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FEDERAL REGISTER

Vol. 80 Friday,

No. 219 November 13, 2015

Pages 70149–70668

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–1140; Airspace Docket No. 15–AWP–5]

Revocation of Class E Airspace; Burbank, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action removes Class E surface area airspace designated as an extension to Class C airspace at Burbank-Glendale-Pasadena Airport, Burbank, CA. After reviewing the airspace, the FAA found no standard instrument approach procedures requiring Class E surface area airspace designated as an extension to the Class C airspace. This action enhances the safety and airspace management within the National Airspace System.

DATES: Effective 0901 UTC, February 4, 2016. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy and ATC Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 29591; telephone: 202–267–8783. The Order is also available for inspection at 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.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Steve Haga, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4500.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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 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 removes controlled airspace designated as an extension at Burbank-Glendale-Pasadena Airport, Burbank, CA.

History

On August 19, 2015, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to remove Class E surface area airspace designated as an extension to Class C airspace at Burbank-Glendale-Pasadena Airport, Burbank, CA (80 FR 50237). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment was received from Jeffrey Aryan, in support of the proposal.

Class E airspace designations are published in paragraph 6003 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, 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.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 removes Class E airspace designated as an extension to Class C airspace at Burbank-Glendale-Pasadena Airport, Burbank, CA. A review of the airspace revealed that there are no standard instrument approach procedures in place requiring Class E surface area airspace designated as an extension to the Class C airspace, and, therefore, is removed from FAA Order 7400.9Z.

Regulatory Notices and Analyses

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. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist

that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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 continues to read as follows:

Authority: 49 U.S.C. 106(f), 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 FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 6003 Class E Airspace Areas Designated as an Extension.

* * * * *

AWP CA E3 Burbank-Glendale-Pasadena Airport, CA [Removed]

Issued in Seattle, Washington, on November 3, 2015.

Christopher Ramirez,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2015–28785 Filed 11–12–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–2890; Airspace Docket No. 15–ASO–8]

Establishment of Class E Airspace; Placida, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E Airspace at Placida, FL, to accommodate new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedures (SIAPs) serving Coral Creek Airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, December 10, 2015. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *http://www.faa.gov/airtraffic/publications/.* For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at 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.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

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:

Authority for This Rulemaking

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 airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace at Coral Creek Airport, Placida, FL.

History

On August 14, 2015, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish Class E airspace extending upward from 700 feet above the earth at Coral Creek Airport, Placida, FL, (80 FR 48767). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9Z dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class E airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Coral Creek Airport, Placida, FL., providing the controlled airspace required to support the new RNAV (GPS) standard instrument approach procedures for Coral Creek Airport.

Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, 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.

Regulatory Notices and Analyses

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, is non-controversial and unlikely to result in adverse or negative comments. 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 only affects air traffic procedures and air navigation, it is

certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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 continues to read as follows:

Authority: 49 U.S.C. 106(f), 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 FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

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

* * * * *

ASO FL E5 Placida, FL [NEW]

Coral Creek Airport, FL
(Lat. 26°51′13″ N., long. 82°15′09″ W.)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Coral Creek Airport.

Issued in College Park, Georgia, on October 27, 2015.

Ryan W. Almasy,

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

[FR Doc. 2015–28782 Filed 11–12–15; 8:45 am]

BILLING CODE 4910–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1204

[Docket Number—NASA–2015–0009]

RIN 2700–AE24

NASA Protective Services Enforcement

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Direct final rule.

SUMMARY: This direct final rule makes nonsubstantive changes to NASA's traffic enforcement regulations to correct citations and to clarify the regulation's scope, policy, responsibilities, procedures, and violation descriptions. The revisions to this rule are part of NASA's retrospective plan under E.O. 13563 completed in August 2011.

