regarding aviation consumer protection as well as two issues identified in the second Enhancing Airline Passenger Protections final rule. In that final rule, the Department instituted many passenger protections including expanding the rules regarding lengthy tarmac delays to non-U.S. carriers, requiring U.S. and non-U.S. carriers to adopt and adhere to minimum customer service standards, increasing the amounts of involuntarily denied boarding compensation, enhancing Web site disclosures for baggage fees and other ancillary service fees, and prohibiting post-purchase price increases. *See* 76 FR 23110 (April 25, 2011). However, the Department declined to impose a requirement on airlines to provide their fee information for ancillary services to Global Distribution Systems (GDSs), stating that the Department needed to learn more about the complexities of the issue. This NPRM addresses the issue of disclosure of ancillary services fee information. Additionally, subsequent to the publication of the 2011 final rule, in response to questions received regarding the post-purchase price increase rule, the Department's Office of Aviation Enforcement and Proceedings (Enforcement Office) issued *Guidance on Price Increases of Ancillary Services and Products not Purchased with the Ticket* on December 28, 2011 available at *http://www.dot.gov/airconsumer.* In that guidance, the Enforcement Office noted the Department's decision to revisit in this NPRM the rule as it relates to post-purchase price increases for certain ancillary services not purchased with the ticket.

This NPRM also addresses certain recommendations made by two Federal advisory committees—the Future of Aviation Advisory Committee (FAAC) and the Advisory Committee on Aviation Consumer Protection. The FAAC was established on April 16, 2010, with the mandate to provide information, advice, and recommendations to the Secretary of Transportation on ensuring the competitiveness of the U.S. aviation industry and its capability to address the evolving transportation needs, challenges, and opportunities of the global economy. On December 15, 2010, the FAAC delivered a report to the Secretary with 23 recommendations. FAAC Recommendation 11 addressed disclosure of ancillary service fees, code-share operations, and air travel statistics. This NPRM incorporates many aspects of FAAC Recommendation 11. For more information regarding the FAAC, please visit *http://www.dot.gov/faac.*

More recently, on May 24, 2012, the Advisory Committee on Aviation Consumer Protection was established to advise the Secretary in carrying out activities related to airline customer service improvements. On October 22, 2012, this Committee submitted its first set of recommendations to the Secretary on a wide range of aviation consumer issues, including adopting FAAC Recommendation 11, which urged greater transparency in the disclosure of ancillary fees and code-share operations. This NPRM addresses the recommendations by the Committee to ensure transparency in air carrier pricing, to require on-time performance data be reported to the Department for all flights and airlines, and to mandate disclosures by online travel agencies and other agents as to which carriers' services they sell. Records relating to the advisory committee, including a transcript and minutes of its meetings and its full recommendation report, are contained in the Department's docket, which is available at *http://www.regulations.gov* under docket number DOT–OST–2012–0087.

Notice of Proposed Rulemaking

1. Clarifying the Definition of ''Ticket Agent''

This NPRM proposes a regulatory definition for the statutory term ''ticket agent'' to clarify for the industry what type of entity the Department considers to be a ticket agent and to ensure that its consumer protection regulations apply to all entities that hold out airfare, schedule, and availability information to consumers. Consumers and stakeholders in the air transportation industry have identified relatively new entities, such as meta-search engines, as primary information sources and entry points for the purchase of air transportation. However, such entities do not consistently provide the

information that the Department views as vital to consumer protection such as code-share disclosure. For example, consumers may begin their search for air transportation options by selecting their flights on one Web site and then completing their purchase on another Web site and, in the process, not be provided disclosures regarding code-share operations, baggage fee information, and other consumer protection information that the Department requires air carriers, foreign air carriers, and ticket agents provide to consumers early in the process.

The Department is considering codifying in its regulations its interpretation of the statutory definition of ''ticket agent'' to make clear that all entities involved in the sale or distribution of air transportation, including those intermediaries that do not themselves sell air transportation but arrange for air transportation and receive compensation in connection with the sale of air transportation, are ticket agents subject to the Department's regulations regarding the display of airfare information. The definition would include all commercial entities that are involved in arranging for the sale of air transportation through the Internet (among other channels), regardless of whether an entity received a share of revenue from a third party for transactions that originated on the entity's Web site, or the entity charged a commission for each transaction that originated on its Web site, or the entity was simply compensated on a cost-per-click for advertisements, or was compensated on some other basis.

The means by which airline itineraries are commonly displayed and sold has changed dramatically and continues to evolve. New entities that were not previously involved in the distribution of air transportation are now an important source of information for consumers as well as a means of distribution for carriers. Online entities, such as Web sites that provide a variety of travel information, advertising, and links as well as meta-search engines that provide flight search tools including fare and schedule information, are now frequently used by consumers to research airfares and schedules and to connect to the airline or travel agent Web site that ultimately books and/or fulfills the consumer's ticket purchase. Meanwhile, some airlines provide direct electronic access to their own internal systems providing fare, schedule, and availability information to certain Internet entities with the condition that when displaying that carrier's flight itineraries in flight search results, the entity must provide a link only to the airline's Web site and not to travel agent Web sites that have similar information. Staff members from the Department have been informed that, in some cases, entities such as meta-search engines and other Web sites that operate flight search tools receive a commission or some other compensation for transactions that originate on their Web sites, for example, from a flight search tool that allowed the consumer to select a particular itinerary. However, in other cases, entities that are involved in arranging for air transportation by allowing a consumer to select an itinerary using a flight search tool are compensated for advertising and not for the individual transaction. But regardless of the manner of compensation, consumers are increasingly relying on those Internet entities in making their air transportation purchasing decisions. In some cases, these Internet entities display schedules, fares and availability but direct consumers to other Web sites to purchase and are not the final point of sale for an airline ticket. They may be earning revenue through advertising sales and providing flight search capabilities based on data gathered from other sources. These entities would be included under our proposed definition of ticket agent along with traditional ticket agents. The Department seeks comment on the differences between traditional ticket agents and entities that provide flight search tools but direct consumers to another site to finalize their purchase. Are there considerations regarding entities that are not the final point of sale for air transportation that should be considered in connection with the regulations proposed in this rulemaking? DOT also seeks comment on the impact on these entities of complying with the Department's existing regulations applicable to ticket agents. For example, what are the impacts on ticket agents that are not the final point of sale for air transportation of the regulations in 14 CFR 399.80 (e.g., prohibition against misrepresentation of quality or kind of service, type or size of aircraft, time of departure or arrival, and so forth; prohibition against misrepresentation of fares and charges)? Are those impacts different from the impacts on traditional ticket agents or other agents that have a different business model?

As noted above, consumers may begin their search by selecting their flights on one Web site and then completing their purchase on another Web site and, in the process, bypass the pages containing disclosures regarding code-share operations, baggage fee information, and other consumer protection information that the Department requires air carriers, foreign air carriers, and ticket agents to provide to consumers before an air transportation purchase is finalized. Accordingly, the Department is considering a definition of ''ticket agent'' that would clarify that global distribution systems, meta-search Internet sites that offer a flight search tool and are compensated for advertisements that are displayed on the same Web site (even if the advertising content is not directly related to air travel), and other such compensated intermediaries, regardless of the manner in which they are compensated for their role in arranging air transportation, are ticket agents for the purposes of the Department's air transportation consumer protection regulations. Such a broad definition would ensure that all commercial entities that receive compensation in connection with air transportation advertising/marketing and that are involved in arranging for air transportation would be required to provide consumers with certain essential information early in the process (e.g., information regarding code-share operations, disclosure about baggage fees). A broad definition of ''ticket agent'' would better ensure passengers are protected regardless of the path they choose to arrange for air transportation. Additionally, this rulemaking proposes to prohibit ticket agents from incorporating undisclosed bias into their displays, and solicits comment on whether ticket agents should be required to disclose information about incentive payments and/or identify the carriers the ticket agent markets or does not market.

We are not aware of whether there is a widespread problem of consumers being confused by Web sites that do not sell tickets but do provide fare, schedule, and availability information that consumers are relying on in planning their travel. However, we believe that there is a risk of harm because some Web sites do not provide all of the disclosures required by the Department. We seek comment from any consumers who have faced these types of problems.

Past litigation has made clear that GDSs are ticket agents. *Sabre* v. *Department of Transportation,* 429 F.3d 1113 (D.C. Cir. 2005). However, meta-search engines that offer a flight search tool have entered into the marketing and distribution of fare and schedule information. In addition, new entities have emerged that receive direct or indirect compensation from the advertising and/or sale of air transportation, while offering flight

search tools and fare displays. The Department sees a benefit in clarifying that those entities are ticket agents, regardless of whether or not they are the final point of sale for air transportation, and are required to comply with air transportation consumer protection regulations that apply to ticket agents. Additionally, at this point, the Department cannot predict the new types of entities that will engage in the marketing and distribution of fare and schedule information or how the marketing and distribution of fare and schedule information will change with new developments in technology. However, it appears that some of these entities may have taken, or will take in the future, a quasi-GDS role. Accordingly, the Department believes its regulations should be clear and should apply equally to entities that are new to the air transportation marketplace as well as existing entities already involved in the marketing and distribution of air transportation. To be clear, only entities operating Web sites that provide flight search tools that manipulate, manage, and display fare, schedule, and availability information and are tools that the Web site operator creates or manipulates and has ultimate control over would be covered. For example, entities such as Kayak and Google that offer flight search tools with fare, schedule, and availability information would be covered. An entity that operated a Web site that simply displayed airfare advertisements without actual flight search capability under its control would not be covered.

The Department seeks comment on whether the definition of ''ticket agent'' should be codified in the regulation so as to clarify the Department's view that it is a broad term and includes entities such as meta-search engines that provide a flight search tool and other Web sites that act as intermediaries between consumers and the ultimate entity that sells the air transportation, whether an airline or another ticket agent. The Department also seeks comment on whether the proposed definition of a ticket agent, which includes an entity that arranges for or sells air transportation for compensation (regardless of the form of compensation), is sufficiently broad and meets the Department's goal of encompassing the variety of entities that use the Internet to arrange for the sale of air transportation. For example, under the proposed definition, an entity that provides a flight search tool that allows consumers to select an itinerary that can be purchased on another site and displays air transportation advertisements for which the entity is compensated on a ''cost-per-click'' basis would fall under the definition of a ticket agent. The Department also seeks comment on whether the definition of a ticket agent should include all entities that operate flight search tools that display itineraries and allow consumers to begin the booking process but are not compensated for the specific transaction. We also request comments on the costs and benefits to consumers, airlines, meta-search engines, and other entities involved in arranging for and selling air transportation, of codifying the definition of ''ticket agent'' to include air transportation intermediaries such as meta-search engines that offer a flight search tool.

As a related matter, the Department is considering whether carriers should be prohibited from restricting the information provided by ticket agents when those ticket agents do not sell air transportation directly to consumers but rather provide consumers with different airlines' flight information for comparison shopping. For example, the Department has been informed that some carriers may not allow certain entities with Web sites that operate flight search tools to display the carrier's fare, schedule and availability information. Should carriers be prohibited from imposing restrictions on ticket agents that prevent ticket agents from including a carrier's schedules, fares, rules, or availability information in an integrated display?

Also, we understand that a number of carriers restrict the links ticket agents may place next to a particular flight itinerary on a display, and in many cases only permit a link to the carrier's own Web site. Why might carriers place such restrictions on travel agents? Should the Department require carriers to allow ticket agents to provide links to the Web sites of the entities listed in an integrated display, including non-carrier Web sites?

2. Display of Ancillary Service Fees Through All Sales Channels

Need for Rulemaking

Many services or products previously included in the price of an airline ticket such as checked baggage, advance seat assignments and priority boarding are now sold separately. Traditional and online travel agents generally access their airline ticket inventory through large Global Distribution Systems (GDSs) and often do not have access to the fees associated with ancillary services/products and thus cannot disclose this information to consumers without looking directly at carriers' Web sites. In discussions with the Department, consumers and corporate travel companies have identified the lack of complete transparency of fees for unbundled services and products as a problem. Specifically, when consumers are making decisions on whether to purchase air transportation and if so, from which entity, they continue to have difficulty determining the total cost of travel because the fees for the basic ancillary services are not available through all sales channels. This lack of transparency also creates challenges in the corporate and managed travel community. Currently, approximately 50% of air transportation is booked through a channel that involves a ticket agent rather than the airline's own reservation agents or its Web site, whether it is through a traditional brick-and-mortar travel agency, a corporate travel agent, or an online travel agency.[1] Consumers and corporate travel companies often search various Web sites to try to determine the fees for ancillary services. They have raised concerns with the Department regarding how the lack of clear disclosure of ancillary fees makes it difficult to determine the true cost of travel and compare different airline flight and fare options.

In the NPRM that led to the second Enhancing Airline Passenger Protections rule, the Department reiterated its goal of increasing notice to consumers of the fees carriers charge for optional or ancillary services, including checked baggage fees and carry-on baggage fees, by proposing a series of disclosure requirements related to ancillary service fees. When drafting the disclosure regime in the second Enhancing Airline Passenger Protections rule, the Department recognized that a problem in the marketplace existed because ticket agents did not have access to real-time and accurate fee data for ancillary services. Therefore, in the NPRM, the Department asked whether it should require that carriers provide fee information for ancillary services and products to the GDSs in which each carrier participates, in an up-to-date and useful fashion. Although the

[1] According to estimates by PhoCusWright (2011), 31 percent of passengers purchased tickets through Travel Management Companies (TMCs) (e.g., American Express, Carlson Wagonlit), and 16 percent via an online travel agency (OTA). Since both TMCs and OTAs use GDSs to book air tickets, the share of passengers who will benefit from improved salience on ancillary service fees would be the total of both ticket distribution channels (47 percent), unless TMCs or OTAs connect directly to airlines. Other higher proxy estimates were also found. InterVISTAS estimated that 50 percent of US national round trip passengers book their ticket via a GDS.

Department did not propose rule text, it invited comment on the ''GDS proposal.'' The comment period closed on September 24, 2010.

The Department received numerous comments regarding the GDS proposal from interested industry parties and consumer advocacy groups both before and after the closing of the comment period. The comments demonstrated to the Department that before it issued a final rule it needed more information on the contractual and historical relationships between the GDSs and the carriers, as well as an in-depth cost-benefit analysis of such a requirement. Therefore, in the Final Rule for Enhancing Airline Passenger Protections published in the **Federal Register** on April 25, 2011, 76 FR 23110, the Department did not include a requirement that carriers provide all ancillary service fee information to GDSs. Instead, it stated that it would continue to consider the issue, gather more information, and defer final action on this topic.

In the 2011 final rule, the Department did impose various disclosure requirements on both carriers and travel agents via the new 14 CFR 399.85. However, in recognition of the fact that the Department had not required the dissemination of ancillary service fee information through GDSs and, therefore, agents would not necessarily have access to the most up-to-date and accurate ancillary service fee information, the Department promulgated different baggage disclosure requirements for ticket agents from those required of carriers. For example, the rule allows ticket agents with Web sites marketed to consumers in the United States to disclose baggage fees through hyperlinks displayed with itinerary search results and included in e-ticket confirmations which link to static lists. Also, 14 CFR 399.85(a) requires carriers but not ticket agents to disclose on their homepage for three months any change to their baggage fees. Additionally, under 14 CFR 399.85(d), carriers must provide a listing of all optional service fees on one Web page. There must be a link to that listing on the homepage. Agents are not required to have this listing, as they do not necessarily have access to all carriers' current optional service fee information on a real-time basis.

While the Department considers the disclosure requirements in its 2011 final rule to be a step in the right direction, these requirements do not fully address the problem of lack of transparency of ancillary services and products. Consumers who book transportation through a ticket agent still do not receive accurate and real-time information about fees for ancillary services and products and are unable to determine the total cost of travel. Consumers also can't use the list of optional services and fees that airlines post on their Web site to determine the cost of travel since airlines generally provide a range of fees for ancillary services aside from baggage and acknowledge that the fees vary based on a number of factors such as the type of aircraft used, the flight on which a passenger is booked or the time at which a passenger pays for the service or product. Further, the list of optional services and fees that the airlines post on their Web sites are static lists. In many cases, it is not possible for consumers to know the specific fees that would apply to them based on these lists as there are numerous possible fare and fee combinations and routings for any given trip. With respect to baggage, the existing disclosure requirements mandate specific information, but passengers must still review lengthy and complex charts to determine the exact fee that they would be charged for their baggage.

The Department remains of the view that as carriers continue to unbundle services that used to be included in the price of air transportation, passengers need to be protected from hidden and deceptive fees and allowed to price shop for air transportation in an effective manner. However, we lack sufficient data to be able to quantify the extent of this problem for consumers. We request comment from consumers about whether it is difficult to find baggage and seat assignment fee information and how much of an impact this has on their ability to comparison shop among carriers. The Department also requests comment from consumers on whether and how much the fee disclosures required of carriers and travel agents in Passenger Protections II have improved their ability to find information on fees.

Consumers and consumer groups have reiterated to the Department through comments in the second Enhancing Airline Passenger Protections rulemaking and comments to the docket for the Advisory Committee on Aviation Consumer Protection the difficulty in determining the specific fees that apply to ancillary services. Additionally, members of Congress, representing their constituents, have expressed support for full disclosure of ancillary fees during the rulemaking period for the second Enhancing Airline Passenger Protections rule. The Department also receives consumer complaints that reflect the confusion consumers experience regarding fees for ancillary services, particularly in connection with baggage and seat assignments. For example, consumers complain that when shopping for air transportation they do not know how much it will cost them to book seats together for family members or to transport all of their baggage. Similarly, representatives of business travelers complain that it is difficult to advise clients on the best and most cost-effective flights because the fee information for seat assignments or baggage is not readily available. Additionally, the issue has been raised at meetings of the Advisory Committee on Aviation Consumer Protection by various industry stakeholders and consumer advocates. The Department believes that regulation is needed to address the lack of transparency regarding the true cost of air transportation and is proposing to require that fees for certain ancillary services be disclosed to consumers through all sale channels. The Department seeks input on this proposal as well as any innovative solutions that we may not have considered to address the problem of lack of transparency.

Current Airline Distribution System

In the final rule that was issued on April 25, 2011, the Department announced its intention to address in a future rulemaking the transparency of ancillary fees at all points of sale. Since that time, the Department has met with numerous stakeholders with an interest in the distribution of ancillary service fee information and conducted an inquiry regarding current distribution models as well as the contractual and historical relationships between the GDSs and the carriers. Representatives of carriers, GDSs, consumer advocacy organizations, and trade associations, as well as other interested entities, including third-party technology developers, have met with Department staff to explain their views. They have also provided information to the Department's economists. The description of the current airline distribution system provided below is largely based on the information that the Department received from these stakeholders.

Today, airlines sell airfares in two ways: Directly through their Web sites, call centers, or employees at airports or indirectly through ticket agents. Approximately 50% percent of airline tickets are purchased indirectly through ticket agents, whether it is through a traditional brick-and-mortar travel agency, a corporate travel agent, or an online travel agency. Ticket agents that display or sell air transportation

typically get the fare, schedule and availability information about the air transportation through a GDS. In the United States, three GDSs (Sabre, Travelport and Amadeus) control the distribution of the airline product for the ticket agent channel. In recent years, Sabre had more than 50 percent of the market, Travelport had approximately 40 percent and Amadeus had less than 10 percent of the market in the U.S. though Amadeus has a much larger percentage of the market worldwide.

Most U.S. airlines use GDSs to distribute their products. Some low cost carriers [2] such as Southwest participate on a selective basis in GDSs while other low cost carriers do not use GDSs, presumably because there are costs attached to each transaction. GDSs charge airlines a booking fee based on the total number of flight segments in the consumer's itinerary. Airlines presently pay booking fees that can range from a few dollars to much more for each flight segment. For example, if a booking fee is $5 per segment and a passenger purchases an itinerary that consists of four flight segments, the airline will be charged approximately $20 in booking fees. A transaction through an airline's own system costs the carrier less. However, GDSs have emphasized that there have been substantial discounts of domestic booking fees for the major airlines since 2005.

Nevertheless, airlines have expressed frustration about paying what they view as more in fees to GDS than the value they feel they receive now that technology provides new ways of selling fares and ancillary services. Still these airlines are not able to forgo using GDSs to aggregate flight schedule and fare information because airlines earn a large percentage of their revenue from business travelers, and the majority of the world's managed business travel is booked through travel management companies which use GDSs. Unlike Southwest, the legacy carriers do not have the option to participate on a selective basis in GDSs (i.e., only for business travel). Overall, airline revenue from the GDS channel is higher than direct channels mainly due to the greater proportion of high-yield business bookings.[3]

Airlines' efforts to reduce their reliance on GDSs and transition to direct connections with travel agents have also been difficult. By direct connect, we are referring to agreements between an airline and a travel agent in which the airline provides fare, schedule and availability information to the travel agent directly, bypassing GDSs. Various airlines have reported to the Department that they as well as new-entrant travel technology firms, such as Farelogix, have had difficulty in facilitating direct connections to ticket agents because of highly restrictive agreements between GDSs and ticket agents. Similar assertions were made by other third party technology providers. GDSs have contracts with both airlines and travel agents for use of their services. These contracts tend to be long-term agreements that are renewed every 3 to 5 years. Historically, contracts between carriers and the GDSs generally provided that carriers compensate the GDSs per flight segment booked. These contracts also generally require that carriers offer the same fares through GDSs that are offered through other channels, even if it is cheaper for the carrier to distribute the fares in a different manner, such as direct connect. Contracts between travel agencies and GDSs generally provide for incentive payments to travel agencies for booking travel through GDSs. GDSs also provide travel agencies with the technology used for mid- and back-office solutions such as quality control and office accounting. GDSs do not view the contracts as a barrier to entry for travel technology firms. They assert that the direct connect services will succeed or fail based on whether they meet the needs of travel agencies and the consumers they serve.

It is also worth noting that IATA has filed an application with the Department for approval of its Resolution 787, the agreement that establishes the framework for its New Distribution Capability (NDC). NDC would be based on a common XML based technical standard for direct connect services. Airlines contend that this new standard would allow airlines to custom-tailor product offers that would include different combinations of ancillary services in addition to air transportation and would include a total price. The new standard, if approved by the Department, will be available for use by any party. While the Department acknowledges that carriers are working towards technological solutions to distribute information, such solutions are prospective. Additionally, even if a standard is agreed upon, its use is optional and the information transmitted using the standard would be determined by each carrier. Accordingly, the development of a standard would not solve the immediate problem that some current consumers are not receiving the information that they need to determine the total cost of travel including the cost of certain ancillary services.

While fare, schedule, and availability information is currently provided by the airlines to the GDSs, and by GDSs to the agents that display and sell to consumers, information about the cost of ancillary services is not typically shared. One reason, as it has been explained to Department staff by airline representatives, is that GDSs do not have the modern technology airlines need to merchandise and sell their products the way they choose. The GDSs disagree with the airlines' assessment and contend that they are capable of handling the most complex airline transactions and have worked with airlines, airline associations, and airline-owned intermediaries like ATPCO, ARC and IATA to establish technical standards for the distribution of their products, including ancillary offerings. While expressing a general willingness to distribute ancillary products to travel agents subject to assurances that the technology is in place to conduct transactions in an efficient and cost-effective manner, airlines expressed the need for the flexibility to do so on terms that meet their business needs. Airlines prefer to negotiate with the GDSs for the business terms acceptable to them. They argue that market forces and not government mandates are the best way to ensure that information about ancillary services and fees reaches consumers using the travel agent channel.

Various airlines and airline associations have also asserted to the Department that if it were to require carriers to provide ancillary service fee information to all ticket agents that the carrier permits to distribute its fare and schedule information, including GDSs, the Department would reinforce the existing distribution patterns and stifle innovation in the air transportation distribution marketplace. These carriers argue that since existing business arrangements provide significant benefits to most ticket agents, including GDSs, those entities would strive to retain existing distribution technology and transaction patterns. The carriers have also expressed concern that if they are required to provide information to GDSs, the GDSs will use existing contractual agreements and market power to pressure carriers to provide the

[2] Low-cost carriers operate under a generally recognized low-cost business model, which may include a single passenger class of service, limited in-flight services, and use of smaller and less expensive airports.

[3] GDSs process 64 percent of the total U.S. airline gross sales by revenue. PhoCusWright, *The Role and Value of the Global Distribution Systems in Travel Distribution,* 2009.

information in the existing format for fare filing. If that occurs, some stakeholders allege that carriers would no longer have sufficient financial incentive to invest in new distribution technologies which might ultimately provide more useful and responsive information to consumers by allowing carriers to differentiate their services from competitors. GDSs have disputed the carriers' assertions and contend that Department action is needed because airlines and ticket agents have been unable come to agreements that would allow fee information about ancillary services to be disclosed to consumers at all points of sale.

We agree with the GDSs that there is a need for rulemaking because we believe that consumers continue to have difficulty finding ancillary fee information. The Department is striving to find the most beneficial disclosure rule for consumers while avoiding any adverse impact on innovations in the air transportation marketplace, contract negotiations between carriers and their distribution partners, and a carrier's ability to set its own fees and fares in response to its own commercial strategy and market forces. Also, despite the disputes regarding contract terms and distribution methods, both carriers and GDSs have assured the Department that they share our goal of transparency of ancillary service fee information.

Request for Public Input on Airline Fees

Given our continuing concern that consumers may not be getting sufficient information about carriers' fees, we solicit comment from consumers on the following questions:

- Do you have a problem finding fee information? And if so, how significant is that problem? If you have a problem finding fees, how does it affect your ability to comparison shop?
- What types of fees would you most like to have more information about during the shopping process, prior to purchase?
- When would you like to see that information displayed in your search process—as soon as you see a list of fares or later in the process? How would you like to see the information regarding ancillary fees displayed—as a link, as a specific dollar amount shown with the airfare quote, as a table or menu on the homepage or flight search results list? Should the Department require a standardized format for disclosure?
- Do you feel that our proposed disclosure requirements would improve your search experience? Have we selected the most ancillary fees that are most important to your decision making process? Will disclosure of all these fees at the point of search cause further confusion on ticket agent Web sites (as defined in this proposal), or diminish your user experience (because of screen clutter, diminished usability features, etc.)?
- Is either of our co-proposals outlined below likely to make fees easy to find?

Proposed Solutions and Alternatives Considered

Based on the information gathered, the Department is co-proposing two regulatory texts and seeking input regarding those two proposals. One proposal is to require each carrier to distribute certain ancillary service fee information to all ticket agents (including GDSs) that the carrier permits to distribute its fare, schedule, and availability information. Carriers would not be required to distribute ancillary fee information to any GDS or other ticket agent that the carrier did not permit to distribute its fare, schedule, and availability information. Additionally, under this proposal, the Department would not require carriers to allow ticket agents to sell/transact its ancillary services to consumers but rather would require carriers to provide ''usable, current and accurate'' information on fees for certain ancillary services to all ticket agents so this information can be disclosed to consumers at all points of sale. Each airline would continue to determine where and how its ancillary services may be purchased. For instance, if a carrier chooses to allow a ticket agent to sell its ancillary services directly to consumers, we expect that the carrier and ticket agent would determine through negotiation whether the ticket agent would offer the ancillary services at the same prices that the carrier offers those services. In other words, the proposal would require airlines to provide certain ancillary fee information to ticket agents, including GDSs, in order to enable disclosure to consumers of fees associated with certain ancillary services at all points of sale but would not require that these ancillary services be transactable. Carriers and ticket agents would negotiate regarding the ability of ticket agents to sell a carrier's ancillary services and the price at which those services would be sold.

The second proposal is similar to the first in all ways except one. Unlike the first proposal, the second would omit the requirement that the information on ancillary fees be distributed to GDSs or other intermediaries since GDSs and similar intermediaries would not be subject to any direct consumer notification requirements. Instead, the second alternative would require carriers to distribute certain ancillary service fee information to all ticket agents that the carrier permits to distribute its fare, schedule, and availability information *if* the ticket agent sells the carrier's tickets directly to consumers. Although this proposal would not require carriers to provide ancillary fee information to entities that act as intermediaries and do not deal directly with the public such as GDSs, GDSs are the source through which most travel agents obtain their fare information, so as a practical matter, they may be the most efficient vehicle currently available for carriers to use for dissemination of information on ancillary fees. Additionally, the second proposal would not require carriers to provide ancillary fee information to entities such as meta-search tools like Kayak and Google.

The Department has proposed these two options as it remains of the view that as carriers continue to unbundle services that used to be included in the price of air transportation, passengers need to be protected from hidden and deceptive fees and allowed to price shop for air transportation in an effective manner. The Department believes that failing to disclose basic ancillary service fees in an accurate and up-to-date manner before a consumer purchases air transportation would be an unfair and deceptive trade practice in violation of 49 U.S.C. 41712.

Under both proposals, the Department recognizes that not all ancillary service fee information needs to be available through all channels. However, there are certain basic services that are intrinsic to air transportation that carriers used to include in the cost of air transportation but that they now often break out from the airfare, and the cost of those services is a factor that weighs heavily into the decision-making process for many consumers. We consider these basic ancillary services to consist of the first and second checked bag, one carry-on item and advance seat selection. This rulemaking would require U.S. and foreign air carriers to distribute to ticket agents the fees for these basic ancillary services. However, carriers would not be required to provide ticket agents information about individual customers, such as their frequent flyer status or type of credit card though these factors may impact the fee for an ancillary service. Carriers would, of course, be required to provide ticket agents the fee rules for particular passenger types (e.g., military, frequent flyers, or credit card holders). Under the proposal, the failure of airlines to share this fee information

in an up-to-date and accurate fashion would be considered an unfair and deceptive trade practice in violation of 49 U.S.C. 41712.

As the requirement for carriers to distribute this information to agents would not be helpful to consumers without a disclosure requirement, the Department is also proposing to require all carriers and agents to disclose the fees for these basic ancillary services before the passenger purchases the air transportation. Airlines and agents that have Web sites marketed towards U.S. consumers must disclose, or at a minimum display by a link or rollover, the fees for these basic ancillary services on the first page on which a fare is displayed in response to a specific flight itinerary search request in a schedule/fare database. To comply with this proposed requirement, airlines and agents would have to modify their Web sites to display these basic ancillary service fees adjacent to the fare information on the first page on which a fare for the requested itinerary is displayed. We solicit comment on whether the Department should require the ancillary service fee information to be disclosed only upon the consumer's request, or require that the information be provided in the first screen that displays the results of a search performed by a consumer. The Department also seeks comments on whether it should limit the applicability of the disclosure requirement only to agent and carrier Web site displays marketed to members of the general public, or whether the disclosure requirement should include agent and carrier Web site displays that are not publicly available (e.g., displays used by corporate travel agents).

Under both co-proposals, the fee information disclosed to consumers for a carry-on bag, the first and second checked bag, and advance seat assignment would need to be expressed as specific charges. Airlines would be required to disclose customer-specific fees for these services to the extent the customer provides identifying information, and if the customer does not provide that information, must disclose itinerary-specific fees. Ticket agents would be required to disclose itinerary-specific fees for these services. Ticket agents may also arrange/negotiate with the airlines to obtain data that would enable them to give customer-specific fees for basic ancillary services. ''Customer-specific'' refers to variations in fees that depend on, for example, the passenger type (e.g., military), frequent flyer status, method of payment, geography, travel dates, cabin (e.g., first class, economy), ticketed fare (e.g., full fare ticket—Y class), and, in the case of advance seat assignment, the particular seat on the aircraft if different seats on that flight entail different charges. In other words, the response to a specific flight itinerary search request by a consumer on a carrier's Web site would need to display next to the fare the actual fee to that consumer for his or her carry-on bag, first and second checked bags, and advance seat assignment. Nothing in this proposal would require carriers to compel consumers to provide the passenger-specific details before searching for airfare. Providing such details before conducting a search should be an option and not a requirement for consumers. We note that many carriers already offer seat maps during the online booking process on their Web site that permit consumers to obtain a seat assignment at that time and that disclose the charge for each seat. This process would comply with the proposed rule as long as there is a statement adjacent to the fare on the first screen where an itinerary-specific fare is displayed that informs the consumer that there are fees for advance seat assignments and direct links to the seat map.

The fee information that ticket agents would be required to display to consumers differs from what would be required of airlines in that ticket agents would not be required to include variations in fees that depend on the attributes of the passengers such as the passenger type (e.g., military), frequent flyer status, or method of payment. Ticket agents would be required to take into account variations in fees that are related to the itinerary such as travel dates, geography, ticketed fare and cabin. In addition to providing itinerary-specific fees for a first checked bag, a second checked bag, a carry-on bag and an advance seat assignment, ticket agents would also be required to clearly and prominently disclose that these fees may be reduced or waived based on the passenger's frequent flyer status, method of payment or other characteristic. Ticket agents who have not negotiated an agreement with the airlines to sell advance seat assignments would also be required to disclose that seat availability and fees may change at any time until purchase of the seat assignment. In addition, it is worth noting that carriers and agents would be permitted to offer an ''opt out'' option for consumers who prefer to search for fare information only, without any ancillary fee information, and when this option is selected carriers and agents would not be required to present the fee information.

We ask for comment on whether the Department should only require carriers and agents to provide information on standard baggage fees without taking into account variations based on frequent flyer discounts, loyalty card discounts, geography, ticketed fare, etc. If all of the varieties of baggage fees are displayed, how should the varying fees be arranged? Regarding advance seat assignments, the charges for which also may vary considerably based on, among other things, the location of the seat and how far in advance the seat assignment is purchased, should carriers and agents be required to display all possible advance seat assignment fees, or a range, or the fee for each seat assignment available at the time of the search for a particular city-pair? What is the technological feasibility and cost of providing this information to consumers in a usable fashion, particularly for ticket agents?

As discussed earlier, neither of the Department's two alternative proposals would require that carriers enable agents to sell the carrier's ancillary services; in industry idiom, we are not proposing to require that the fees be ''transactable.'' The Department is addressing the harm caused to consumers of not knowing the true cost of travel before purchasing air transportation. Under the proposed disclosure regime, every point of sale for a particular carrier's fares would also provide access to the carrier's fee information for first and second checked bag, one carry-on bag, and an advance seat assignment. This requirement would place a legal obligation on carriers to disseminate this information to all of their agents; however, the Department is not stating the method the carriers must use to distribute the information, as long as it is in a form that would allow the fee information to be displayed on the first itinerary-specific results page in a schedule/fare database. Carriers would be free to develop cost-effective methods for distributing this information to their agents. Carriers could use existing channels, such as filing the fee information through the ATPCO, or they could develop their own systems to disseminate the information, in conjunction with the agents who would receive the information.

Although neither of the Department's alternative proposals dictate the method that carriers must use to distribute the information, carriers should be mindful that whatever distribution method they might choose must be usable, accurate, and current so the information is accessible in real-time. Similarly, ticket agents must work in good faith with

carriers to come to agreement on the method used to transmit the ancillary service fee information. For example, ticket agents should not use contractual restrictions to prohibit travel agents, carriers, or applications software providers from integrating the ancillary fee information with information obtained from the GDSs. Since the Department's proposal would require ticket agents to provide the ancillary fee information to consumers, in cases where carriers and ticket agents are able to agree on a transmission mode for ancillary fee information other than through a GDS, we would expect GDSs to work in good faith with carriers and other ticket agents to permit the integration of information obtained from other sources with information obtained through the GDS and allow the distribution of fee information directly to the agents. Additionally, under the proposed disclosure requirement, to the extent that carriers have existing contractual relationships with ticket agents acting as intermediaries, such as GDSs, to distribute fare information, those ticket agents would be prohibited from imposing charges for the distribution of ancillary service fee information that are separate from or in addition to the existing charges for the distribution of fare information as it would be unlawful to provide fare information that does not include the fees for the basic ancillary services. The Department invites comments regarding the two proposals: (1) Requiring a carrier to disseminate certain ancillary service fee information to the agents that distribute the carrier's fare, schedule, and availability information and requiring both carriers and agents to disclose accurate and up-to-date fee information to consumers, or (2) requiring a carrier to disseminate certain ancillary service fee information to the agents that distribute the carrier's fare, schedule, and availability information and are a point of sale for the carrier's tickets to consumers, and requiring both carriers and agents to disclose accurate and up-to-date fee information to consumers. What are the costs and benefits of requiring carriers to provide ancillary fee information to all ticket agents, including entities that have not previously considered themselves to be regulated but would fall under the proposed definition of ''ticket agent,'' described above, and what are the costs and benefits of requiring carriers to provide ancillary fee information only to ticket agents that act as sales outlets? If DOT requires disclosure of certain ancillary service fees, but does not require the ability to purchase these services at the time of booking, what would be the preferred way for carriers to collect payment for such services? On the Internet through the airline Web sites prior to check-in, at the airport at the time of check-in, etc.?

Proponents of the first alternative have argued that, because most carriers already rely on GDSs to transmit information to ticket agents that act as a point of sale, the Department could ensure that the information was disseminated in a quick and efficient manner by requiring carriers to provide the information to GDSs. They also assert that such a proposal would resolve the ''market failure'' that has prevented carriers and ticket agents from coming to agreements that would allow the information to be provided to consumers. Advocates of the second alternative state that permitting carriers to decide which intermediaries, if any, to use to provide ancillary fee information to ticket agents acting as sales outlets still provides for consumer disclosure but minimizes government interference with business arrangements. Additionally, they contend that the second proposal provides opportunities for the development of new and innovative technologies and methods of distribution of air transportation while allowing carriers the freedom to use traditional methods if it makes commercial sense for them to do so.

In addition to the two alternative proposals under consideration, we also solicit comment on whether any of the alternatives rejected earlier in the rulemaking process better address the problem of lack of transparency of fees associated with ancillary services. For example, should the Department set design standards (e.g., filing of fees for ancillary services through ATPCO, EDIFACT, XML or some other technology) rather than using performance standards for transmission of ancillary fee data from airlines to ticket agents or from airlines and ticket agents to consumers? Under both alternative proposals, the Department does not prescribe particular standards in order to avoid stifling innovation and imposing more of a burden on industry participants than is necessary to solve the transparency problem. However, we are interested in comments on whether setting a specific technological/information standard could potentially enhance innovation and improve transparency, and if so, how. Would selecting a specific standard allow for new market entrants in the transmission or display of air travel information, by making fare and fee information more open and accessible?

The Department also solicits comment on the issue of whether the basic ancillary services that are disclosed to consumers should also be transactable. Although the Department has tentatively determined that it would be sufficient to require carriers and agents to disclose certain basic ancillary fee information to consumers, it has not closed the door on the possibility of also requiring that those ancillary services be available for purchase through all channels that carriers decide should sell their fares. In other words, should we require these ancillary services to also be ''transactable''?

Representatives of certain consumer advocacy groups and trade associations have argued to the Department that if consumers are not entitled to purchase the ancillary services at the time of booking air transportation, the carrier may increase the price of those ancillary services before the consumer has a chance to purchase the ancillary service on the carrier's Web site or through its reservation center. In the case of advance seat assignments, the problem is particularly acute because in addition to price increases, the consumer risks the possibility that the advance seat assignment that he or she wished to purchase will no longer be available.