DATES: *This rule is effective* January 12, 2016 without further action, unless adverse comments are received by December 14, 2015. If adverse comments are received, NASA will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: Comments must be identified with RIN 2700–AE24 and may be sent to NASA via the *Federal E-Rulemaking Portal*: *http://www.regulations.gov.* Follow the online instructions for submitting comments. Please note that NASA will post all comments on the Internet with changes, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Charles Lombard, 202–358–0891, *charles.e.lombard.nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Direct Final Rule and Significant Adverse Comments

NASA has determined this rulemaking meets the criteria for a direct final rule because it makes nonsubstantive changes to correct citations and clarifies the scope, policy, responsibilities, procedures, and violations described in NASA's traffic enforcement regulations. No opposition to these changes and no significant adverse comments are expected. However, if NASA receives significant adverse comments, it will withdraw this direct final rule by publishing a notice in the **Federal Register**. A significant adverse comment is one that explains: (1) Why the direct final rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of this direct final rule, NASA will consider whether it warrants a substantive response in a notice and comment process.

II. Background

NASA published a final rule in the **Federal Register** at 79 FR 54902 on September 15, 2014, to add subpart 11, Enforcing Traffic Laws at NASA Centers and Component Facilities, that establishes traffic enforcement regulations, authorities, and procedures at all NASA Centers and component facilities. NASA is amending these regulations to make nonsubstantive changes to correct citations and to clarify the scope, policy, responsibilities, procedures, and violations described in these regulations. Amendments to this rule aligns Part 1204 with NASA objectives in the protection of its people and property. The revisions to this rule are part of NASA's retrospective plan under E.O. 13563 completed in August 2011. NASA's full plan can be accessed on the Agency's open Government Web site at *http://www.nasa.gov/feature/compliance-and-other-documents.*

III. Regulatory Analysis Section

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This rule would not have a significant economic impact on a substantial number of small entities because this rule only pertains to NASA employees.

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select the regulatory approach that maximizes net benefits. This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, because this rule relates solely to the internal operations of NASA. Therefore, the Office of Management and Budget did not review this rule.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply to this

rule because it does not contain any information collection requirement that requires approval of the Office of Management and Budget.

Small Business Regulatory Enforcement Fairness Act

This rule relates to agency management or personnel, and therefore the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) does not cover the rule.

Executive Order 13132, Federalism

This rule will not have substantial direct effects on the states, on the relationship between the national Government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, Federalism, NASA has determined that the rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Unfunded Mandates Reform Act

For the purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), this rule would not significantly or uniquely affect small governments and would not result in increased expenditures by state, local, and tribal governments, or by the private sector, of $100 million or more (as adjusted for inflation) in any one year.

List of Subjects in 14 CFR Part 1204

Federal buildings and facilities, Security measures.

Accordingly, under the authority of the National Aeronautics and Space Act, as amended, (51 U.S.C. 20113), 5 U.S.C. 301, and 18 U.S.C. 799, NASA amends 14 CFR part 1204 as follows:

PART 1204—ADMINISTRATIVE AUTHORITY AND POLICY

Subpart 11—Enforcing Traffic Laws at NASA Centers and Component Facilities

■ 1. The authority for subpart 11 is revised to read as follows:

Authority: The National and Commercial Space Program, 51 U.S.C. 20132 and 20133; 5 U.S.C. 301, and 18 U.S.C. 799.

■ 2. Revise § 1204.1100 to read as follows:

§ 1204.1100 Scope of subpart.

This subpart establishes policies pursuant to the requirements of National and Commercial Space Programs (51 U.S.C.) authorizing the NASA Administrator to establish such security requirements, restrictions, and safeguards as he deems necessary in the interest of national security, under 5 U.S.C. 301, and 18 U.S.C. 799, providing for the imposition of fines and imprisonment for violating NASA regulations for the protection and security of NASA assets or assets that are in NASA's custody. The provisions of this subpart apply to all NASA installations, including NASA Headquarters, NASA Centers, and component facilities. NASA installations refers to all NASA-owned, controlled, or leased property, with exclusive or concurrent Federal jurisdiction, including non-contiguous or unfenced areas and including areas otherwise open to the public at large. These provisions are also applicable to all persons who are in or on a NASA installation over which the United States exercises exclusive or concurrent legislative jurisdiction.

■ 3. Revise § 1204.1101 to read as follows:

§ 1204.1101 Policy.

(a) It is NASA policy that an effective, standardized, and comprehensive traffic safety program be established and maintained at all NASA Centers, and component facilities, as prescribed in NASA Procedural Requirement (NPR) 8715.C, NASA General Safety Program Requirements. A traffic safety program is essential for the protection and security of NASA laboratories, stations, bases, or other facilities of NASA's aircraft, missiles, spacecraft, or similar vehicles or part thereof and of NASA's real and personal property, including property in the custody of NASA contractors and subcontractors.