Carriers are prohibited from increasing the price of baggage fees after a consumer purchases air transportation under the current 14 CFR 399.88, but under the *Guidance on Price Increases of Ancillary Services and Products not Purchased with the Ticket* issued by the Enforcement Office on December 28, 2011, and under the proposed change to section 399.88 discussed below, carriers would not be prohibited from increasing the price of an advance seat assignment until the seat assignment itself is purchased. Prices for advance seat assignment are often dynamic and change based on route, aircraft size, availability, and time of purchase. Proponents of transactability argue that without the ability to purchase the seats at the time of ticket purchase, consumers will be further harmed because desired seats may not be available when the passenger decides to purchase them or is allowed by the carrier to purchase them or they may cost more. The Department seeks comment on requiring disclosure plus transactability of advance seat assignment fees at all points of sale. We also seek information on the costs and benefits of requiring transactability and how requiring transactability would affect existing contracts between the GDSs and the airlines. We also invite interested persons to provide their views on whether disclosure plus

transactability should be required not only for advance seat assignments but also for fees associated with first and second checked bags and carry-on bags. As noted above, of the ancillary services traditionally included in the price of a ticket, the Department views the first and second checked bag, one carry-on bag, and an advance seat assignment as the services that are intrinsic to air transportation and of primary importance to many consumers when making air transportation purchasing decisions. The Department invites comments on whether the list should be expanded to include services such as in-flight wireless Internet access, seating section upgrades, food and beverages, or priority boarding. If the list should be expanded, how should carriers and agents display the information related to these additional services?

The Department also solicits comment on leaving the disclosure requirements established in 14 CFR 399.85 unchanged instead of adopting new proposed requirements for customer-specific information about one carry-on bag, the first and second checked bag, and an advance seat assignment. Under the existing regulation, consumers may visit individual carrier Web sites to ascertain all of the fees associated with ancillary services. This information is in a centralized location accessible from a link on each carrier's homepage. Leaving the existing requirements in place would not require carriers to enable agents to provide up-to-date and real-time pricing for ancillary services, but it would still require that passengers be made aware that ''baggage fees may apply'' on the first page on which a fare quote is given for a flight search. The Department asks consumers to comment on the existing requirements, particularly whether the disclosure requirements under section 399.85 have aided in their ability to price shop and their ability to understand the true cost of travel before purchasing. The Department also asks carriers and ticket agents to comment regarding whether they believe the current disclosure requirements are sufficient and effective and why or why not. The Department also asks agents to comment on how the current disclosure requirements are affecting their businesses and whether consumers are aided under the disclosure requirements. If the Department decides to maintain the current disclosure requirements, should the Department require carriers to list the fees for advance seat assignments in a more specific manner, rather than a range, on the page listing ancillary fees and on e-ticket confirmations? Comments on the cost and benefits of the proposal and all of the alternatives are invited. Further, we encourage interested parties to provide comment regarding any innovative alternatives/solutions that Department may not have considered but that would address the lack of disclosure of ancillary service fees in all sales channels.

3. Expanding the Definition of ''Reporting Carrier'' Under 14 CFR Part 234

In 14 CFR Part 234, the Department sets forth requirements for ''reporting carriers'' to file certain performance data with the Department and provide flight on-time performance information to the public. ''Reporting carrier'' is defined in 14 CFR 234.2 as an air carrier certificated under 49 U.S.C. 41102 that accounts for at least one percent of domestic scheduled-passenger revenues. In addition to reporting carriers, any carrier that does not reach the reporting carrier threshold may voluntarily file Part 234 reports, provided that the Department's Bureau of Transportation Statistics (BTS) is advised beforehand and such data will be submitted voluntarily for 12 consecutive months.

Pursuant to Part 234, reporting carriers are required to submit to BTS' Office of Airline Information their domestic scheduled passenger on-time performance data and mishandled baggage information, and provide on-time performance codes to computer reservation systems (CRS). These carriers also must disclose to consumers the on-time performance code, on a flight-by-flight basis, for all domestic scheduled flights that they market to the public, including the flights operated by code-share partners. The on-time performance codes must be disclosed to consumers during in-person or telephone communication (including but not limited to reservations or ticketing transactions) upon reasonable inquiry. For flight schedule Web site displays, the on-time performance information must be provided either on the initial listing of the flights or via a prominent hyperlink. Furthermore, to implement a statutory requirement of the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (Pub. L. 106–81), the Department amended Part 234 in 2005 to require all U.S. air carriers (not only ''reporting carriers'') to file a report with the Department's Aviation Consumer Protection Division on any incident involving the loss, injury, or death of an animal during air transportation.[4] Additionally, under 14 CFR Part 250, reporting carriers are also required to submit to the Department information on passengers denied boarding on their domestic and outbound international scheduled flights.

Since their implementation, Parts 234 and 250 have been effective tools for the Department to collect on-time performance, mishandled baggage, and oversales data and use these data to monitor the quality of service provided by each reporting carrier to the flying public and to provide such information to consumers. On October 22, 2013, BTS issued a Technical Reporting Directive (Technical Directive #23) to update the list of reporting air carriers that are required to file ''Airline Service Quality Performance Reports'' under 14 CFR Part 234 for calendar year 2014. Technical Directive #23 identified the following 14 air carriers that reached the reporting threshold of one percent of domestic scheduled-passenger revenue in the 12-month period ending June 30, 2013: AirTran Airways, Alaska Airlines, American Airlines, American Eagle Airlines, Delta Air Lines, ExpressJet Airlines, Frontier Airlines, Hawaiian Airlines, JetBlue Airways, SkyWest Airlines, Southwest Airlines, United Airlines, US Airways, and Virgin America.

The one percent domestic scheduled-passenger revenue threshold for reporting carriers was set in a final rule that initiated the reporting requirements contained in Part 234. 52 FR 34056 (September 9, 1987). In that final rule, the Department considered some comments asserting that flight delays affect passengers without regard to the size of the carrier or the length of the flight. The Department concluded, however, that compliance with the rule was likely to be much more costly for small carriers than for large carriers, particularly due to the fact that, at the time when the rule was finalized, large carriers were more likely than small carriers to maintain their flight performance data in a computerized form. Therefore, the Department made the determination that as an initial matter, it would limit the application of

[4] On June 29, 2012, the Department issued a Notice of Proposed Rulemaking (RIN 2105–AE07, Docket No. DOT–OST–2010–0211), seeking comments on whether the Department should expand the reporting carrier pool for reporting animal death, loss and injury incidents to cover all U.S. carriers operating domestic and international scheduled passenger air transportation using at least one aircraft with a design capacity of more than 60 seats. See 77 FR 38747 (June 29, 2012). Because our determination on the scope of reporting carrier with respect to animal death, loss or injury incidents will be addressed separately in the final rule of that rulemaking, interested parties should provide comments regarding animal reporting to the Department through the docket designated for RIN 2105–AE07.

this rule to large air carriers. Nonetheless, the Department noted that it would continue to review the carriers covered and would extend the reporting requirements to smaller carriers if it became necessary.

Twenty-five years have passed since the issuance of that final rule. Technology innovations that have fundamentally reshaped our world in many ways have also profoundly changed almost every aspect of the commercial aviation industry's operations. In 1987, for a small carrier to file data with the Department, it had to commit to either a significant capital investment in a comprehensive computer data tracking system or to a significant human resource investment so it could compile and file reports manually. Conversely, in this day and age, virtually all air carriers are using computerized recordkeeping methods to store and distribute data to file reports with the Department or are conducting internal performance evaluations, or both, which makes reporting data a much easier and less costly task.

Moreover, we believe that requiring smaller carriers to report service quality data to the Department will greatly benefit the public in several ways. First, adding these smaller carriers' performance data to the data currently collected by BTS will enable the Department to obtain and provide to the flying public a more complete picture of the performance of scheduled passenger service in general. These data will, in turn, provide consumers with more meaningful information on which to base their purchasing decisions. For example, based on BTS-provided domestic scheduled passenger revenue and enplanement data for 2010, the carriers that reach the one percent threshold represent approximately 90 percent of total domestic scheduled passenger revenue, and 80 percent of total domestic scheduled passenger enplanements. If we were to lower the threshold to 0.5 percent of domestic scheduled passenger revenue, the reporting carrier pool would capture approximately 98 percent of domestic scheduled passenger revenue and 94 percent of the domestic scheduled passenger enplanements.

Further, the public benefits of including smaller carriers in the reporting pool were also recognized and supported by a September 2011 Report to Congressional Requesters prepared by the Government Accountability Office (GAO). In the report titled *Airline Passenger Protections, More Data and Analysis Needed to Understand Effects of Flight Delays,* GAO recommended that in order to enhance aviation consumers' decision-making, the Department should collect and publicize more comprehensive on-time performance data to include information on most flights, to airports of all sizes. GAO specifically recommended that one way this goal could be accomplished was by requiring airlines with a smaller percentage of total domestic scheduled passenger service revenue, such as airlines that operate flights for other airlines, to report flight performance information. Furthermore, expanding the reporting carrier pool would enhance the Department's ability to analyze the cause of flight disruptions such as delays and cancellations, particularly with respect to airports in smaller communities and smaller airlines. For example, according to GAO's analysis of the performance record of two legacy airlines [5] and their regional partners, the regional partners generally have worse on-time performance records. GAO further notes that while flight cancellations to smaller communities may inconvenience a relatively small number of passengers, they may result in long trip delays if those smaller communities have infrequent service. What's more, requiring smaller carriers to file on-time performance, mishandled baggage, and oversales data with the Department will increase the level of public scrutiny of these carriers' performance, which in turn will function as an incentive for these carriers to continuously improve the quality of their service. The enhanced service quality will increase these carriers' competitiveness and benefit the regional markets that they primarily serve.

For these reasons, we are proposing in this NPRM to amend the definition of ''reporting carrier'' under Part 234 to include carriers that account for at least 0.5 percent of annual domestic scheduled-passenger revenue. Additionally, since for years BTS has been using June 30, instead of March 31, as the cutoff date to compile a carrier's annual domestic scheduled-passenger revenue percentage, we propose to codify this change in the definition of ''reporting carrier.'' We seek public comments on whether 0.5 percent is a reasonable threshold to achieve our goal of maximizing the scope of data collection from the industry while balancing that benefit against the burden of increasing reporting requirements on carriers, particularly small businesses. If 0.5 is not the most reasonable threshold, we seek comment on an even larger expansion, e.g., to 0.25 percent of domestic scheduled passenger revenue, or a smaller expansion to 0.75 percent of domestic scheduled passenger revenue. Additionally, we seek comment on whether we should require that all carriers that provide domestic scheduled passenger service report to the Department. We especially welcome comments that provide specific cost estimates or analysis by small carriers that would potentially be impacted by this proposal. We also request comments regarding whether a carrier's share of domestic scheduled passenger revenue remains an appropriate benchmark. Should we use a carrier's share of domestic scheduled passenger enplanements instead? If so, what percentage is a reasonable threshold for triggering the reporting obligation?

Finally, in relation to the burden associated with implementing a reporting mechanism within a carrier's operation system, what is the approximate time period that a newly reporting carrier will likely need to prepare for the new reporting duties? Although not proposed in the rule text, we are contemplating that should this proposal be finalized, we would permit carriers that otherwise would not have been reporting carriers but become a reporting carrier under a new threshold to file their first Part 234 report by February 15 for the first January that is at least six months after the effective date of this rule. We believe this would provide carriers adequate time to implement necessary procedures for filing the reports and amending their Web sites to comply with the flight on-time performance disclosure requirements contained in section 234.11, to the extent that the Web sites directly market flights to consumers. Having the initial reports start in January would provide the added benefit of preserving the consistency of the Department's data for a full calendar year during the transition. We seek comments on whether this rationale for determining the compliance date for the reporting requirement would be helpful to newly reporting carriers.

In addition to expanding the pool of reporting carriers, we are also contemplating expanding the scope of ''reportable flights'' in relation to airports. The current rule only requires reports for flights operated to and from U.S. airports that count for at least 1% of domestic enplanements (large hub airports). However, since the inception of the rule, the reporting carriers have chosen to file reports for scheduled passenger flights to all U.S. airports

[5] A ''legacy'' airline is a carrier that was operating when the industry was deregulated. They are typically large airlines with a hub-and-spoke route system.

where they operate. In this NPRM, we seek comments on whether we should eliminate the concept of reportable flights and simply mandate reports for all scheduled flights operated by reporting carriers to and from all U.S. airports. Without this amendment, the expansion of ''reporting carrier'' to include smaller carriers could be rendered less meaningful because a large percentage of flights operated by these smaller carriers are not to or from large hub airports. In addition to comments on whether and how such expansion of scope of reportable flights may benefit different stakeholders, we also welcome information on cost comparisons for carriers to report only flights to and from (1) large hub airports, (2) large, medium, small, and non-hub U.S. airports, and (3) all airports.

4. Carriers To Report Data for Certain Flights Operated by Their Code-Share Partners

The Department of Transportation provides information each month on the quality of services provided by the airlines through its Air Travel Consumer Report (ATCR). This Report is divided into six sections: Flight delays, mishandled baggage, oversales, consumer complaints, customer service reports to the Transportation Security Administration, and airline reports of the loss, injury, or death of animals during air transportation. The sections that deal with flight delays, mishandled baggage, and oversales are based on data collected by BTS pursuant to 14 CFR Part 234 and Part 250. The section that deals with animal incidents during air transport is based on reports required by section 234.13 and collected by the Aviation Consumer Protection Division.

With respect to flight delay information, in addition to the monthly overview of each reporting carrier, the ATCR also ranks each reporting carrier's performance at all large hub U.S. airports from which it operates. These performance tables, particularly the rankings, are widely accepted as important indicators of the carriers' quality of service, and are frequently referred to in news reports, industry analyses, and consumer commentaries and forums. Moreover, it is not uncommon that these rankings are used as the key references in institutional studies, the results of which are often cited in news reports with attention-grabbing headlines such as ''The Best and Worst Airlines of the U.S.'' Although headlines like this tend to over-simplify the complexity of airline operations, being named as one of ''the best'' or ''the worst'' airlines in the country in a national news outlet does have a significant impact on a carrier's image and brand identity and either affords the carrier a great marketing tool or causes some consumers to avoid selecting that carrier's flights when making purchase decisions which acts as an incentive for the carrier to improve its performance.

Because of the influence of the ATCR on consumer perception of carriers as well as its effect on the perception of carriers within the industry, it is vitally important that the information provided by these reports remains accurate. Since the Department began to issue the ATCR, the Aviation Consumer Protection Division and BTS have been working closely to ensure that the published reports accurately reflect the data received by the Department. However, this continuing effort does not address the growing problem of an inadequate scope of data collection, the most significant area being that a marketing carrier's data do not include its flights operated by code-share partners.

The data that carriers file under Part 234 and Part 250 are the primary source from which each monthly ATCR is developed. A ''reportable flight'' under Part 234 refers to any domestic scheduled nonstop flight reported to the Department by a reporting carrier pursuant to 14 CFR Part 241, Uniform System of Accounts and Reports for Large Certificated Air Carriers. Part 241 in turn defines a ''reporting carrier'' for the purpose of Form T–100 (U.S. air carrier traffic and capacity data by nonstop segment and on-flight market) as ''the carrier in operational control of the flight, *i.e.,* the carrier that uses its flight crew under its own FAA operating authority.'' Therefore, the on-time performance and mishandled baggage data collected under Part 234 from each reporting carrier are limited to the data for a reporting carrier's domestic scheduled passenger nonstop flight segments operated by that reporting carrier. Part 250 also limits the oversales reporting requirement to reporting carriers, although it is not limited to domestic flights (see 14 CFR 250.10).

If the reporting carrier engages in code-sharing arrangements in which the reporting carrier is the marketing carrier but not the operating carrier, the performance data for those flights are not included in the reporting carrier's Part 234 and Part 250 reports. If the operating carrier of a code-share flight is a reporting carrier itself, the performance data for its code-share flights that are also marketed by another carrier will be reported to the Department, but data for those flights will not be attributed to the marketing carrier. What's more, some operating carriers of code-share flights marketed by larger carriers do not meet the current reporting threshold of Part 234, and a certain number of operating carriers of code-share flights marketed by larger carriers would not meet the proposed lower reporting threshold of 0.5 percent of annual domestic scheduled passenger revenue. Therefore, the on-time performance, mishandled baggage, and oversales data for those flights are not currently reported to the Department at all and, even under a revised reporting threshold, not all of those operating carriers of code-share flights marketed by larger carriers would necessarily be required to report performance data.

The Department considers the current scope of reportable flights under Part 234 inadequate to truly capture many carriers' quality of service, so as to be accurately reflected in the ATCR. The limited scope of the current reporting requirements may result in consumer confusion or misperception. We note that the majority of legacy/mainline U.S. carriers continue to seek brand consolidation, while still maintaining the ''hub and spoke'' operation structure. For economic reasons, those legacy carriers' regional short-haul flights are operated, in many markets, by code-share partners on a fee-for-flight basis and these operating carriers do not engage in the sale of tickets at all. According to the data contained in the FAA's Aerospace Forecast for fiscal years 2012–2032, mainline carriers provided 16 percent less domestic passenger capacity in 2011 than they did in 2001. Over the same ten-year period, however, regional carriers' capacity overall has increased to 153 percent of the 2001 level. Further, a recent Official Airline Guide (OAG) survey provides a snapshot of the current operations of mainline carriers and their regional partners and indicates the comparative scope of code-share operations. It shows that in 2011, each of the top five legacy carriers had more than 45% of its domestic scheduled flights operated by code-share regional partners, with the carrier on the top of the survey list having almost 70% of its domestic scheduled flights operated by code-share regional partners. The service quality data for these code-shared flights are not reported by the legacy carriers and are not attributed to these carriers' records and rankings in the ATCR. However, those flights are marketed by the legacy carriers with their own airline designator codes and usually their own brands, sometimes bearing trademarks such as

''Connection'' or ''Express'' in addition to the mainline carriers' trade names. In many instances, the mainline carriers also handle virtually all aspects of ground operations including scheduling and customer service related issues, such as dealing with oversales situations, providing denied boarding compensation, and resolving baggage claims. Consumers may consider these code-share flights operated by code-share regional partners to be air transportation service provided by the mainline carrier just as much as the flights actually operated by the mainline carriers.

The Department is also concerned that the inadequacy of the scope of service quality reports may hinder competition. The Department is mindful that on-time performance data in the ATCR may have a limited influence on a consumer's purchase decision regarding a particular flight, because the consumer is more likely to refer to that specific flight's on-time performance record, which under 14 CFR 234.11 must be provided on a marketing carrier's Web site, regardless of whether it is operated by a code-share partner. Nonetheless, a carrier's ATCR ranking speaks of the carrier's performance quality from a macro perspective, and is often used by carriers as a powerful marketing tool in developing brand loyalty, recruiting talented employees, and negotiating with suppliers and airports, as well as promoting its service in a newly developed or targeted geographic market. Most importantly, the ATCR numbers and rankings are benchmarks carriers use to assess their performance among competitors and to seek effective ways to improve. As stated above, recent numbers show that virtually all legacy carriers have at least 45% of their domestic scheduled passenger flight segments operated by code-share partners, which means data for those flights are not reported by the marketing carriers under Part 234 and Part 250 or attributed to the carrier in the ATCR. By contrast, most relatively new carriers that are ranked in the ATCR operate a ''point-to-point'' network and follow a different business model, the so-called ''low cost'' model. Under this business model, carriers engage in very few, if any, code-share arrangements. As a result, the ATCR is comparing the service quality of all flights marketed by a low-cost carrier with the service quality of 55% or less of the flights marketed under legacy carriers' brands and codes. We will not seek to determine how including code-share flight records in the ATCR would affect legacy carriers' rankings, but we are of the tentative opinion that requiring all reporting carriers to report data for all flights marketed under that carrier's name and code would put carriers on an equal footing in this important competitive arena.

Additional support for our proposal comes from the aforementioned final report by FAAC, which noted that the Competitiveness and Viability Subcommittee recommended that the Department should continue to require marketing carriers to provide clear and transparent notification of operations conducted by an air carrier other than the marketing carrier. Further, some subcommittee members also believed that more detailed disclosure regarding regional carriers' operations should be included in the ATCR, and that the report should include metrics organized not only by operating air carrier, but by the marketing air carrier.

For the reasons stated above, we are proposing to expand the scope of ''reportable flight'' under Part 234, and consequently under Part 250. Pursuant to this proposal, a reporting carrier would continue to file Form 234 and Form 251 (the oversales report required by Part 250) with respect to nonstop scheduled flights operated by the reporting carrier. In addition, each reporting carrier would file a separate Form 234 and a separate Form 251 to include both flights that are operated by the reporting carrier itself and all nonstop scheduled flights that are operated by a code-share partner and sold under the reporting carrier's code. Reportable flights under Part 234 (on-time performance and baggage data) are limited to domestic nonstop flight segments. The Form 251 oversales report has always included data for outbound international flights from the United States, and that will continue to be the case for the proposed new report that would include service operated by code-share partners. However, this new report, like the original report, would be limited to service operated by ''a certificated carrier or commuter air carrier''—both of which are U.S. air carriers—and consequently the new report would not collect data on code-share flights operated for a reporting carrier by a foreign-carrier code-share partner. Our primary regulatory interest at this time is collecting and publishing data on code-share service operated by the regional-carrier partners of the larger U.S. airlines. We are not proposing at this time to collect oversales data for flights from the United States (the oversales rule doesn't apply to inbound international flights to the United States) that are operated by large foreign carriers that do not already report these data.

For this purpose it is irrelevant whether the actual operating carrier in the code-share arrangement is a reporting carrier itself and is required to file data for that flight under the reporting requirements applicable to the operating carrier. Under our proposed rule, the marketing carrier reporting data on flights operated by another carrier would not need to distinguish flights operated by different code-share partners. We are proposing to require the marketing carrier to provide aggregated consumer statistics for all flights operated under its code (i.e., flights it operates and flights operated by its code-share partners). This would be an additional reporting requirement (second set of reports) and is not intended to replace the existing requirement for a reporting carrier to provide separate data for flights it operates. We seek comment on whether the second sets of reports should only contain the performance records of all flights operated for the reporting carrier by its code-share partners but not the flights operated by the reporting carrier. Alternatively, rather than having all code-share partners' records in aggregation, we ask if we should require the marketing carrier to provide separate data on flights operated by each of its code-share partner's operations. What are the benefits of separating each code-share partner's records and what are the costs, if any, added to the reporting carriers? Finally, since many regional carriers operate flights under the code of more than one large carrier, we seek comment on whether ''double-counting,'' i.e., situations where a given flight carries the code of more than one large carrier, is an issue and if so, how to avoid it. Do regional carriers that have code-share agreements with more than one large carrier ever operate a given flight for more than one marketing carrier, or on the other hand, do these flights always operate in discrete city-pair markets? How should we deal with the situation of large U.S. carriers that code-share with each other?

Our proposal to expand the scope of reportable flights will necessitate amendments to the rule text of 14 CFR 234.6, Baggage Handling Statistics. On July 15, 2011, the Department issued an NPRM, Reporting Ancillary Airline Passenger Revenues (RIN 2105–AE31, Docket No. DOT–RITA–2011–0001) that proposes, among other things, to amend section 234.6 by changing the way it computes mishandled baggage rates, from mishandled baggage reports per unit of domestic enplanements to mishandled baggage per unit of checked

bags. The proposed amendments to section 234.6 also include a new and separate requirement for collecting statistics for mishandled wheelchairs and scooters used by passengers with disabilities. In this NPRM, our proposed amendments to section 234.6 are tentatively based on the proposed rule text in the ancillary revenues reporting NPRM. Our adoption of the rule text as proposed in RIN 2105–AE31 in this rulemaking is not indicative of whether we are going to adopt the text as proposed in the final rule for the ancillary revenue reporting proposal. Further, although that NPRM's comment period has ended, any comments regarding the proposed computation method for mishandled baggage and the proposed inclusion of mishandled wheelchairs and scooters in the reporting should be submitted to the ancillary revenue reporting rulemaking docket and will be considered to the extent practicable.

We note that if the operating carrier is already a reporting carrier, the data for the code-share flights that will be added to the marketing carrier's report will have to be prepared and submitted to the Department by the operating carrier to meet the existing reporting requirement. In these instances, we expect that the cost to the marketing carrier to obtain this data would be negligible. With respect to flights operated by a code-share partner that is not a reporting carrier, we believe the cost of obtaining data would be higher but not significant, as most carriers, large or small, already have internal systems in place that track the major elements of flight performance quality. There are also costs related to compiling data for the code-share flights and setting up the reporting infrastructure to file the compiled report with the Department. We seek comments from carriers and the public regarding the costs associated with adding data on flights operated by code-share partners to reports filed with the Department. We further note that 14 CFR 234.8 requires reporting carriers to calculate and assign an on-time performance code for each ''reportable flight.'' Currently section 234.8 only covers domestic scheduled flights operated by a reporting carrier, so our proposal to expand the scope of ''reportable flight'' under Part 234 will require that reporting carriers also calculate and assign an on-time performance code for each domestic scheduled flight operated by a code-share partner. However, since April 29, 2010, all current reporting carriers have been required by section 234.11 to disclose on their Web sites that provide schedule information detailed on-time performance records, on a monthly basis, for each domestic scheduled flight, including each domestic code-share flight. In this regard, we expect that these current reporting carriers are already adequately prepared to comply with requirement of section 234.8 with respect to code-share flights. Finally, we ask what the reasonable implementation period should be if this proposal becomes a final rule.

5. Minimum Customer Service Standards for Ticket Agents

In the Department's first Enhancing Airline Passenger Protections final rule, 74 FR 68983, the Department required U.S. carriers in 14 CFR 259.5 to adopt a customer service plan. In the second Enhancing Airline Passenger Protections final rule, 76 FR 23110, the Department extended this requirement to foreign carriers and required both U.S. and foreign carriers to adopt minimum standards for their customer service plans. Among other standards, the Department requires carriers to provide prompt ticket refunds where ticket refunds are due, in accordance with existing Department rules; hold a reservation at the quoted fare or permit the reservation to be cancelled without penalty for at least 24 hours after a customer books the ticket; disclose cancellation policies, seating configuration, and lavatory availability to consumers; notify travelers of changes in travel itineraries; and respond to consumer-related complaints in a timely manner. Section 259.5 only applies to U.S. and foreign carriers that provide scheduled passenger service using at least one aircraft with an original designed passenger capacity of 30 or more seats. In a *Frequently Asked Questions* guidance document issued by the Department's Enforcement Office, in response to questions regarding whether section 259.5 applies to ticket agents, the Enforcement Office clarified that these customer service provisions are not applicable to agents. Therefore, agents are not currently required to hold a reservation for 24 hours or respond to consumer complaints or notify passengers of changes to travel itineraries.

The Department is proposing to amend 14 CFR 399.80, which addresses unfair and deceptive practices by ticket agents, because the Department believes that all airline passengers should benefit from certain customer service plan protections. Not all of the customer service standards set forth in 14 CFR 259.5 should apply to agents, but the Department sees no reason not to extend the standards related to ticket purchases and information dissemination to ticket agents that sell air transportation. As such, the Department is proposing to require these ticket agents to adopt minimum customer service standards in select areas. The customer service standards would not apply to ticket agents that don't sell air transportation but rather arrange for air transportation and receive compensation in connection with air transportation sold by others. Additionally, as proposed, the standards would only apply to those ticket agents with annual revenue of $100 million or more that market to the general public in the United States. A majority of U.S. travelers who bought their airline tickets through an avenue other than a carrier used large ticket agents.

As carriers are already required to allow reservations to be held at the quoted fare without payment or cancelled without penalty for at least 24 hours after a reservation is made if the reservation is made one week or more prior to a flight's departure, the Department is proposing to extend this requirement to ticket agents that sell air transportation. The Department feels that such agents should be able to allow reservations to be held at the quoted fare, as carriers are already required to provide this option. Moreover, through this proposal, the benefits of reserving without payment or canceling without penalty will reach consumers who use an agent to book air transportation. Similar to carriers, this proposal would only require ticket agents that sell air transportation to hold the fare at the quoted price. The proposal would not require agents to hold for 24 hours the price for other related items such as fees associated with ancillary services or tour components (e.g., hotel stay) although agents are, of course, free to do so if they wish. We solicit comment on whether the Department should require specific disclosure by agents and airlines about what is and is not being held for 24 hours.

The Department also seeks comments on requiring both agents and carriers to inform consumers, when engaging in oral communications with them about changes to a reservation, of the consumer's right to cancel without penalty if applicable. The Department has received complaints alleging that airlines are not disclosing to consumers when they are eligible to change their reservation without penalty and charging consumers change fees when consumers are unaware that they can cancel without penalty and rebook. Should carriers and agents be required to disclose the 24-hold policy to a consumer who is making a change within 24 hours of booking? Should the

Department require that the policy be prominently disclosed during the booking process? Currently, many carriers only disclose the policy in their ''Customer Service Commitment'' but not during the booking process. Would it be beneficial for consumers to have this information during booking?

Additionally the Department is proposing to require agents to provide prompt refunds where ticket refunds are due. This requirement would mirror 14 CFR 259.5(b)(5), which requires carriers to submit a refund for a credit card purchase within 7 days of the complete refund request, and in the case of cash or check purchases, within 20 days of receiving a complete refund request. Oftentimes, if a consumer has to cancel a trip, and a refund is due, they find themselves going between the airline and the agent for the refund in cases where the passenger purchased the airline ticket through an agent. This requirement would prevent this type of hassle and back-and-forth for consumers and clarify the agent's responsibility in assisting consumers when ticket refunds are due.

The Department is also proposing that agents disclose cancellation policies, seating configuration, and lavatory availability upon request to a passenger before a consumer books a selected flight. Many consumers who choose to book through a ticket agent are unaware of restrictions or fees associated with canceling the ticket. Additionally, consumers are not always aware that they are booking a flight on a smaller aircraft or an aircraft that may not have a bulkhead seat or lavatory available. As carriers are required to provide this information to consumers on their Web sites and upon request from their telephone reservation staff, the Department feels agents should also provide the information. Under this proposal, agents would have to make this information available on their Web sites that are marketed to U.S. consumers, and upon request for reservations made over the telephone. The Department invites interested parties to comment on this proposal, specifically whether agents already have this information to share with consumers. If agents do not have information about carriers' cancellation policies, aircraft seating configurations and lavatory availability, should the Department impose a requirement for carriers to provide their agents this information or should agents be required to provide links so that consumers can obtain that information? The Department also invites comments regarding the methods for disclosing cancellation policies, seating configurations, and lavatory availability information to consumers. Should the Department require that this information be placed at a particular location on a carrier's Web site, e.g., next to every flight in a search-result list for a particular itinerary?

The Department is also proposing that agents adopt a customer service standard to notify consumers of changes in travel itineraries in a timely manner. A carrier is not required to notify a consumer about a change in his or her travel itinerary if the carrier does not have contact information for that individual, and an agent is not required to provide a client's contact information to an airline. Therefore, consumers who use agents that do not provide contact information to carriers may not receive direct or timely notice of changes to their itinerary. This requirement is intended to ensure that consumers are timely notified of such changes.

Finally, the Department is proposing that agents be required to substantively respond to consumer complaints. Agents would be required to acknowledge receipt of a consumer-related complaint within 30 days of receipt of the complaint. Where the complaint (in whole or in part) is about the agent's service, the agent must substantively respond to the complaint within 60 days. If all or part of the complaint is about services furnished (or to be furnished) by an airline or other travel supplier, the agent must forward the complaint to that supplier for response. If no part of the complaint is about the agent's service and the agent sends the complaint to the appropriate supplier(s), the agent's substantive reply can consist of the agent informing the passenger that his or her complaint has been forwarded to the appropriate party and providing contact information to the passenger for that entity. This proposal closes the gap that exists in 14 CFR 259.5(b)(11) and 259.7, which require carriers to respond to consumer complaints but do not provide for complaints related to a ticket agent's services.

Although the subjects that we are proposing that ticket agents that sell air transportation address in their customer service plans are identical to those that carriers are already required to include in their customer service plans with respect to ticket purchases and information dissemination, we request comment on whether any of these subjects would be inappropriate if applied to ticket agents. Why or why not? Some of these items may be under direct control of the air carrier, and not the ticket agent. In commenting on these customer service commitments, large ticket agents should address the extent to which they are responsible for each of these items. Moreover, we seek comment on whether the Department should require that ticket agents address any other subjects in their customer service plans. For example, should ticket agents be required to prominently disclose to individuals who will be issued more than one ticket for their trip that their bags may not be checked through, as airlines typically check a passenger's baggage between the origin and destination points that are issued on a single ticket? Should ticket agents also be required to disclose to such individuals that they may have to pay multiple and different bag fees if ticketed separately as the Department's requirement for one set of baggage allowances and fees throughout a passenger's itinerary only applies when there is a single ticket? If so, when should this disclosure occur—before or after a ticket is purchased? We also seek comment on the appropriate form for such a disclosure (e.g., orally, on the ticket agent's Web site, on e-ticket confirmation). The Department is proposing to apply these customer service standards only to large ticket agents (those with annual revenue of $100 million or more) that market to the general public in the United States. The Department invites comment on whether the applicability should be expanded to cover other ticket agents, e.g., smaller ticket agents, or ticket agents who do not sell to members of the general public.

The Department recognizes that requiring these minimum customer service standards for agents would place a cost burden on these agencies. However, the Department believes that the benefits to consumers of receiving timely information, permitting reservations to be held for 24 hours without risk, and having their complaints addressed outweigh the costs. These proposals put all airline passengers on an equal footing when it comes to customer service standards, regardless of how they purchased their tickets.

The Department invites comments on the costs and benefits of these proposed customer service standards. For consumers who use agents, have you had problems in the past determining the cancellation policies associated with your ticket or being informed of changes in travel itineraries? For carriers, do you see any cost in sharing the information with the agents that the agents would be required to provide to consumers? For agents, what are the costs and benefits that you see in the proposal? Are you already receiving the information that

you would have to disclose to consumers from carriers? Should agents also be required to review their adherence to the customer service plans each year and retain the records of the audits for two years following the date of any audit, just as carriers are required to do today? Should agents be required to post their customer service plans on their Web sites if the Web sites are marketed towards U.S. consumers? Are there unforeseen consequences of the proposal, and, if so, what are they?

6. Codifying 49 U.S.C. 41712(c) Regarding Web site Disclosure of Code-Share Service and Other Amendments to 14 CFR Part 257

Code-sharing is an arrangement whereby a flight is operated by a carrier other than the airline whose designator code is used in schedules and on tickets. The Department's current regulation on the disclosure of code-sharing and long term wet lease arrangements, 14 CFR 257.5, was initially issued in 1999. Based on the statutory prohibition against unfair and deceptive practices in the sale of air transportation, 49 U.S.C. 41712, the purpose of § 257.5 is to ensure that consumers are aware of the identity of the airline actually operating their flight in code-sharing and long-term wet lease arrangements in domestic and international air transportation. *See* 64 FR 12838 (March 15, 1999). The Department has long recognized the economic benefits of airline code-sharing and long term wet lease arrangements but has been aware that such arrangements may cause consumer confusion regarding the identity of the operating carrier of a flight. For simplicity, we refer to both code-sharing arrangements and long term wet lease arrangements (covered in Part 258) as ''code-share'' arrangements, as the disclosure requirements for both types of operations are essentially identical. Code-share disclosure is important because the identity of the operating carrier is a factor that affects many consumers' purchasing decisions. In that regard, we believe that strengthening the code-share disclosure requirements by codifying requirements in Part 257 is an effective way to prevent potential consumer confusion.

Pursuant to § 257.5, carriers and ticket agents are required to inform consumers, when engaging in oral communications with the public, of code-share service ''before booking transportation'' and to ''identify the transporting carrier by its corporate name and any other name under which that service is held out to the public'' (section 257.5(b)). Written notice of code-sharing arrangements is also required when a ticket purchase is made, regardless of whether an itinerary is issued (section 257.5(c)). In ''printed'' advertisements, including those appearing on a Web site, the code-sharing relationship must be ''prominently'' disclosed and an abbreviated notice must be included in any radio or television advertisement (section 257.5(d)). With respect to all schedule information that is publicly available in writing, including on Web site displays, section 257.5(a) requires that any code-share service be indicated with ''an asterisk or other easily identifiable mark and that the corporate name of the transporting carrier and any other name under which that service is held out to the public'' also be disclosed. As a matter of enforcement policy, since the issuance of section 257.5, we have permitted entities providing schedules on Web sites to provide disclosure of an operating carrier's corporate name and other pertinent names through rollover or hyperlinked displays.

In February 2009, a flight operated by a regional air carrier under a mainline air carrier's code crashed during landing. In the aftermath of that fatal incident, family members of some victims questioned the adequacy of disclosure regarding the code-sharing nature of that operation. In response to these concerns and in recognition of the necessity of further strengthening the disclosure requirements of code-sharing arrangements, Congress amended 49 U.S.C. 41712 in August 2010 to add a subsection (c) that requires that in any oral, written, or electronic communications with the public, U.S. and foreign air carriers and ticket agents disclose the name of the carrier providing the air transportation for each flight segment prior to the ticket purchase. In addition, subsection (c) provides that if an offer to sell tickets is provided on a Web site, such information must be disclosed ''on the first display of the Web site following a search of a requested itinerary in a format that is easily visible to a viewer.'' *Airline Safety and Federal Aviation Administration Extension Act of 2010,* Public Law 111–216, Title II, section 210, 124 Stat. 2362 (August 1, 2010). In light of Congress' specific requirement regarding Web site ticket offer disclosure, on January 14, 2011, the Department's Enforcement Office issued *Guidance on Disclosure of Code-Share Service Under Recent Amendments to 49 U.S.C. 41712,* in which the Enforcement Office revised its enforcement policy and explained that under the statute any disclosure of code-share service in the context of Web site displays by carriers and ticket agents must be on the same screen as the itinerary and immediately adjacent to that itinerary and to each alternative itinerary, if any. The guidance provided notice that carriers or ticket agents whose Web sites failed to provide full disclosure of code-share service arrangements or that provided disclosure only through rollovers or hyperlinks would potentially be subject to enforcement action.

In this NPRM, we are proposing to amend 14 CFR 257.5 to codify the requirements of 49 U.S.C. 41712(c) and the Department's current enforcement policy with respect to Web site disclosure of code-share and long term wet lease arrangements. In addition, we are proposing to update certain other disclosure requirements of 14 CFR 257.5 in order to reflect the technology changes in the airline industry's reservation and ticketing systems that have resulted in the predominance of electronic ticketing and the significant use of online transactions. As noted in the background section of this NPRM, these proposals are also intended to implement the Future of Aviation Advisory Committee and the Advisory Committee on Aviation Consumer Protection recommendation that the Secretary should ensure transparency regarding flight operators, such as disclosure of the identity of the operator on regional-carrier code-share flights. See *FAAC Final Report,* April 11, 2011. It is important to emphasize that we believe the changes proposed in this NPRM to the text of section 257.5 are primarily non-substantive and would not affect what carriers and ticket agents are already obligated to do under the combination of the current section 257.5, the amended 49 U.S.C. 41712, and the Department's guidance document.

(a) Disclosure in Flight Itinerary and Schedule Displays

14 CFR 257.5 contains subsections (a) through (d), which deal with disclosure in schedule displays, oral notice to prospective consumers, written notice to ticket purchasers, and disclosure in advertisements, respectively. Most code-share disclosure requirements under 14 CFR 257.5 cover both carriers and ticket agents, but section 257.5(a), notice in schedules, only covers U.S. air carriers and foreign air carriers. On the other hand, 49 U.S.C. 41712(c) (enacted in 2010), as well as the January 10, 2011, notice issued by the Department's Enforcement Office, are explicit that the same heightened requirements regarding

code-share disclosure, including Web site schedule display disclosure, apply to both carriers and ticket agents. As a result of this inconsistency, under the current rule, ticket agents that fail to adequately disclose code-share arrangements in schedule displays would violate section 41712 but not section 257.5(a).