(b) To ensure a safe and secure workplace and to provide better for preservation of life and property, all persons on or in a NASA installation or component facility shall comply with the vehicular and pedestrian traffic requirements of the installation per this Subpart.

(c) *Vehicular and pedestrian traffic.* The following requirements apply to the drivers or all vehicles on or in NASA-owned, controlled, or leased property:

(1) A driver shall be in possession of a current and valid state- or territory-issued driver's license and vehicle registration, and the vehicle shall display all current and valid tags and licenses required by the jurisdiction in which it is registered.

(2) A driver who has had his or her privilege or license to drive suspended or revoked by any state or territory shall not drive any vehicle in or on such property during such period of suspension or revocation.

(3) Drivers shall drive in a careful and safe manner at all times and shall comply with the signals and directions of security personnel and other authorized individuals; all posted traffic signs, including speed limits; and all rules implemented under section 1204.1102.

(4) Drivers shall not block entrances, driveways, walks, loading platforms, or fire hydrants.

(5) Drivers shall not park without authority, park in unauthorized locations or in locations reserved for other persons, park continuously in excess of 18 hours without permission, or park in any manner contrary to the direction of posted signs.

(d) A copy of this subpart shall be posted in an appropriate place at each NASA Center or component facility.

■ 4. In § 1204.1102, revise paragraph (a) to read as follows:

§ 1204.1102 Responsibilities.

(a) Consistent with this subpart and applicable statutes, Center Directors of NASA installations and the Executive Director for Headquarters Operations, over which the United States has exclusive or concurrent legislative jurisdiction, are delegated the authority to establish specific vehicular and pedestrian traffic rules and regulations for their installations; to specify maximum punishments for violating such rules and regulations; and to issue citations, including District Court Violation Notices to persons who violate such rules and regulations.

* * * * *

■ 5. Revise § 1204.1103 to read as follows:

§ 1204.1103 Procedures.

The Center Directors and the Executive Director for Headquarters Operations shall issue local policies and procedural requirements, which will implement this regulation for their respective NASA Centers and component facilities.

■ 6. Revise § 1204.1104 to read as follows:

§ 1204.1104 Violations.

As authorized by and consistent with 18 U.S.C. 799, local policies and procedural requirements issued under section 1204.1103 may provide for punishments for offenses, which shall be classified in accordance with 18 U.S.C. 3559(a)(6)–(9). A person found in violation, in or on a NASA installation, of any vehicular or pedestrian traffic law, or local installation vehicular or

pedestrian traffic rule or regulation made applicable to the installation under the provisions of this subpart, is subject to punishment as provided for by the applicable local policies and procedural requirements that a Center Director or the Executive Director for Headquarters Operations has issued under section 1204.1102 and in accordance with section 1204.1103.

Nanette Jennings,

NASA Federal Register Liaison Officer.

[FR Doc. 2015–28813 Filed 11–12–15; 8:45 am]

BILLING CODE 7510–13–P

DEPARTMENT OF COMMERCE

15 CFR Part 4

[Docket Number: 150902802–5802–01]

RIN 0605–AA39

Freedom of Information Act and Privacy Act Regulations, Nomenclature Change

AGENCY: Department of Commerce (Commerce).

ACTION: Final rule.

SUMMARY: The Department of Commerce (Department) amends its regulations under the Freedom of Information Act (FOIA) and the Privacy Act (PA) to reflect an organizational change in the Department's Office of General Counsel (OGC). Specifically, this action removes from the provisions on FOIA appeals and the PA all references to the position of Assistant General Counsel for Administration, and replaces them with references to the new ''Assistant General Counsel for Litigation, Employment, and Oversight.'' The Department's OGC recently eliminated the position ''Assistant General Counsel for Administration,'' and this amendment updates the rules to implement that change. The rule also reflects that the Office of the Assistant General Counsel for Litigation, Employment, and Oversight will be conducting FOIA appeals and responding to requests for corrective action or review under the PA for the Department. This action merely makes a nomenclature change; the change has no substantive impact to the public, because the OGC has in the past and will continue to handle the FOIA and PA actions described above.

DATES: This action is effective on November 13, 2015.