The inclusion of ticket agents in section 41712(c) reflects the fact that, through the growth and development of the Internet and related technologies, more and more ticket agents, especially online travel agencies (OTAs), are able to provide flight schedules and itinerary search functions to the public. The Department applauds new technologies that increase the number of venues from which consumers can search and compare airfares and schedules and perform one-stop shopping for airfares along with other components of travel packages. However, it is our firm belief that information is useful and beneficial to the public only if it is accurate and complete. As a result, we are proposing to codify the code-share disclosure requirement in section 41712(c) concerning schedule displays and make it applicable to both carriers and ticket agents doing business in the United States with respect to flights in, to, or from the United States. Although the rule text and the preamble of the final rule issued in 1999 did not specify what constitutes ''doing business in the United States,'' we are tentatively of the opinion that any ticket agent that markets and is compensated for the sale of tickets to consumers in the United States, either from a brick-and-mortar office located in the United States or via an Internet Web site that is marketed towards consumers in the United States, would be considered as ''doing business in the United States.'' This interpretation would cover any travel agent or ticket agent that does not have a physical presence in the United States but has a Web site that is marketed to consumers in the United States for purchasing tickets for flights within, to, or from the United States. We also note that with the usage of mobile devices gaining popularity among consumers, our code-share disclosure requirement with respect to flight schedule and itinerary displays covers not only conventional Internet Web sites under the control of carriers and ticket agents, but also those Web sites and applications specifically designed for mobile devices, such as mobile phones and tablets.

Furthermore, the text of section 257.5(a) states that any code-sharing arrangements must be disclosed in flight schedules provided to the public in the United States, which we interpret to include electronic schedules on Web sites marketed to the public in the United States, by an asterisk or other easily identifiable mark. As discussed above, the new amendment to section 41712 and the guidance provided by the Enforcement Office make it clear that for schedules posted on a Web site in response to an itinerary search, disclosure though a rollover, pop-up window or hyperlink is no longer sufficient. Moreover, as stated in the rationale behind our recently amended price advertising rule, 14 CFR 399.84, which ended the practice of permitting sellers of air transportation to disclose airfare taxes and mandatory fees through rollovers and pop-up windows, we believe that the extra step a consumer must take by clicking on a hyperlink or using a rollover to find out about code-share arrangements is cumbersome and may cause some consumers to miss this important disclosure.

Our proposal codifies the requirement of section 41712(c)(2) that the code-share disclosure must appear on the first display of the Web site following an itinerary search. Further, section 41712(c)(2) requires that the disclosure on a Web site must be ''in a format that is easily visible to a viewer.'' In that regard, we are proposing that the disclosure must appear in text format immediately adjacent to each code-share flight displayed in response to an itinerary request by a consumer. We ask whether the proposed requirement is sufficient to meet the statutory requirement that the disclosure must be in a format that is easily visible by a viewer. We further seek comments on whether we should specify minimum standards on the text size of the disclosure in relation to the text size of the schedule itself. As an alternative to the proposed standard, we ask whether a code-share disclosure appearing immediately adjacent to the entire itinerary as opposed to appearing immediately adjacent to each code-share flight would be a sufficient way to meet the ''easily visible'' standard.

With regard to flight schedules provided to the public (whether the schedules are in paper or electronic format), we propose that the code-share disclosure be provided by an asterisk or other identifiable mark that clearly indicates the existence of a code-sharing arrangement and directs the readers' attention to another prominent location on the same page where the identity of the operating carrier is fully disclosed. We seek public comments on whether we should impose the same standard for flight schedules as for flight itineraries provided on the Internet in response to an itinerary search, i.e., requiring that the disclosure be provided immediately adjacent to each applicable flight.

(b) Disclosure to Prospective Consumers in Oral Communications

Section 257.5(b) requires that carriers and ticket agents must identify the actual operator of a code-share flight the first time that a code-share flight is cited to a consumer in person, over the telephone, or through other means of oral communication. With respect to covered entities, this section currently applies to, and, under this proposal, will continue to apply to, both U.S. and foreign air carriers, as well as ticket agents doing business in the United States. We are not proposing any changes to this provision, but we propose to interpret the phrase ''ticket agent doing business in the United States'' in the same manner as described in the discussion of that phrase in section 259.5(a) above. Consequently, a ticket agent that sells air transportation via a Web site marketed toward U.S. consumers (or that distributes other marketing material in the United States) is covered by section 259.5(b) even if the agent does not have a physical location in the United States, and such an agent must provide the disclosure required by section 259.5(b) during a telephone call placed from the United States even if the call is to the agent's foreign location.

(c) Disclosure of Code-Share at Time of Purchase

With respect to written notice of code-share arrangements provided to ticket purchasers, we propose to retain the basic requirements listed in 14 CFR 257.5(c)(1) but delete the language in 14 CFR 257.5(c)(3). The basic requirements in section 257.5(c)(1) are as follows: if a code-share flight segment has its own designated flight number, the code-share disclosure must be immediately adjacent to that flight number; if a single-flight number service involves one or more code-share segments, each code-share segment must be identified immediately adjacent to that flight number in the format ''Service between XYZ City and ABC City will be operated by Jane Doe Airlines d/b/a ORS Express.'' Section 257(c)(3) states that the written code-share notice required by section 257.5(c) must accompany the ticket if the transportation is purchased far enough in advance of travel to allow for advance delivery of the ticket. If time does not allow for advance delivery of the ticket, ''or in the case of ticketless travel,'' the required written notice is to be provided no later than the time that

the consumer checks in at the airport for the first flight in his or her itinerary.

The first part of section 257.5(c)(3) appears to refer to paper tickets, as it speaks of the time required for delivery of the ticket, and it draws a contrast with ''ticketless travel'' in the next sentence. (Ticketless travel is a term that used to be used for what is now referred to as electronic ticketing or e-tickets.) We believe that the required written notice should in all cases be provided ''at the time of purchase'' as indicated at the beginning of section 257.5(c), regardless of whether a paper ticket is subsequently issued or the consumer will receive an e-ticket. Section 257.5(c)(2) states that if a consumer does not receive an itinerary, the selling carrier or ticket agent must provide a separate written notice that identifies the operating carrier. Thus, the existing rule anticipates situations in which the required written code-share notice is not automatically generated by industry purchase/ticketing systems and states that in such cases the selling carrier or ticket agent must manually generate and furnish a written disclosure of the identity of the carrier(s). We do not believe that a written code-share notice that is provided at the airport is sufficient though currently permitted under section 257.5(c)(3) for passengers who purchase their air transportation in advance but do not receive a paper ticket until a date close to the scheduled departure date and for e-ticketed passengers including those who have purchased their transportation weeks or months in advance. Accordingly, we propose to make it clear that written code-share disclosure must be provided at the time of purchase.

(d) Disclosure in City-pair Specific Advertisements

Subsection (d) deals with disclosure requirements in city-pair specific advertisements. We are proposing to use the phrase ''written advertisement'' to replace the phrase ''printed advertisement,'' which in the current rule text refers to both advertisements printed in paper and advertisements published on the Internet. We believe the word ''written'' is more accurate in describing both formats of advertisements.

In addition, we are proposing to add a descriptive phrase to specify the scope of the disclosure requirements on Internet advertisements in an effort to eliminate any possible ambiguity. Specifically, the current rule states that our requirements cover advertisements ''published in or mailed to or from the United States'' including those published on the Internet. As the Internet is a global information network, this language may leave it unclear what would constitute an Internet advertisement that is ''published'' in the United States. For example, a Web site that is hosted on a server located in the United States could arguably fall within the scope of our rule. Conversely, a Web site hosted on a server located outside of the United States could still be marketing airfares to consumers in the United States. For this reason, and to achieve consistency with the Department's other airline consumer protection rules, we are proposing to specify that our code-share disclosure requirements regarding advertisements published on the Internet would apply to advertisements for service in, to or from the United States that are marketed to consumers in the United States. This standard is consistent with the recently amended full-fare advertising rule, 14 CFR 399.84, which only covers Internet advertisements published on Web sites marketed to United States consumers. As explained in a *Frequently Asked Questions* document issued by the Department's Enforcement Office following the publication of that rule, we will look at a variety of factors to determine whether a Web site is marketed to United States consumers, such as whether the Web site is in English, whether the seller of air transportation displays prices in U.S. dollars, or whether sales can be made to persons with addresses or telephone numbers in the United States.

We note that this proposed standard will cover all advertisements appearing on a carrier's or a ticket agent's own Web site, as well as advertisements that are presented to U.S. consumers through other paid advertising venues on the Internet (such as a news media Web site or a travel blog Web site) and social media Web sites (such as Facebook or Twitter). We seek comments with regard to whether imposing the same standard to advertisements on all of these Web sites is reasonable and technically practical. We specifically ask what type of code-share disclosure is considered adequate from a consumer's point of view, in light of the brevity of the Facebook and Twitter posting formats. Finally, we are proposing some editorial changes to 14 CFR 257.5. First, we propose to replace the term ''transporting carrier'', which is used throughout section 257.5, with the term ''operating carrier'' to refer to the carrier in a code-share or wet lease arrangement that has the operational control of a flight but does not market the flight in its own name. In doing so, we are trying to achieve consistency with other recently amended consumer protection rules, see, e.g., 14 CFR 259.4(c) (code-share partners' responsibilities in tarmac delay contingency plans) and 14 CFR 399.85(e) (notice of baggage fees for code-share flights). Another stylistic change proposed in this NPRM concerns the example disclosure statement that a seller of air transportation must include in a radio or television broadcasting advertisement. The current sample statement includes the phrase ''[s]ome services are provided by other airlines.'' Because the words '' services'' and ''provided'' cover a wide range of activities, including ground operations, customer service, etc., they do not accurately convey the information we intended to relate, which was regarding the actual operation of a flight. Accordingly, we propose to change the sentence to read ''[s]ome flights are operated by other airlines.''

7. Disclosure That Not All Carriers are Marketed and Identification of Carriers Marketed on Ticket Agent Web sites

The Department is considering requiring large travel agents to disclose in online displays the fact that not all carriers that serve a particular market are marketed by the travel agent if that is the case. Consumers deserve complete information regarding whether a particular ticket agent provides flight and fare information for all carriers or just a subset of carriers. Many online travel agents provide flight and fare information for a significant number of carriers serving a particular city-pair market but not all carriers that serve that market. In some markets, they may not provide information regarding any carrier serving the market. Online travel agents do not necessarily identify the carriers whose schedule and fare information is or is not provided in search results. As a result, consumers may believe they are searching all possible flight options for a particular city-pair market when in fact there may be other options available. The Advisory Committee for Aviation Consumer Protection recommended that DOT require ticket agents, including online ticket agents, to disclose the fact that they do not offer for sale all airlines' tickets, if that is the case, and that additional airlines may serve the route being searched, so that consumers know they may need to search elsewhere if they want to find all available air travel options. Accordingly, the Department is considering requiring large ticket agents, such as online travel agents, that operate Web sites that display schedules or fares and/or sell tickets for air transportation of more than one carrier to disclose whether they display the airfares of all

carriers serving any market that can be searched on the travel agent's Web site. One alternative would be to merely require travel agents to prominently note on their Web sites that not all U.S. air carriers and non-U.S. air carriers serving the U.S. are displayed on the Web site or marketed by the travel agent. Another option would be to prominently display a statement in connection with a search of a particular city pair that not all air carriers serving those cities are displayed on the Web site or marketed by the travel agent. Alternatively, online travel agents could be required to specifically identify all of the air carriers that are marketed by the travel agent.

The Department is not providing rule text for this proposal. Instead, it seeks comment on how such a requirement should be implemented. For example, should the disclosure be made with a general statement on the travel agent's home page with a link to more detailed information? Or should the disclosure be made through a statement on the search results page that displays itineraries in response to a consumer search? If the general disclosure statement is linked to a page with more detailed information, what additional information should be provided? Additionally, the Department seeks comment on whether such a rule should be limited to ticket agents of a certain size or should include all ticket agents, and if the rule should be limited to ticket agents of a certain size, what parameters should the Department use to define the ticket agents included in the requirement. The Department also seeks comment on the costs and benefits of requiring Web sites to state whether a particular carrier's schedule information is provided on that Web site and of identifying those air carriers that must be included in such disclosure. For example, what are the costs and benefits of a disclosure that says, ''These schedules do not include all carriers in these markets'' versus a disclosure that would *list* the carriers that are included?

8. Prohibition on Undisclosed Airfare Display Bias by Ticket Agents and Carriers

In connection with electronic displays of multiple carriers' airfares and schedules, the Department is proposing to prohibit any undisclosed bias in any presentation of carrier schedules, fares, rules or availability. A Department prohibition on airfare display bias is not unprecedented. In the past, Department regulations contained a limited prohibition on bias of computer terminal displays provided to travel agents by computer reservation systems (CRSs), the precursors to GDSs. At that time, there was a concern that the owners of the CRSs (initially airlines and, subsequently, other entities) would potentially engage in display bias or other unfair, deceptive, predatory, or anticompetitive practices absent Department regulation of their operations (14 CFR Part 255). This rule prohibited CRSs used by travel agents from using factors relating to carrier identity in determining how airfares were displayed. Among other things, the CRSs were required to use the same editing and ranking criteria for ''both on-line and interline connections and not give on-line connections a system-imposed preference over interline connections.'' 14 CFR 255.4(a)(1). However, Part 255 sunset on July 31, 2004 (see 14 CFR 255.8).

Recently, the Enforcement Office has been informed of allegations that certain ticket agents, including GDSs, have biased their displays to disadvantage certain airlines in the course of hard-fought contract negotiations. Those ticket agents have allegedly biased the listing of available itineraries displayed in response to searches by consumers or travel agents on their Web sites. The display bias allegedly resulted in consumers and travel agents being presented with favored carriers' fare and schedule information first. Complainants also assert that although some ticket agents may have received limited disclosure regarding certain instances of display bias, the general public received no notice or disclosure. Moreover, we are concerned that GDSs and other ticket agents could sell bias to certain airline competitors or bias displays toward carriers that pay higher segment fee compensation to GDSs and such bias could be difficult to detect. The prohibition would also apply to flight search tools operated by meta-search engines and similar entities engaged in the distribution of certain air transportation information. As discussed earlier, the Department would view such entities as being ticket agents.

The Department is considering a regulation that would require any carrier or ticket agent that provides electronic display of airfare information to provide unbiased displays or disclose the biases in the display. The regulation would apply to all electronic displays of multiple carriers' fare and schedule information, whether the display is available on an unrestricted basis, e.g., to the general public, or is only available to travel agents who sell to the public. The requirement to provide unbiased displays or disclose biases in the display would also apply to electronic displays used for corporate travel unless a corporation agrees by contract to biases in the display used by its employees for business travel. If not, the regulation would require carriers and ticket agents that provide airfare information electronically to display the lowest generally available airfares and most direct routings that meet the parameters of the search in response to an inquiry for an airfare quotation for a specific itinerary. It would also prohibit biasing displays such that less direct routings that are equivalently priced, or more expensive fares with an equally direct routing, and that meet the parameters of a search, are displayed more prominently or earlier in the search results list than a more direct routing or a lower fare simply to benefit a particular favored carrier or penalize a disfavored carrier. In the alternative, carriers and ticket agents could provide biased displays so long as they have prominent and specific disclosure of the bias. The requirements would apply to displays in response to airfare inquiries by a consumer for a particular itinerary and displays in response to airfare inquiries made by a travel agent or other intermediary in the sale of air transportation for a particular itinerary.

Under this proposal, undisclosed display bias would not be permitted on displays publicly available directly to consumers or displays directed toward travel agents, such as those working for corporations or other travel management companies. To the extent the consumer or travel agent placed restrictions on the search, for example, by limiting to one or more specific carriers or classes of service, the display would not be considered to contain undisclosed display bias as long as the display disclosed the lowest available fares and most direct itineraries that met the search parameters. In addition to prohibiting display bias, the Department is considering requiring any ticket agent that decided to bias its displays and disclose the existence of bias to also disclose any incentive payments it is receiving. We seek comment on what kind of disclosure of the existence of incentive payments would be most helpful for consumers. When providing notice, should the ticket agent list the companies, air carriers, and foreign air carriers offering the incentives? If so, should the list rank companies in order of the company providing the incentives of the greatest monetary value? Or should it group them based on whether the incentive is provided in the form of payments, rebates, discounts, commissions, volume-based compensation, or another method? Should the requirement apply to

incentives earned by the travel agent in the previous calendar year or some other time period? Should it be limited to incentives with a certain monetary value?

The Department seeks comment on whether the prohibition on display bias should be limited to airfare and routings. We also seek comment on the costs and benefits of a prohibition on display bias.

9. Prohibition on Post-Purchase Price Increases for Baggage Fees

In the second Enhancing Airline Passenger Protections rule, the Department prohibited an air carrier or agent from increasing the price of air transportation after the passenger purchases a ticket. Under 14 CFR 399.88, carriers and other sellers of air transportation are now prohibited from increasing the price of air transportation to a particular passenger after the purchase of a ticket, including but not limited to the price of a seat, the price for the carriage of passenger baggage, and the price for any applicable fuel surcharge. The rule includes a limited exception for an increase in a government-imposed tax or charge. In response to questions received after publication of the final rule, the Department's Enforcement Office clarified that there could not be an increase to a particular passenger in the charge for any ancillary service after a ticket is purchased, including services not purchased with the ticket. The reasoning behind this was twofold. First, by using the phrase ''including but not limited to'' when describing the types of items that sellers of air transportation are prohibiting from price increases after ticket purchase, the Department made it clear that these items are simply examples and not an exhaustive list. Second, under the disclosure requirements of 14 CFR 399.85(c), sellers of air transportation are required to inform passengers about baggage charges on their e-ticket confirmations as a means of preventing consumers from being surprised about hidden fees. If these fees could change after the passenger purchases the ticket, the information provided in the e-ticket would be useless.

However, after the rule became final, certain carriers raised concerns that had not been raised previously: That a prohibition on an increase in the price of any ancillary service after a ticket purchase could prove cumbersome for carriers in practice. For example, one passenger might be entitled to pay a lesser amount for a drink or a snack than the passenger sitting next to him or her. They contended that the cost of developing systems to keep track of the price of every ancillary service at the time of passenger purchase and charging those prices on an individualized basis would be prohibitive.

In light of the problems in application of the rule as it relates to ancillary services that are not purchased with the ticket, the Enforcement Office issued *Guidance on Price Increases of Ancillary Services and Products not Purchased with the Ticket* on December 28, 2011. In that guidance, the Department's Enforcement Office noted that the Department had decided to revisit the issue through a further rulemaking to examine the application of the rule to fees for ancillary services not purchased with the ticket. The Department also announced that with respect to fees for ancillary services that were not purchased with the air transportation, it would only enforce the prohibition on post-purchase price increases for carry-on bags and first and second checked bags. The application of the prohibition of the post-purchase price increase was also at issue in a lawsuit filed by two airlines against the Department. The court considered the rule as applied under the December 28, 2011, guidance and upheld the Department's rule prohibiting post-purchase price increases as it is currently being applied. *Spirit Airlines, Inc.,* v. *U.S. Dept. of Transportation* (D.C. Cir. July 24, 2012), slip op. at 20–21. Petition for Writ of Certiorari denied on April 1, 2013.

The Department is now proposing to modify 14 CFR 399.88 to prohibit a price increase after the purchase of air transportation for any mandatory charge the consumer must pay (such as the air fare or an applicable fuel surcharge), and the price for the carriage of any passenger baggage. Sellers of air transportation would also continue to be prohibited from increasing the price of any ancillary service after it is purchased. The logistical and financial burdens placed on carriers related to ancillary services other than baggage that are not purchased with the ticket are too great. Ensuring that in-flight crew have the information and tools to impose varying service fees depending on when a passenger purchased a ticket would likely lead to unreasonable costs for carriers, significant confusion, and ultimately consumer harm by incentivizing carriers to set prices for ancillary services artificially high. However, the Department believes that transporting baggage is intrinsic to air transportation and baggage fees are a major factor for consumers when deciding which air transportation to purchase, and should be subject to the rule prohibiting post-purchase price increases. Therefore, under the proposed rule, the price for the transportation of passenger baggage that applies when a passenger buys a ticket is the price that they will pay, even if they do not pay for the transportation of baggage at the time they purchase the ticket. This interpretation is consistent with guidance given by the Department in 2008 which states that ''[i]n no case should more restrictive baggage policies or additional charges be applied retroactively to a consumer who purchased his or her ticket at a time when the charges did not apply, or when a lower charge applied.'' *Notice of the Assistant General Counsel for Aviation Enforcement and Proceedings, ''Guidance on Disclosure of Policies and Charges Associated with Checked Baggage,''* May 13, 2008.

In addition, under the revised 14 CFR 399.88, after a ticket is purchased, carriers and other sellers of air transportation would continue to be prohibited from raising the price of the air transportation or of ancillary services that are purchased with the ticket. For example, if a passenger buys a ticket that costs $200 (total fare, inclusive of taxes and fees) and pays an additional $25.00 for a priority boarding pass, and the carrier subsequently increases the price of a priority boarding pass effective on a date before this passenger travels, the carrier cannot retroactively increase the price for the consumer who already purchased their priority boarding pass. The new 14 CFR 399.88 would still allow for the limited exception of an increase in the price of a ticket if there is an increase in a government-imposed tax or fee; that tax/fee could still be retroactively applied to the passenger's travel if the required notice is provided to consumers prior to the ticket purchase. However, any other increase in price of any already purchased ancillary service would constitute an unfair and deceptive practice.

The Department is also considering the alternative of keeping the original interpretation of the rule. Under this interpretation, the price of ancillary services and products for a given consumer is capped at the time that he or she purchases the air transportation whether or not these items are purchased along with the air transportation, as the existence of a fee for other services or products related to the air transportation, as well as the amount of any such fee, can influence a customer's purchasing decision. The Department invites comments on the costs and benefits of retaining the rule as originally interpreted and on the new

proposal to prohibit only an increase in the price of the carriage of baggage if not purchased with the fare.

Finally, the Department is also contemplating revising the post-purchase price provision to better address the issue of ''mistaken fares.'' As explained above, section 399.88 essentially bans sellers of air transportation from increasing the price of an airline ticket to a consumer who has purchased and paid for the ticket in full. As a result, the Department's Enforcement Office explained in a guidance document that, under section 399.88, ''if a consumer purchases a fare and that consumer receives confirmation (such as a confirmation email and/or the purchase appears on their credit card statement or online account summary) of their purchase, then the seller of air transportation cannot increase the price of that air transportation to that consumer, even when the fare is a 'mistake.' '' Since then, the Enforcement Office has investigated a number of incidents where passengers complained that airlines or ticket agents would not honor tickets that had been paid for in full because the sellers of the air transportation erroneously let them book flights for less than the actual value. The Enforcement Office has become concerned that increasingly mistaken fares are getting posted on frequent-flyer community blogs and travel-deal sites, and individuals are purchasing these tickets in bad faith and not on the mistaken belief that a good deal is now available. We solicit comment on how best to address the problem of individual bad actors while still ensuring that airlines and other sellers of air transportation are required to honor mistaken fares that were reasonably relied upon by consumers.

Additionally, industry and consumers have raised questions regarding when transportation is considered to touch upon the United States and thus covered by the prohibition on post-purchase price increases. Currently, section 399.88 states that it is an unfair and deceptive practice for any seller of scheduled air transportation within, to, or from the United States or of a tour or tour component that includes scheduled air transportation within, to, or from the United States, to increase the price of that air transportation to a consumer after the air transportation has been purchased by the consumer, except in the case of a government-imposed tax or fee and only if the passenger is advised of a possible increase before purchasing a ticket. We are considering defining the phrase ''air transportation within, to, or from the United States'' for the purposes of this section to mean any transportation that begins or ends in the United States or involves a connection or stopover in the United States that is 24 hours or longer. We ask for comments on whether this new definition would provide greater clarity to members of the public and the regulated entities on when sellers of air transportation would be required to honor mistaken fares.

10. Amendments/Corrections to Second Enhancing Airline Passenger Protections Rule and Certain Other Provisions

In response to questions and concerns from airlines and other regulated entities, the proposed amendments to the rules described below are intended to correct drafting errors, provide clarifications and reflect minor changes to the second Enhancing Airline Passenger Protections rule to increase consistency and conform to guidance issued by the Department's Enforcement Office regarding its interpretation of the rule. On its own initiative, the Department is also making administrative changes to another rule.

a. Baggage Disclosure Requirements Under Sections 399.85(a) and (b)

In sections 399.85(a) and 399.85(b) the final rule inadvertently refers to Web sites that are ''accessible'' from the United States. In this NPRM, we are proposing to codify the guidance given in Frequently Asked Question #25, page 25, and amend sections 399.85(a) and 399.85(b) to reflect the intended applicability of those sections to Web sites ''marketed to'' U.S. consumers. This change also makes sections 399.85(a) and 399.85(b) consistent with the other provisions in 14 CFR 399.85 that apply to Web sites that market air transportation to U.S. consumers. The Department invites comment on this proposal.

In further regard to section 399.85(b), after issuing the rule and assisting carriers and online travel agents with their efforts to come into compliance, it became clear that the Enforcement Office needed to clarify two aspects of this disclosure rule. The first issue is when a carrier or agent needs to notify a passenger that ''baggage fees may apply.'' The rule text states that an agent or carrier must ''clearly and prominently disclose on the first screen in which the agent or carrier offers a fare quotation for a specific itinerary selected by a consumer that additional airline fees for baggage may apply and where consumers can see these baggage fees.'' Although section 399.85(b) may be amended in accordance with the proposal regarding the ''[d]isplay of ancillary service fees through all sales channels,'' if the Department decides not to adopt that proposal it would amend section 399.85(b) to conform to the guidance previously issued. In that case, section 399.85(b) would state that the first screen on which the carrier offers a fare quotation after a passenger initiates a search for flight itineraries must include notification that baggage fees may apply. For example, if a passenger performs a search for flights from San Francisco to Dallas on a carrier or agent's Web site, the first page displayed in response to that search that includes a fare quote must also note that baggage fees may apply. The second issue is that the Department wishes to clarify that in showing ''where consumers can see these baggage fees,'' the search results screen of the Web site of the agent or carrier must include a hyperlink that takes the consumer to the up-to-date and accurate baggage fee listings. An agent may link to a chart of information that it generates itself, to a third party site containing the information, or to the carrier's page, as it is allowed to do under the current rule.

b. Standard Applicable to Reportable Tarmac Delays Under Part 244

In 14 CFR Part 244, the Department requires U.S. and foreign air carriers to file Form 244 ''Tarmac Delay Report'' with the Department with respect to any covered flight that experienced a lengthy departure or arrival delay on the tarmac at a large, medium, small, or non-hub U.S. airport. A ''lengthy'' tarmac delay for purposes of this report is defined in Part 244 as any tarmac delay that lasts ''three hours or more.'' This standard is inconsistent with the standard applicable to the tarmac delay contingency plan requirements under 14 CFR Part 259 and the existing reporting requirements of BTS, both of which refer to any tarmac delay of ''more than three hours.'' In a Frequently Asked Questions document issued by the Department following the issuance of the final rule for Part 244, we acknowledged this discrepancy and stated that we intend to correct it in a future rulemaking. In this NPRM, we are proposing to amend the rule text of Part 244 and to adopt the ''more than three hours'' standard so this Part would be consistent with other Parts of our rules. Under this proposal, any tarmac delay that lasts exactly three hours would not be covered under the requirements of Part 244.

c. Civil Penalty for Tarmac Delay Violations

In the first and second Enhancing Airline Passenger Protections final rule, the Department stated that failure to comply with the assurances required by the tarmac delay rule will be considered an unfair and deceptive practice within the meaning of 49 U.S.C. 41712 that is subject to enforcement action by the Department. Under 49 U.S.C. 46301, the Department has authority to impose a civil penalty of ''of not more than $27,500'' for each violation of the specifically listed aviation-related laws and regulations, which would include DOT's tarmac delay rule. Nevertheless, in recent years, there have been questions raised as to whether the Department has the authority under the civil penalty statute (49 U.S.C. 46301) to assess a civil penalty on a per passenger basis for tarmac delay violations. As such, we are amending the tarmac delay rule to clarify that the Department may impose penalties for tarmac delay violations on a per passenger basis.

It has long been the Department's policy that each consumer affected by an unlawful carrier practice is a separate violation. For example, if a flight is canceled and ten people on that flight cannot be rerouted and thus are entitled to a refund of their unused transportation, and the carrier fails to comply with the Department's refund rules, each person whose refund was not provided in compliance with our rules would constitute a separate violation. Similarly, if five people were involuntarily denied boarding from an oversold flight and none were paid denied boarding compensation as required by our oversales rule that would be five violations. Our authority to calculate a civil penalty on a per passenger basis for tarmac delay violations is just as clear. Each passenger on a flight that experiences a tarmac delay that exceeds three hours for domestic flights or four hours for international flights experiences the inconvenience that this rule was designed to prevent and gives rise to a separate violation. Likewise, each passenger who is not offered food and water at the two-hour mark during a tarmac delay gives rise to a separate violation. Indeed, a number of carriers have recognized this fact and complained in public filings and press reports of the prospect of incurring $27,500 per passenger in fines for tarmac delay violations.

The purpose of the tarmac delay rule is clearly to mitigate hardships for individual airline passengers during lengthy tarmac delays. To that end, the rule requires carriers to develop contingency plans for lengthy tarmac delays, and to provide an assurance that the carrier will not allow an aircraft to remain on the tarmac for more than three hours for domestic flights and for more than four hours for international flights without each passenger being given an opportunity to deplane. The preambles to both the first and second Enhancing Airline Passenger Protections final rules refer to protecting individual passengers. Carriers are also required to tell passengers what they can expect by posting their contingency plans on their Web site. To the extent that carriers do not live up to the assurances that they provided to any passenger, it is an unfair and deceptive practice with respect to each affected passenger and therefore a separate violation of 49 U.S.C. 41712 with respect to each such passenger.

d. Required Oral Disclosure of Material Restrictions on Travel Vouchers Offered to Potential Volunteers in Oversale Situations Under Part 250

Another inconsistency in the second Enhancing Airline Passenger Protections final rule concerns the requirement in 14 CFR Part 250 to provide oral disclosure of any material restrictions on travel vouchers offered to any passenger a carrier solicits to voluntarily give up his or her confirmed reservation on an oversold flight. The preamble to the final rule discussed extensively the reason for requiring such oral disclosure to both voluntarily and involuntarily bumped passengers who are orally offered a voucher, but inadvertently, the new Part 250 rule text only requires oral disclosures to passengers who are involuntarily denied boarding. The rule text, as it currently stands, allows carriers to provide such disclosure solely by written notice to passengers who are orally solicited to be volunteers in exchange for travel vouchers. However, for the reasons discussed in the preamble to the second Enhancing Airline Passenger Protections rule, we are unconvinced that such written notice alone is adequate at times when the solicitation itself is oral and passengers are constrained by time pressure to make a quick decision as to whether to volunteer. Many times, the written notice is incorporated in the printed contents of the travel voucher, and the passenger frequently would not have time to review the notice before he or she commits to the acceptance of the voucher. We continue to believe that a brief oral summary of the material restrictions applicable to the travel vouchers that are orally offered to potential volunteers (as well as continuation of the requirement to orally disclose this information to involuntarily bumped passengers who are offered the option of a travel voucher) will provide further protections to these passengers so they can make an informed decision. As such, we are proposing to amend section 250.2b(c) to reflect this notion. Under this proposal, when carriers orally solicit volunteers and offer travel vouchers as incentives, they would also be required to orally describe any material restrictions applicable to the travel vouchers.

e. Limitation of Flight Status Notification Requirement of 14 CFR 259.8

Section 259.8 requires that covered carriers must notify passengers and other interested persons of flight status changes within 30 minutes after the carrier becomes aware of such changes. Flight status changes in this section include a flight cancellation, a delay of more than 30 minutes, or a diversion. Although the preamble and rule text did not specify how far in advance of the date of the scheduled operation carriers must comply with the notification requirements, the *Frequently Asked Questions* guidance document issued by the Enforcement Office in relation to the second Enhancing Airline Passenger Protections rule stated that, as an enforcement policy, the rule applies to any flight status changes that occur within seven calendar days of the scheduled date of the operation. *See* Frequently Asked Questions, Section VIII, #2. We further explained that the purpose of this rule is to avoid or reduce unnecessary waits at, or pointless trips to, an airport, which are most likely to occur on the date of the scheduled travel. Therefore, the closer to the date of the scheduled operation, the more important it is for carriers to provide notice of a flight status change promptly. In this NPRM, we propose to codify this ''seven-calendar-day'' timeframe as we believe that requiring carriers to provide notifications of schedule changes within 30 minutes after they become aware of such changes is not necessary if the changes occur more than seven days before the date of the operation. To require notifications within 30 minutes for changes occurring more than seven days in advance of the date of operation would likely greatly increase carriers' burden yet result in little additional benefit to the public. We do emphasize, however, that notifications of changes that occur earlier than the seven-day threshold are still required to be delivered to the

passengers in a timely manner; see 14 CFR 259.5(b)(10).

We are also proposing some editorial changes to section 259.8 to clarify that flight status change notifications required in this section should be provided not only to passengers, but also to any member of the public who may be affected by the changes, including persons meeting passengers at airports or escorting them to or from airports. This is a point we made clear in the preamble of the final rule document but not in the rule text. In this regard, we are proposing to change the word ''passengers'' to ''consumers'' in the title of section 259.8, to change the first instance of the word ''passengers'' in subsection 259.8(a)(1) to the phrase ''passengers and other interested persons,'' and to change the second instance of that word to ''subscribers.''

f. Removing the Rebating Provision in Section 399.80(h)

Section 399.80(h) states that it is an unfair or deceptive practice or unfair method of competition for a ticket agent to advertise or sell air transportation at less than the rates specified in the tariff of the air carrier, or offer rebates or concessions, or permit persons to obtain air transportation at less than the lawful fares and rates. This provision is a vestige of the period before deregulation of the airline industry. Domestic air fares were deregulated effective 1983, and in most cases international air fares to and from the United States are no longer contained in tariffs that specify ''lawful'' fares. In those markets where international fares are still subject to regulation, carriers that do not comply with their tariff are potentially subject to enforcement action under 49 U.S.C. 41510 concerning adherence to tariffs or 49 U.S.C. 41712 concerning unfair or deceptive practices and unfair methods of competition (the statutory basis for section 399.80(h)). The Department's Enforcement Office has said that it will pursue enforcement action against a carrier that does not comply with its tariff when there is clear evidence of a pattern of direct consumer fraud or deception, invidious discrimination, or violations of the antitrust laws. It has been the longstanding policy of that office to decline to prosecute instances of noncompliance with tariff obligations that result in benefits to consumers absent clear evidence of such behavior. (*See* the Frequently Asked Questions for ''Rule #2'' of the Enhancing Airline Passenger Protections regulation, *www.dot.gov/individuals/air-consumer/aviation-rules,* section X, question 38a, footnote 1.) There have been no enforcement actions solely for tariff compliance for over 20 years, and should such action become appropriate in the future it can proceed under the authority of sections 41510 or 41712. 14 CFR 399.80(h) is not necessary, and consequently we are proposing to remove this provision.

Regulatory Analyses and Notices

A. Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

This action has been determined to be significant under Executive Order 12866 and the Department of Transportation's Regulatory Policies and Procedures. It has been reviewed by the Office of Management and Budget under that Executive Order. The Regulatory Evaluation finds that the costs for the proposed rule exceed the monetized benefits as the benefits from all provisions, with the exception of provision 2, could not be measured and valued with confidence. The benefits which could be estimated for provision 2 do not include the value of all likely benefits, as values for some of those could not be adequately estimated. The total present value of monetized passenger benefits from the proposed requirements over a 10-year period at a 7% discount rate is $25.1 million and the total present value of monetized costs incurred by carriers and other sellers of air transportation over a 10-year period at a 7% discount rate is $80.5 million. The net present cost of the rule for 10 years at a 7% discount rate is $53.8 million. However, if the value of the unquantified benefits, per passenger, is any amount greater than one cent, and unquantified costs are minimal, then the entire rule is net beneficial. In other words, if passengers are willing to pay, on average, one penny per trip for all eight provisions of the proposal, then the value of the proposal outweighs its costs.

Below, we have included a table outlining the projected costs and benefits of this rulemaking.

TABLE—SUMMARY OF COSTS AND BENEFITS OVER 10 YEARS, DISCOUNTED AT 7 PERCENT

[Millions $]

Provisions	10 Year analysis period		
	7% Discount rate		
	Costs	Benefits	Net benefits
1 Definition of Ticket Agent			
Monetized Costs and Benefits	N/A	N/A	N/A
2 Carriers provide ancillary fee information to ticket agencies for display			
Monetized Costs and Benefits	$46.2	$25.1	($21.1)
Unquantified/non-monetized benefits or costs *Greater Competition and Lower Overall Prices for Ancillary service fees* *Greater Efficiency by Consumers in Flight Purchases* Unquantified/non-monetized Costs: *May Inhibit New Entrants* *May Decrease Carrier Flexibility to Customize Services*	*Value of Unquantified Benefits per PAX Needed for Benefits to Equal or Exceed Costs.* Less than $0.00 *(21.06 M net cost/1,666 M travelers purchasing via internet—10 yrs).*		
3 & 4 Expand reporting threshold to 0.50% and reporting as mainline carriers and code-share partners combined			
Monetized Costs and Benefits	$29.8	N/A	($29.8)

TABLE—SUMMARY OF COSTS AND BENEFITS OVER 10 YEARS, DISCOUNTED AT 7 PERCENT—Continued

[Millions $]

Provisions	10 Year analysis period		
	7% Discount rate		
	Costs	Benefits	Net benefits
Unquantified/non-monetized benefits: *Improved On-Time Performance for Newly Reporting Carriers and Code-Share Flights for All Reporting Carriers* *Improved Handling of Baggage for Newly Reporting Carriers and Code-Share Flights for All Reporting Carriers* *Decrease in Oversales* *Improved Customer Good Will Towards Carriers* *Insurance Value* *Improved Public Oversight of the Industry* Unquantified/non-monetized Costs: *Increased Training Costs for Gathering Data to Report (some carriers only)* *Increased Management Costs To Improve Carrier Performance*	*Value of Unquantified Benefits per PAX Needed for Benefits to Equal or Exceed Costs.* $0.7 *($29.75 M net cost/43.9 M PAX on newly reporting carriers 10 yrs) to Less than $0.00 ($29.75M net cost/7,335 M all domestic PAX 10 yrs).*		
5 Minimum customer service standards for ticket agents			
Monetized Costs and Benefits	$3.0	N/A	($3.0)
Unquantified/non-monetized benefits: *Improved Customer Good Will Towards Ticket Agents* *Reduced Legal and Administrative Costs to Manage Complaints* *Faster Resolution of Complaints/Refunds* *Potential Increase in Competitiveness of Travel Agents vs. Carriers with Customer Protections Similar to Carriers* *Unquantified/non-monetized Costs:* *Increased Training Costs* *Increased Management Costs* *Increased Staff Time*	*Value of Unquantified Benefits per PAX Needed for Benefits to Equal or Exceed Costs. Less than $0.00 (2.95 M net cost/3,405 M domestic PAX purchasing via travel agents 10 yrs).*		
6 Disclosure of code-share segments in schedules, advertisements and communications with consumers			
Monetized Costs and Benefits	N/A	N/A	N/A
7 Disclosure of carriers marketed by ticket agents (no proposed rule text—seeking comments)			
8 Prohibition on undisclosed biasing			
Monetized Costs and Benefits	N/A	N/A	N/A
Unquantified/non-monetized benefits: *Decrease in Incentive Payments to Ticket Agents from Carriers Potentially Leading to Lower Costs to Consumers* *Potential Decrease in Consumers Not Noticing Flights which Better Meet Their Criteria* Unquantified/non-monetized Costs: *Programming Costs to Change Ranking Software/Systems or to Post Notice* *Legal Costs to Adjust Existing Contracts Currently Requiring Preferential Display*			
9 Prohibition of post-purchase price increase for ancillary service fees			
Monetized Costs and Benefits	N/A	N/A	N/A
Unquantified/non-monetized benefits: *Improved Customer Good Will Towards Ticket Agents* *Reduced Legal and Administrative Costs to Manage Complaints*			
TOTAL (All Proposed Provisions)*	$80.5	$25.1	($53.8)
Value of Unquantified Benefits Per Passenger Needed for		*$0.01*	

* **Note:** Details may not sum to totals in table due to rounding.