ADDRESSES: The final rule is available at *www.regulations.gov,* or by contacting the Department of Commerce: Room 1854, 1401 Constitution Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Joseph Bartels, 202–482–3084.

SUPPLEMENTARY INFORMATION: This rule modifies the sections of the Department of Commerce's FOIA and PA regulations addressing appeals of denials of requests under FOIA and requests for review or corrective action under the PA by updating the name and address of the office in the OGC that decides appeals. The current FOIA regulations state that the Assistant General Counsel for Administration (AGC-Admin) decides all appeals from FOIA requests (except those made to the Office of the Inspector General, or to the AGC-Admin). The regulations also require appellants to address requests for corrective action or review for overly delayed responses under the PA to the AGC-Admin.

The Department of Commerce's Office of General Counsel (OGC) has recently reorganized its offices, and the position of AGC-Admin no longer exists. In its place, the Assistant General Counsel for Litigation, Employment, and Oversight has been delegated the authority from the General Counsel to make final decisions on appeal of initially denied requests for records under FOIA. *See* Department Administrative Order 205–12, sections 4 and 5.

Accordingly, this rule amends part 4 of title 15 of the Code of Federal Regulations to remove references to the now non-existent AGC-Admin, and replace it with the term ''Assistant General Counsel for Litigation, Employment, and Oversight.'' This action is merely a nomenclature change, and does not modify or revise in any substantive way the Department of Commerce's FOIA or PA regulations, or FOIA or PA requirements.

Classification

Executive Order 12866

This rule is limited to agency organization, and therefore is not considered a ''regulation'' under Executive Orders 12866 and 13563. Accordingly, it is exempt from review by the Office of Management and Budget.

Regulatory Flexibility Act

Because this rule addresses a matter of agency organization, and therefore is not subject to the notice and comment requirements of the Administrative Procedure Act, it is also exempt from the requirements of the Regulatory Flexibility Act. Accordingly, a regulatory flexibility analysis is not required for this action, and none has been prepared.

Paperwork Reduction Act

This action is merely administrative in nature, and addresses a matter of agency organization. It does not contain a ''collection of information'' as that term is defined in the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*

List of Subjects in 15 CFR Part 4

Freedom of information, Privacy.

Dated: October 28, 2015.

Catrina D. Purvis,

Chief Privacy Officer and Director for Open Government, Department of Commerce.

For the reasons set forth above, the Department of Commerce amends 15 CFR part 4 as follows:

PART 4—DISCLOSURE OF GOVERNMENT INFORMATION

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

Authority: 5 U.S.C. 301; 5 U.S.C. 552; 5 U.S.C. 552a; 5 U.S.C. 553; 31 U.S.C. 3717; 44 U.S.C. 3101; Reorganization Plan No. 5 of 1950.

■ 2. Amend § 4.10 by revising paragraphs (b)(1) and (c) to read as follows:

§ 4.10 Appeals from initial determinations or untimely delays.

* * * * *

(b)(1) Appeals, other than appeals from requests made to the Office of Inspector General, shall be decided by the Assistant General Counsel for Litigation, Employment, and Oversight. Written appeals should be addressed to the Assistant General Counsel for Litigation, Employment, and Oversight, at U.S. Department of Commerce, Office of the General Counsel, Room 5875, 14th and Constitution Avenue NW., Washington, DC 20230. An appeal may also be sent via facsimile at 202–482–2552. For a written appeal, both the letter and the appeal envelope should be clearly marked ''Freedom of Information Act Appeal.'' Appeals may also be submitted electronically either by email to *FOIAAppeals@doc.gov* or online at the FOIAonline Web site, *http://foiaonline.regulations.gov,* if requesters have a FOIAonline account. In all cases, the appeal (written or electronic) should include a copy of the original request and initial denial, if any. All appeals should include a statement of the reasons why the records requested should be made available and why the adverse determination was in error. No opportunity for personal appearance, oral argument or hearing on appeal is provided. Upon receipt of an appeal, the Assistant General Counsel for Litigation, Employment, and Oversight ordinarily

shall send an acknowledgement letter to the requester which shall confirm receipt of the requester's appeal.* * *

(c) Upon receipt of an appeal involving records initially denied on the basis of FOIA exemption (b)(1), the records shall be forwarded to the Deputy Assistant Secretary for Security (DAS) for a declassification review. The DAS may overrule previous classification determinations in whole or in part if continued protection in the interest of national security is no longer required, or no longer required at the same level. The DAS shall advise the Assistant General Counsel for Litigation, Employment, and Oversight, the General Counsel, the General Counsel to the Inspector General, or Deputy Inspector General, as appropriate, of his or her decision.