We invite comment on the quantification of costs and benefits for each provision, as well as the methodology used to develop our cost and benefit estimates. We also seek comment on how unquantified costs and benefits could be measured. More detail on the estimates within this table can be found in the preliminary Regulatory Impact Analysis associated with this proposed rule.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities. The regulatory initiatives discussed in this NPRM would have some impact on some small entities. A direct air carrier or foreign air carrier is a small business

if it provides air transportation only with small aircraft (i.e., aircraft with up to 60 seats/18,000 pound payload capacity). See 14 CFR 399.73. A travel agency is considered to be small if it makes $3.5 million or less in annual revenues. While most of the proposals in this rulemaking impact carriers, certain elements also impact ticket/travel agents.

The Initial Regulatory Flexibility Analysis found that there are some costs, though not substantial, to certain small entities from provision 3 which would expand the definition of a reporting carrier to one that accounts for at least 0.5% of domestic scheduled passenger revenues; provision 4, which would expand the reporting requirements for reporting carriers to include an additional, combined set of reports for both the carrier's own flights and its code-share partner flights; and provision 2, which would require that U.S. and foreign air carriers and ticket agents disclose certain ancillary service fees to a consumer who requests such information.

Our analysis estimates that a total of 87 small U.S. and foreign air carriers may be impacted by this rulemaking. We believe that the economic impact on these entities would not be significant. The estimated cost to small carriers from all the provisions would be $5.1 million for the first year and $24.7 million for a 10-year period discounted at 7 percent. On the basis of this examination, I certify that this rulemaking would not have a significant economic impact on a substantial number of small entities. A copy of the Initial Regulatory Flexibility Analysis has been placed in docket.

C. Executive Order 13132 (Federalism)

This NPRM has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This notice does not propose any provision that (1) has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government; (2) imposes substantial direct compliance costs on State and local governments; or (3) preempts State law. States are already preempted from regulating in this area by the Airline Deregulation Act, 49 U.S.C. 41713. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

D. Executive Order 13084

This NPRM has been analyzed in accordance with the principles and criteria contained in Executive Order 13084 (''Consultation and Coordination with Indian Tribal Governments''). Because none of the options on which we are seeking comment would significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13084 do not apply.

E. Paperwork Reduction Act

This NPRM proposes two new collections of information that would require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 49 U.S.C. 3501 *et seq.*). Under the Paperwork Reduction Act, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing notice of the proposed collection of information and a 60-day comment period, and must otherwise consult with members of the public and affected agencies concerning the proposed collection.

The first collection of information proposed here is a requirement that more carriers report on-time performance, mishandled baggage, and oversales data to the Department (i.e., expansion of reporting carriers from any U.S. airline that accounts for at least one percent of annual domestic scheduled passenger revenue to any U.S. airline that accounts for at least 0.5 percent of annual domestic scheduled-passenger revenues). The second information collection is a requirement that mainline carriers provide enhanced reporting for their domestic code-share partner operations including requiring reporting carriers to separately report on-time performance, mishandled baggage, and oversales data for all domestic scheduled passenger flights marketed by the reporting carriers.

For each of these information collections, the title, a description of the respondents, and an estimate of the annual recordkeeping and periodic reporting burden are set forth below:

1. Requirement for More Carriers To Report On-Time Performance, Mishandled Baggage, and Oversales Data to the Department

Respondents: U.S. carriers that operate passenger service and account for at least 0.5 percent of domestic passenger service, but less than 1 percent of domestic passenger service (eight new reporting carriers, among which five carriers do not market directly to consumers and three carriers market directly to consumers).

Estimated Annual Burden on Respondents: The first-year cost for eight new reporting carriers would total 26,877 hours, or 3,360 hours on average (for eight carriers). For each of the five new reporting carriers that do not market directly to consumers, the costs would include the following: (1) One-time cost to set up systems to collect and report the data for each newly reporting carrier of 1,118 hours (set-up costs of $100,762 divided by hourly cost of $90.10, both figures derived from respondent interviews); and (2) an annual cost for each newly reporting carrier to report data regarding on-time performance, baggage, and oversales of 496 hours (480 hours to collect data for form 234 and 16 hours to collect data for form 251). For each of the three new reporting carrier that market directly to consumers, the costs would include the following: (1) One-time cost to set up systems to collect and report the data for each newly reporting carrier of 1,118 hours (set-up costs of $100,762 divided by hourly cost of $90.10, both figures derived from respondent interviews); (2) an annual cost for each newly reporting carriers to report data regarding on-time performance, baggage, and oversales of 496 hours (480 hours to collect data for form 234 and 16 hours to collect data for form 251); and (3) one-time cost for setting up systems to post flight on-time performance information on the carrier's Web site of 4,655 hours (set-up costs of $419,394 divided by hourly cost of $90.10).

Estimated Total Annual Burden: First year costs total 26,877 which would include the system set-up costs for new reporting carriers of 8,944 hours (8 carriers times 1,118 hours each), annual labor cost for new reporting carriers to report data of 3,968 hours (8 carriers times 496 hours each), 13,965 hours (for three carriers to set up systems to post on-time performance data on their Web sites). Burdens for subsequent years would be 4,528 hours on average annually for reporting carriers to collect and report their own data regarding on-time performance, baggage, and oversales.

Frequency: Monthly for on-time performance and baggage reports and posting on-time performance on marketing carriers' Web sites; quarterly for filing oversales report; estimates of burden are annual.

2. Requirement for Reporting Carriers That Market Code-Share Flights To Report Their Code-Share Flights in Addition to Their Own Flights To Provide Enhanced Reporting for Domestic Code-Share Partner Operations

Respondents: U.S. carriers that operate passenger service and account for at least 0.5 percent of domestic passenger service and market code-share partners (9 existing reporting carriers that market code-share flights).

Estimated Annual Burden on Respondents: The annual cost for each code-share partner to process and report data regarding on-time performance, mishandled baggage, and oversales to each separate marketing, reporting carrier with which it code-shares would be 496 hours (480 hours to collect data for form 234 and 16 hours to collect data for form 251), whether or not the marketing carrier compensates its code-share partner for the costs or the code-share partner takes the burden itself.

Estimated Total Annual Burden: The total first-year burden would be 30,752 hours (62 code-share partners' times 496 hours each). Each year after the first year, the total average burden would be 34,731 hours (higher than the first year to reflect the rate of growth of flights and passengers over the 10 year period of analysis). These estimates likely overestimate the actual costs to some carriers that code-share with multiple partners. Carriers that code-share any flights with more than one code-share partners should experience some efficiencies in the collection, management, and reporting of data regarding those flights for use by multiple code-share partners.

Frequency: Monthly reports for on-time performance and mishandled baggage; quarterly reports for oversales; estimates of burden are annual.

The Department invites interested persons to submit comments on any aspect of each of these two information collections, including the following: (1) The necessity and utility of the information collection, (2) the accuracy of the estimate of the burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) ways to minimize the burden of collection without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized or included, or both, in the request for OMB approval of these information collections.

F. Unfunded Mandates Reform Act

The Department has determined that the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply to this NPRM.

Issued this 21st day of May, 2014, in Washington, DC.

Anthony R. Foxx,

Secretary of Transportation.

List of Subjects

14 CFR Part 234

Air carriers, Consumer protection, Reporting and recordkeeping requirements.

14 CFR Part 244

Air carriers, Consumer protection, Reporting and recordkeeping requirements.

14 CFR Part 250

Air carriers, Consumer protection, Reporting and recordkeeping requirements.

14 CFR Part 255

Air carriers, Antitrust.

14 CFR Part 256

Air carriers, Antitrust.

14 CFR Part 257

Air carriers, Air rates and fares, Consumer protection, Reporting and recordkeeping requirements.

14 CFR Part 259

Air carriers, Air rates and fares, Consumer protection.

14 CFR Part 399

Administrative practice and procedure, Air carriers, Air rates and fares, Air taxis, Consumer protection, Small businesses.

PART 234—[AMENDED]

■ 1. The authority citation for part 234 revised to read as follows:

Authority: 49 U.S.C. 329 and chapters 401 and 417.

■ 2. In § 234.2, the definition of ''reporting carrier'' is revised to read as follows:

§ 234.2 Definitions.

* * * * *

Reporting carrier means an air carrier certificated under 49 U.S.C. 41102 that accounted for at least 0.5 percent of domestic scheduled-passenger revenues in the most recently reported 12-month period as defined by the Department's Office of Airline Information, and as reported to the Department pursuant to Part 241 of this title. Reporting carriers will be identified periodically in accounting and reporting directives issued by the Office of Airline Information.

* * * * *

■ 3. Section 234.3 is revised to read as follows:

§ 234.3 Applicability.

This part applies to certain domestic scheduled passenger flights that are held out to the public by certificated air carriers that account for at least 0.5 percent of domestic scheduled passenger revenues. Certain provisions also apply to voluntary reporting of on-time performance by carriers.

■ 4. Section 234.4 is amended by revising paragraph (a) introductory text and adding paragraph (k) to read as follows:

§ 234.4 Reporting of on-time performance.

(a) Each reporting carrier shall file BTS Form 234 ''On-Time Flight Performance Report'' with the Office of Airline Information of the Department's Bureau of Transportation Statistics on a monthly basis, setting forth the information for each of its reportable flights operated by the reporting carrier and held out to the public on the reporting carrier's Web site and the Web sites of major online travel agencies, or in other generally recognized sources of schedule information. (See also paragraph (k) of this section.)

* * * * *

(k) Each reporting carrier shall file a separate BTS Form 234 ''On-Time Flight Performance Report'' with the Office of Airline Information on a monthly basis, setting forth the information for each of its reportable flights held out with the reporting carrier's code on the reporting carrier's Web site, on the Web sites of major online travel agencies, or in other generally recognized sources of schedule information, including reportable flights operated by any code-share partner that is a certificated air carrier or commuter air carrier. The report shall be made in a form and manner consistent with the requirements set forth in paragraphs (a) through (j) of this section.

■ 5. Section 234.6 is revised to read as follows:

§ 234.6 Baggage-handling statistics.

(a) Each reporting carrier shall report monthly to the Department on a domestic system basis, excluding charter flights, the total number of checked bags, including gate checked baggage, the total number of wheelchairs and scooters transported in the aircraft cargo compartment, the total number of mishandled checked bags, including gate checked baggage, and the number of mishandled wheelchairs and

scooters that were carried in the cargo compartment. Each reporting carrier shall submit a separate monthly report on the mishandled baggage, wheelchairs and scooters as described above for all domestic scheduled passenger flight segments that are held out with the reporting carrier's code on the reporting carrier's Web site, on the Web sites of major online travel agencies, or in other generally recognized sources of schedule information, including flights operated by code-share partners that are certificated air carriers or commuter air carriers. For flights operated by a code-share partner that also carry passengers ticketed under another carrier's code, the reporting carrier shall only report baggage information applicable to passengers ticketed under its own code.

(b) This information shall be submitted to the Department within 15 days after the end of the month to which the information applies and must be submitted with the transmittal letter accompanying the data for on-time performance in the form and manner set forth in accounting and reporting directives issued by the Director, Office of Airline Information.

PART 244—[AMENDED]

■ 6. The authority citation for part 244 continues to read as follows:

Authority: 49 U.S.C. 40101(a)(4), 40101(a)(9), 40113(a), 41702, and 41712.

■ 7. Section 244.2 is amended by revising the last sentence of paragraph (a) to read as follows:

§ 244.2 Applicability.

(a) * * * Covered carriers must report all passenger operations that experience a tarmac time of more than 3 hours at a U.S. airport.

* * * * *

■ 8. Section 244.3 is amended by revising paragraph (a) to read as follows:

§ 244.3 Reporting of tarmac delay data.

(a) Each covered carrier shall file BTS Form 244 ''Tarmac Delay Report'' with the Office of Airline Information of the Department's Bureau of Transportation Statistics setting forth the information for each of its covered flights that experienced a tarmac delay of more than 3 hours, including diverted flights and cancelled flights on which the passengers were boarded and then deplaned before the cancellation. The reports are due within 15 days after the end of any month during which the carrier experienced any reportable tarmac delay of more than 3 hours at a U.S. airport.

* * * * *

PART 250—[AMENDED]

■ 9. The authority citation for part 250 is revised to read as follows:

Authority: 49 U.S.C. chapters 401, 411, 413 and 417.

■ 10. Section 250.2b is amended by revising paragraph (c) to read as follows:

§ 250.2b Carriers to request volunteers for denied boarding.

* * * * *

(c) If a carrier offers free or reduced rate air transportation as compensation to volunteers, the carrier must disclose all material restrictions, including but not limited to administrative fees, advance purchase or capacity restrictions, and blackout dates applicable to the offer before the passenger decides whether to give up his or her confirmed reserved space on the flight in exchange for the free or reduced rate transportation. If the free or reduced rate air transportation is offered orally to potential volunteers, the carrier shall also orally provide a brief description of the material restrictions on that transportation at the same time that the offer is made.

■ 11. Section 250.5 is amended by adding a sentence at the end of paragraph (c)(3) to read as follows:

§ 250.5 Amount of denied boarding compensation for passengers denied boarding involuntarily.

* * * * *

(c) * * * (See also section 250.9(c)).

* * * * *

■ 12. Section 250.10 is revised to read as follows:

§ 250.10 Report of passengers denied confirmed space.

(a) Each reporting carrier as defined in § 234.2 of this chapter and any carrier that voluntarily submits data pursuant to § 234.7 of this chapter shall file, on a quarterly basis, the information specified in BTS Form 251. The reporting basis shall be flight segments originating in the United States operated by the reporting carrier. The reports must be submitted within 30 days after the end of the quarter covered by the report. The calendar quarters end March 31, June 30, September 30 and December 31. ''Total Boardings'' on Line 7 of Form 251 shall include only passengers on flights for which confirmed reservations are offered. Data shall not be included for inbound international flights.

(b) Each reporting carrier and voluntary reporting carrier shall file a separate BTS Form 251 for all flight segments originating in the United States operated under the reporting carrier's code, including flight segments operated by a code-share partner that is a certificated air carrier or commuter air carrier using aircraft that have a designed passenger capacity of 30 or more seats. For code-share flight segments that also carry passengers ticketed under another carrier's code, the reporting carrier shall only report information applicable to passengers ticketed under its own code.

PART 255—[REMOVED AND RESERVED]

■ 13. Under the authority of 49 U.S.C. chapters 401 and 417, part 255 is removed and reserved.

■ 14. Part 256 is added to read as follows:

PART 256—ELECTRONIC AIRLINE INFORMATION SYSTEMS

Sec.
256.1 Purpose.
256.2 Applicability.
256.3 Definitions.
256.4 Accurate EAIS display of information and prohibition of undisclosed display bias.
256.5 Prohibition against inducing undisclosed bias.

Authority: 49 U.S.C. chapters 401 and 417.

§ 256.1 Purpose.

(a) The purpose of this part is to set forth requirements for the operation of electronic airline information systems that provide air carrier or foreign air carrier schedule, fare, rule, or availability information, including, but not limited to, global distribution systems (GDSs) and Internet flight search engines, for use by consumers, carriers, ticket agents, and other business entities as well as for related air transportation distribution practices so as to prevent unfair and deceptive practices in the distribution and sale of air transportation.

(b) Nothing in this part exempts any person from the operation of the antitrust laws set forth in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12).

§ 256.2 Applicability.

(a) This part applies to any air carrier, foreign air carrier, or ticket agent that:

(1) Creates or develops the content of an electronic airline information system that combines the schedules, fares, rules, or availability information of more than one air carrier or foreign air carrier for the distribution or sale in the United States of interstate and foreign air transportation; or

(2) Operates an electronic airline information system, e.g., GDS or Internet flight search tool.

(b) This part applies only if the electronic airline information system is displayed on a Web site marketed to consumers in the United States or on a proprietary display available to travel agents, business entities, or a limited segment of consumers of air transportation in the United States.

§ 256.3 Definitions.

For purposes of this part,

(a) *Lowest fare generally available* means the lowest price offered for air transportation between designated points including all mandatory taxes and fees but not ancillary fees for optional services. The term does not cover fares restricted to a limited category of travelers, (e.g., negotiated corporate or government fares or discount fares available only to travel agents).

(b) *Availability* means information provided in displays with respect to the seats a carrier holds out as available for sale on a particular flight.

(c) *Display* means the presentation of air carrier or foreign air carrier schedules, fares, rules or availability to a consumer or agent or other individual involved in arranging air travel for a consumer by means of a computer or mobile computing device.

(d) *Integrated display* means any display that includes the schedules, fares, rules, or availability of more than one carrier.

(e) *Listed carrier* means an air carrier or foreign air carrier whose schedules, fares, or availability is included in an electronic airline information system.

(f) *Electronic airline information system or EAIS* means a system that combines air carrier or foreign air carrier schedule, fare, rule, or availability information for transmission or display to air carriers or foreign air carriers, ticket agents, other business entities, or consumers. It includes direct connections between a ticket agent and the internal reservations systems of an individual carrier if the direct connection provides schedules, fares, rules, or availability of more than one air carrier or foreign air carrier (unless all of the listed carriers are under the same ownership or the individual carrier's direct connection only provides information on flights operated under its own code).

§ 256.4 Accurate EAIS display of information and prohibition of undisclosed display bias.

Each air carrier, foreign air carrier, and ticket agent that operates an EAIS that provides at least one integrated display must comply with the requirements of this section.

(a) Each EAIS shall display accurately all schedule, fare, rules, and availability information provided by or on behalf of listed carriers or obtained from third parties by the EAIS operator.

(b) Each EAIS that uses any factors directly or indirectly relating to carrier identity in ordering the information contained in an integrated display must clearly disclose that the identity of the carrier is a factor in the order in which information is displayed.

(c) Undisclosed display bias in an integrated display is prohibited.

(1) Each EAIS's integrated display must use the same editing and ranking criteria for each listed carrier's flights and must not give any listed carrier's flights a system-imposed preference over any other listed carrier's flights unless the preference is prominently disclosed.

(2) EAISs may organize information on the basis of any service criteria that do not reflect carrier identity provided that the criteria are consistently applied to all carriers and to all markets. Unless any display bias is specifically and prominently disclosed, when providing information in response to a search by a user of the EAIS, the EAIS must order the information provided so that the lowest fare generally available that best satisfies the parameters of the request (e.g., date and time of travel, number of passengers, class of service, stopovers, limitations on carriers to be used or routing [e.g., nonstop only], etc.) is displayed conspicuously and no less prominently than any other fare displayed. To the extent the user (e.g., consumer or travel agent) is entitled to access to any fares restricted to a limited category of travelers, the lowest of those fares must also be displayed conspicuously and no less prominently than any other fare displayed.

§ 256.5 Prohibition against inducing undisclosed bias.

(a) No air carrier, foreign carrier, or ticket agent may induce or attempt to induce the developer or operator of an EAIS to create a display that would not comply with the requirements of § 256.4 of this part or provide inaccurate schedule, fare, rules, or availability information that would result in a display that would not comply with the requirements of § 256.4.

(b) Nothing in this section requires an air carrier, foreign air carrier, or ticket agent to allow a system to access its internal computer reservation system or to permit ''screen scraping'' or ''content scraping'' of its Web site; nor does it require an air carrier or foreign air carrier to permit the sale of the carrier's services through any ticket agent or other carrier's system. ''Screen scraping'' refers to a process whereby a company uses computer software techniques to extract information from other companies' Web sites. In the travel industry, screen scraping companies generally extract schedule and fare information from the Web sites of airlines or online travel agencies (OTAs) in order to display the lowest rates on their own Web site and eliminate the need for consumers to compare offerings from site to site.