* * * * *

§§ 4.23, 4.25, 4.28, and 4.29 and Appendix B [Amended]

■ 3. In addition to the amendments made above, in 15 CFR part 4, remove the words ''Assistant General Counsel for Administration'' and add, in their place, the words ''Assistant General Counsel for Litigation, Employment, and Oversight'' in the following places:

■ a. Section 4.23(d)(2);

■ b. Section 4.25(a)(2) and (g)(3)(ii);

■ c. Section 4.28(a)(1)(ii) and (a)(2)(ii)(D);

■ d. Section 4.29(b), (c), (e), (g)(1), (h), and (i); and

■ e. Appendix B.

[FR Doc. 2015–28712 Filed 11–12–15; 8:45 am]

BILLING CODE 3510–BW–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Parts 101, 113, and 133

[CBP Dec. 15–15, USCBP–2006–0013]

RIN 1515–AD56 [formerly 1505–AB54]

Customs and Border Protection's Bond Program

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule, with changes, proposed amendments to the U.S. Customs and Border Protection (CBP) regulations that serve to centralize the processing of continuous bonds at CBP's Revenue Division within the Office of Administration. Upon consideration of comments received from the public in response to the proposed rulemaking, and in light of CBP's ongoing efforts concerning the development of electronic bonds, CBP has determined not to proceed at this time with certain proposed regulatory changes relating to the application, approval, and execution of bonds. CBP has also determined not to proceed with proposals relating to provisions that are the subject of other rulemakings currently under inter-departmental review. In the notice of proposed rulemaking, CBP used the terms ''CBP-approved electronic data interchange system'' and ''electronic filing'' to describe the manner by which continuous bonds may be submitted to CBP. In this final rule, these terms are clarified to reflect that continuous bonds may be scanned and submitted to CBP as an email attachment, or by facsimile. This document also amends the CBP regulations to allow for the filing of single transaction bonds pursuant to these methods. In this rulemaking, CBP also clarifies the CBP regulations to reflect that intellectual property rights sample bonds are posted to protect the importer or owner of the sample, and changes provisions of the international carrier bond regarding the payment of fees. Lastly, this final rule adopts non-substantive amendments to the regulations regarding nomenclature and organizational changes, including editorial changes to enhance general readability, and makes technical corrections to reflect statutory amendments.

DATES: Effective December 14, 2015.

FOR FURTHER INFORMATION CONTACT: Kara Welty, Chief, Debt Management Branch, Revenue Division, Office of Administration, Tel. (317) 614–4614.

SUPPLEMENTARY INFORMATION:

Background

Proposed Rule

On January 5, 2010, U.S. Customs and Border Protection (CBP) published in the **Federal Register** (75 FR 266) a proposal to amend title 19 of the Code of Federal Regulations (19 CFR) regarding CBP's bond program. The proposed amendments to CBP's bond regulations were intended to update and modernize CBP's bond program and centralize the filing, review and approval of continuous bonds at CBP's Revenue Division, Office of Administration, in Indianapolis, Indiana, which assumes the bond functions previously performed at the port level. In that document, CBP also proposed to amend § 113.64, which prescribes international carrier bond conditions, to state that an obligor must pay liquidated damages for failure to timely submit to CBP passenger processing fees that were required to be collected. In addition, CBP proposed to amend the regulations in part 133 to reflect that bonds relating to allegations of counterfeit trademarks are permitted to be continuous bonds.

Bond Final Rule Separate and Distinct From eBond Test

Title VI of the North American Free Trade Agreement Implementation Act, Public Law 103–182, 107 Stat. 2057 (Dec. 8, 1993), establishes the National Customs Automation Program (NCAP), an automated and electronic system for the processing of commercial importations. CBP is currently conducting a voluntary NCAP eBond test. In a general notice published in the **Federal Register** (79 FR 70881) on November 28, 2014, CBP described the terms and conditions of the eBond test which provides for the transmission to the Automated Commercial Environment (ACE) of electronic bond contracts (eBonds) between principals and sureties, with CBP as the third-party beneficiary, for the purpose of linking those eBonds to the transactions they are intended to secure (eBond system). The test deployed on January 3, 2015, and a modification to the test was published in the **Federal Register** (80 FR 899) and went into effect on January 7, 2015.