PART 257—[AMENDED]

■ 15. The authority citation for part 257 continues to read as follows:

Authority: 49 U.S.C. 40113(a) and 41712.

§ 257.3 [Amended]

■ 16. In § 257.3, paragraph (g) is amended by removing the term ''transporting carrier'' and adding ''operating carrier'' in its place.

■ 17. Section 257.5 is revised to read as follows:

§ 257.5 Notice requirement.

(a) *Notice in flight itineraries and schedules.* Each air carrier, foreign air carrier, or ticket agent providing flight itineraries and/or schedules for scheduled passenger air transportation to the public in the United States shall ensure that each flight segment on which the designator code is not that of the operating carrier is clearly and prominently identified and contains the following disclosures.

(1) In flight schedule information provided to U.S. consumers on desktop browser-based or mobile browser-based Internet Web sites or applications in response to any requested itinerary search, for each flight in scheduled passenger air transportation that is operated by a carrier other than the one listed for that flight, the corporate name of the transporting carrier and any other name under which the service is held out to the public must appear prominently in text format on the first display following the input of a search query, immediately adjacent to each code-share flight in that search-results list. Roll-over, pop-up and linked disclosures do not comply with this paragraph.

(2) For static written schedules, each flight in scheduled passenger air transportation that is operated by a carrier other than the one listed for that flight shall be identified by an asterisk or other easily identifiable mark that leads to disclosure of the corporate

name of the operating carrier and any other name under which that service is held out to the public.

(b) *Notice in oral communications with prospective consumers.* In any direct oral communication in the United States with a prospective consumer, and in any telephone call placed from the United States by a prospective consumer, concerning a flight within, to, or from the United States that is part of a code-sharing arrangement or long-term wet lease, a ticket agent doing business in the United States or a carrier shall inform the consumer, the first time that such a flight is offered to the consumer, that the operating carrier is not the carrier whose name or designator code will appear on the ticket and shall identify the transporting carrier by its corporate name and any other name under which that service is held out to the public.

(c) *Notice in ticket confirmations.* At the time of purchase, each selling carrier or ticket agent shall provide written disclosure of the actual operator of the flight to each consumer of scheduled passenger air transportation sold in the United States that involves a code-sharing arrangement or long-term wet lease. For any flight segment on which the designator code is not that of the operating carrier the notice shall state ''Operated by'' followed by the corporate name of the transporting carrier and any other name in which that service is held out to the public. In the case of single-flight-number service involving a segment or segments on which the designator code is not that of the transporting carrier, the notice shall clearly identify the segment or segments and the operating carrier by its corporate name and any other name in which that service is held out to the public. The following form of statement will satisfy the requirement of this paragraph (c): *Important Notice: Service between XYZ City and ABC City will be operated by Jane Doe Airlines d/b/a QRS Express.* At the purchaser's request, the notice required by this part may be delivered in person, or by fax, electronic mail, or any other reliable method of transmitting written material.

(d) In any written advertisement distributed in or mailed to or from the United States (including those that appear on an Internet Web site that is marketed to consumers in the United States) for service in a city-pair market that is provided under a code-sharing arrangement or long-term wet lease, the advertisement shall prominently disclose that the advertised service may involve travel on another carrier and clearly indicate the nature of the service in reasonably sized type and shall identify all potential operating carriers involved in the markets being advertised by corporate name and by any other name under which that service is held out to the public. In any radio or television advertisement broadcast in the United States for service in a city-pair market that is provided under a code-sharing or long-term wet lease, the advertisement shall include at least a generic disclosure statement, such as ''Some flights are operated by other airlines.''

PART 259—[AMENDED]

■ 18. The authority citation for part 259 continues to read as follows:

Authority: 49 U.S.C. 40101(a)(4), 40101(a)(9), 40113(a), 41702, and 41712.

■ 19. Section 259.4 is amended by revising paragraph (f) to read as follows:

§ 259.4 Contingency Plan for Lengthy Tarmac Delays.

* * * * *

(f) *Civil penalty.* A carrier's failure to comply with the assurances required by this section and contained in its Contingency Plan for Lengthy Tarmac Delays will be considered to be an unfair and deceptive practice within the meaning of 49 U.S.C. 41712 with respect to each affected passenger and therefore a separate violation for each passenger for each unfulfilled assurance under 49 U.S.C. 46301.

■ 20. Section 259.8 is amended by revising the second sentence in paragraph (a) introductory text and paragraph (a)(1) to read as follows:

§ 259.8 Notify consumers of known delays, cancellations, and diversions.

(a) * * * A change in the status of a flight means, at a minimum, a cancellation, diversion or delay of 30 minutes or more in the planned operation of a flight that occurs within seven calendar days of the scheduled date of the planned operation. * * *

(1) With respect to any U.S. air carrier or foreign air carrier that permits passengers and other interested persons to subscribe to flight status notification services, the carrier must deliver such notification to such subscribers, by whatever means the carrier offers that the subscriber chooses. * * *

PART 399—[AMENDED]

■ 21. The authority citation for part 399 is revised to read as follows:

Authority: 49 U.S.C. 40101 *et seq.*

■ 22. Section 399.80 is amended by:

■ a. Revising the introductory text;

■ b. Removing and reserving paragraph (h);

■ c. Revising paragraph (1);

■ d. Adding paragraphs (o), (p), (q), and (r); and

■ e. Revising paragraph (s).

The revisions and additions read as follows:

§ 399.80 Unfair and deceptive practices of ticket agents.

It is the policy of the Department to regard the practices enumerated in paragraphs (a) through (m) of this section by a ticket agent of any size and the practices enumerated in paragraphs (o) through (r) of this section by a ticket agent that sells air transportation and has annual revenue of $100 million or more as an unfair or deceptive practice or unfair method of competition:

* * * * *

(l) Failing or refusing to make proper refunds promptly when service cannot be performed as contracted or representing that such refunds are obtainable only at some other point, thus depriving persons of the timely use of the money to arrange other transportation, or forcing them to suffer unnecessary inconvenience and delay or requiring them to accept transportation at higher cost, or under less desirable circumstances, or on less desirable aircraft than that represented at the time of sale. For purposes of this subsection ''promptly'' means processing a credit card refund (e.g., forwarding a credit to the merchant bank) within seven business days and a cash, check or debit card refund within 20 days. These deadlines are calculated from the time that the ticket agent receives all information from the consumer that is necessary to process the refund. The ticket agent must request any missing information without delay. A ticket agent's need to collect information from its own records does not suspend these deadlines.

* * * * *

(o) Failure to hold a reservation at the quoted fare without payment or to permit it to be cancelled without penalty for at least 24 hours after the reservation is made if the reservation is made one week or more prior to a flight's departure. (The ticket agent may choose between these two methods; it need not offer both options to consumers.)

(p) Failure to disclose cancellation policies applicable to a consumer's selected flights, the aircraft's seating configuration, and lavatory availability on the aircraft on its Web site, and upon request, from the telephone reservations staff.

(q) Failure to notify consumers in a timely manner of carrier-initiated changes to the consumer's air travel itinerary about which the carrier notifies

the agent or about which the agent becomes aware through other means.

(r) Failure to respond to consumer problems by acknowledging receipt of a consumer complaint within thirty days of receiving the complaint and sending a substantive written response within sixty days of receiving the complaint. If all or part of the complaint is about services furnished (or to be furnished) by an airline or other travel supplier, the agent must send the complaint to that supplier for response. If no part of the complaint is about the agent's service and the agent sends the complaint to the appropriate suppliers, the agent's substantive reply can consist of advising the consumer where the agent has sent the complaint and why.

(s) As used in this subpart G and in 14 CFR parts 257 and 258, ''Air carrier'', ''foreign air carrier'', and ''ticket agent'' have the same definitions as set forth in 49 U.S.C. 40102. The term ''person . . . arranging for [,] air transportation'' as set forth in the definition of ''ticket agent'' in section 40102(40) includes any person that acts as an intermediary involved in the sale of air transportation directly or indirectly to consumers, including by operating an electronic airline information system, if the person holds itself out as a source of information about, or reservations for, the air transportation industry and receives compensation in any way related to the sale of air transportation (e.g., cost-per-click for air transportation advertisements, commission payment, revenue-sharing, or other compensation based on factors such as the number of flight segments booked, number of sales made, or number of consumers directed or referred to an air carrier, foreign air carrier, or ticket agent for the sale of air transportation). The term does not include persons who only publish advertisements of fares and are paid only per click for linking consumers to the Web sites of the carriers or agents that provided the advertisement.

■ 23. Section 399.85 is amended by revising paragraphs (a), (b), and (c) to read as follows:

§ 399.85 Notice of baggage fees and other fees.

(a) If a U.S. or foreign air carrier has a Web site marketed to U.S. consumers where it advertises or sells air transportation, the carrier must promptly and prominently disclose any increase in its fee for carry-on or first and second checked bags and any change in the first and second checked bags or carry-on allowance for a passenger on the homepage of that Web site (e.g., provide a link that says ''changed bag rules'' or similarly descriptive language that takes the consumer from the homepage directly to a pop-up or a place on another Web page that details the change in baggage allowance or fees and the effective dates of such changes).

(b) All U.S. and foreign air carriers and ticket agents must disclose the current ancillary services fees for a first and second checked bag, for a carry-on bag, and for an advance seat assignment to a consumer who requests such information. On Web sites marketed to the general public in the U.S., the fees for a first checked bag, a second checked bag, one carry-on bag, and an advance seat assignment must be disclosed (and at a minimum displayed by a link or rollover) at the first point in a search process where a fare is listed in response to a specific flight itinerary request from a passenger, and on the summary page provided to the consumer at the completion of any purchase.

(c) On all e-ticket confirmations for air transportation within, to or from the United States, including the summary page at the completion of an online purchase and a post-purchase email confirmation, an air carrier, foreign air carrier, agent of either, or ticket agent that advertises or sells air transportation in the United States must include information regarding the passenger's free baggage allowance and/or the applicable fee for a carry-on bag and the first and second checked bag, including size and weight limitations. Carriers and agents must provide this information in text form in the e-ticket confirmation.

* * * * *

■ 24. Section 399.88 is amended by revising paragraph (a) to read as follows:

§ 399.88 Prohibition on post-purchase price increases.

(a) It is an unfair and deceptive practice within the meaning of 49 U.S.C. 41712 for any seller of scheduled air transportation within, to or from the United States, or of a tour (i.e., a combination of air transportation and ground or cruise accommodations), or tour component (e.g., a hotel stay) that includes scheduled air transportation within, to, or from the United States, to increase the price of that air transportation, tour or tour component to a consumer, including but not limited to an increase in the price of the airfare, an increase in the price for the carriage of passenger baggage, or an increase in an applicable fuel surcharge, after the air transportation has been purchased by the consumer, except in the case of an increase in a government-imposed tax or fee. A purchase is deemed to have occurred when the full amount agreed upon for the air transportation has been paid by the consumer. An itinerary that does not begin or end in the United States or include a stopover of 24 hours or more in the United States is not considered air transportation for purposes of this section. This prohibition on a post-purchase price increase extends to all mandatory fees and charges a consumer must pay in order to obtain air transportation and to fees associated with transporting baggage. This prohibition does not extend to fees for optional services ancillary to air transportation that are not purchased with the ticket except for baggage. The price for other ancillary services not purchased at the time of ticket purchase may be increased until the consumer purchases the service itself.

* * * * *

■ 25. Section 399.90 is added to subpart G to read as follows:

Option A

§ 399.90 Transparency in airline pricing, including ancillary fees

(a) The purpose of this section is to ensure that air carriers, foreign air carriers and ticket agents doing business in the United States clearly disclose to consumers at all points of sale the fees for certain basic ancillary services associated with the air transportation consumers are buying or considering buying. Nothing in this section should be read to require that these ancillary services must be transactable (e.g., purchasable online).

(b) Each air carrier and foreign air carrier shall provide useable, current, and accurate information for certain ancillary service fees to all ticket agents that receive and distribute the U.S. or foreign carrier's fare, schedule, and availability information. For purposes of this section, the fees that must be provided are: fees for a first checked bag, a second checked bag, one carry-on bag, and an advance seat assignment. Fees for an advance assignment to a seat adjacent to a window or aisle, bulkhead seat, exit row seat, or any other seat for which a consumer must pay an additional fee to receive an advance seat assignment are to be provided.

(c) Each ticket agent that provides a U.S. or foreign carrier's fare, schedule, and availability information to consumers in the United States must disclose the U.S. or foreign carrier's fees for a first checked bag, a second checked bag, one carry-on bag, and an advance seat assignment. The fee information disclosed to consumers for these ancillary services must be expressed as itinerary-specific charges. ''Itinerary-

specific'' refers to variations in fees that depend on, for example, geography, travel dates, cabin (e.g., first class, economy), ticketed fare (e.g., full fare ticket -Y class), and, in the case of advance seat assignment, the particular seat on the aircraft if different seats on that flight entail different charges. Ticket agents must also disclose that advance seat assignment and baggage fees may be reduced or waived based on the passenger's frequent flyer status, method of payment or other characteristic. When providing the fees associated with advance seat assignments, ticket agents must also disclose that seat availability and fees may change at any time until the seat assignment is purchased.

(d) Each U.S. or foreign air carrier that provides its fare, schedule and availability information directly to consumers in the United States must also disclose its fees for a first checked bag, a second checked bag, one carry-on bag, and an advance seat assignment. The fee information disclosed to a consumer for these ancillary services must be expressed as customer-specific charges if the consumer elects to provide his or her personal information to the carrier, such as name and frequent flyer number. ''Customer-specific'' refers to variations in fees that depend on, for example, the passenger type (e.g., military), frequent flyer status, method of payment, geography, travel dates, cabin (e.g., first class, economy), ticketed fare (e.g., full fare ticket -Y class), and, in the case of advance seat assignment, the particular seat on the aircraft if different seats on that flight entail different charges. If a consumer does not provide his or her personal information and submits an anonymous shopping request, the fee information disclosed to that consumer for these ancillary services must be expressed as itinerary-specific charges.

(e) If a U.S. or foreign air carrier or ticket agent has a Web site marketed to U.S. consumers where it advertises or sells air transportation, the carrier and ticket agent must disclose the fees for a first checked bag, a second checked bag, one carry-on bag, and an advance seat assignment as specified in paragraphs (c) and (d) of this section at the first point in a search process where a fare is listed in connection with a specific flight itinerary. Carriers and ticket agents may permit a consumer to opt out of seeing this basic ancillary fee information so that the consumer will see only fares. The opt-out option must not be pre-selected and must notify the consumer that fees may include charges for a first and second checked bag (including oversize and overweight charges), a carry-on bag, and an advance seat assignment.

(f) In any oral communication with a prospective consumer and in any telephone calls placed from the United States, the carrier or ticket agent must inform a consumer, upon request, of the fees for a first checked bag, a second checked bag, one carry-on bag, and an advance seat assignment as specified in paragraphs (c) and (d) of this section.

(g) Ticket agents with an existing contractual agreement with an air carrier or foreign air carrier for the distribution of that carrier's fare and schedule information shall not charge separate or additional fees for the distribution of the ancillary service fee information described in paragraph (b) of this section. Nothing in this paragraph should be read as invalidating any provision in an existing contract among these parties with respect to compensation.

(h) Failure of an air carrier or foreign carrier to provide the ancillary fee information as described in paragraph (b) of this section to its ticket agents and failure of a U.S. carrier, foreign carrier, or ticket agent to provide the information to consumers as described in paragraph (c) and (d) of this section will be considered an unfair and deceptive practice in violation of 49 U.S.C. 41712.

Option B

§ 399.90 Transparency in airline pricing, including ancillary fees.

(a) The purpose of this section is to ensure that air carriers, foreign air carriers doing business in the United States, and ticket agents doing business in the United States and selling a carrier's tickets directly to consumers clearly disclose to consumers at all points of sale the fees for certain basic ancillary services associated with the air transportation consumers are buying or considering buying. Nothing in this section should be read to require that these ancillary services must be transactable (e.g., purchasable online).

(b) Each air carrier and foreign air carrier shall provide useable, current, and accurate information for certain ancillary service fees to all ticket agents that receive and distribute the U.S. or foreign carrier's fare, schedule, and availability information, and sell that carrier's tickets directly to consumers. For purposes of this section, the fees that must be provided are: fees for a first checked bag, a second checked bag, one carry-on bag, and an advance seat assignment. Fees for an advance assignment to a seat adjacent to a window or aisle, bulkhead seat, exit row seat, or any other seat for which a consumer must pay an additional fee to receive an advance seat assignment are to be provided.

(c) Each ticket agent that provides a U.S. or foreign carrier's fare, schedule, and availability information to consumers in the United States and sells that carrier's tickets directly to consumers must provide the U.S. or foreign carrier's fees for a first checked bag, a second checked bag, one carry-on bag, and an advance seat assignment. The fee information disclosed to consumers for these ancillary services must be expressed as itinerary-specific charges. ''Itinerary-specific'' refers to variations in fees that depend on, for example, geography, travel dates, cabin (e.g., first class, economy), ticketed fare (e.g., full fare ticket -Y class), and, in the case of advance seat assignment, the particular seat on the aircraft if different seats on that flight entail different charges. Ticket agents that sell the carrier's tickets directly to consumers must also disclose that advance seat assignment and baggage fees may be reduced or waived based on the passenger's frequent flyer status, method of payment or other characteristic. When providing the fees associated with advance seat assignments, such ticket agents must also disclose that seat availability and fees may change at any time until the seat assignment is purchased.

(d) Each U.S. or foreign air carrier that provides its fare, schedule and availability information directly to consumers in the United States must also provide its fees for a first checked bag, a second checked bag, one carry-on bag, and an advance seat assignment. The fee information disclosed to a consumer for these ancillary services must be expressed as customer-specific charges if the consumer elects to provide his or her personal information to the carrier, such as name and frequent flyer number. ''Customer-specific'' refers to variations in fees that depend on, for example, the passenger type (e.g., military), frequent flyer status, method of payment, geography, travel dates, cabin (e.g., first class, economy), ticketed fare (e.g., full fare ticket -Y class), and, in the case of advance seat assignment, the particular seat on the aircraft if different seats on that flight entail different charges. If a consumer does not provide his or her personal information and submits an anonymous shopping request, the fee information disclosed to that consumer for these ancillary services must be expressed as itinerary-specific charges.

(e) If a U.S. or foreign air carrier, or ticket agent that sells such a carrier's

tickets directly to consumers, has a Web site marketed to U.S. consumers where it advertises or sells air transportation, the carrier and ticket agent must disclose the fees for a first checked bag, a second checked bag, one carry-on bag, and an advance seat assignment as specified in paragraphs (c) and (d) of this section at the first point in a search process where a fare is listed in connection with a specific flight itinerary. Carriers and ticket agents may permit a consumer to opt out of seeing this basic ancillary fee information so that the consumer will see only fares. The opt-out option must not be pre-selected and must notify the consumer that fees may include charges for a first and second checked bag (including oversize and overweight charges), a carry-on bag, and an advance seat assignment.

(f) In any oral communication with a prospective consumer and in any telephone calls placed from the United States, the carrier and ticket agent that sells that carrier's tickets directly to consumers must inform a consumer, upon request, of the fees for a first checked bag, a second checked bag, one carry-on bag, and an advance seat assignment as specified in paragraphs (c) and (d) of this section.

(g) Ticket agents that sell a carrier's tickets directly to consumers and have an existing contractual agreement with an air carrier or foreign air carrier for the distribution of that carrier's fare and schedule information shall not charge separate or additional fees for the distribution of the ancillary service fee information described in paragraph (b) of this section. Nothing in this paragraph should be read as invalidating any provision in an existing contract among these parties with respect to compensation.

(h) Failure of an air carrier or foreign carrier to provide the ancillary fee information as described in paragraph (b) of this section to its ticket agents and failure of a U.S. carrier, foreign carrier, or ticket agent to provide the information to consumers as described in paragraph (c) and (d) of this section will be considered an unfair and deceptive practice in violation of 49 U.S.C. 41712.

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