The eBond test is separate and distinct from this bond final rule. In this regard, it is noted that the eBond test pertains to electronic bonds that are not submitted on the CBP Form 301 and that are transmitted through an electronic data interchange to ACE to secure a limited subset of ACE entry types. The bond regulations contained in this final rule, however, pertain to all entry types and provide for the filing of both continuous bonds and single transaction bonds primarily on the CBP Form 301. As a result of this rule, CBP Form 301 bonds may be scanned and emailed to CBP as a computer file attachment (*i.e.,* in a .pdf or a .tif format), or submitted by facsimile (fax) or mail. Bonds emailed or faxed to CBP on the CBP Form 301 are not submitted via a ''CBP-approved electronic data interchange system'' in that they do not constitute a computer-to-computer interchange of strictly formatted messages. To clarify this fact, this final rule no longer refers to CBP Form 301 bonds, or the submission of bonds outside of the eBond test, as ''electronic'' or submitted or filed

''electronically'' or via a ''CBP-authorized electronic data interchange system.'' Moreover, as bonds may still be submitted to CBP outside of the eBond test, it is important to note the following:

- Non-eBond test participants must adhere to the regulatory provisions set forth in Chapter 1 of title 19 of the Code of Federal Regulations.
- For eBond test participants, the regulatory provisions set forth in Chapter 1 of title 19 of the CFR are suspended to the extent that they conflict with the terms of the eBond test.

Amendments Suggested by Commenters

This final rule adopts changes suggested by commenters in response to the proposed rulemaking that are a natural outgrowth of that document. Specifically, the changes:

- Permit both single transaction bonds (STBs) and continuous bonds to be scanned and submitted to CBP as an email attachment or by fax.
- Liberalize the existing procedure, set forth in § 113.37(d), by which agents or attorneys acting for a corporate surety may identify themselves to CBP by permitting the submission of a surety-generated 9-digit alphanumeric identification number as a substitute for submission of a social security number.
- Remove the reference, in § 113.38(c)(4), to ''port director'' as among the CBP personnel authorized to determine whether CBP will accept the bonds of a particular surety.
- Effect a technical correction to § 113.52, which currently requires that CBP report a bonded debt to the Department of Justice for prosecution if unpaid for 90 days. As section 2103 of the Miscellaneous Trade and Technical Corrections Act of 2004 amended 19 U.S.C. 1514 by extending the time to file and amend a protest from 90 days to 180 days after the date of liquidation or reliquidation, or date of the decision, order, or finding being protested for entries made on or after December 18, 2004, the 90-day period should be changed to 180 days to reflect that fact.

Clarifying and Conforming Amendments

This document also amends the regulations to effect clarifications that better explain the bond process and conform the regulations to reflect amendments to title 19 of the CFR that went into effect after publication of the proposed rule. Specifically, these changes:

- Clarify in § 113.14, which pertains to situations where the approved form of a bond is inadequate, that in situations where CBP determines that none of the conditions contained in Subpart G, CBP Bond Conditions, of part 113 are applicable to a transaction sought to be secured, either the Director, Revenue Division, or the port director, may draft conditions that cover the transaction as CBP deems appropriate and the port director is not limited to drafting conditions only for single transaction bonds (STBs) in these instances. This change is necessary to reflect the fact that there are certain continuous bonds for which the port director, and not the Revenue Division, will draft bond conditions that are specific to the issues and the geography of the port involved.
- Clarify in § 113.15, which prescribes the retention of approved bonds, that except for bonds containing the agreement to pay court costs (condemned goods) (*see* § 113.72), and as may otherwise be deemed appropriate by CBP, bonds that are approved by the port director will be retained at the port office and bonds that are approved at the Revenue Division (including bonds relating to repayment of erroneous drawback payments containing the conditions set forth in § 113.65) will be retained at the Revenue Division.
- Clarify the introductory language in § 113.39(a) to state that reports to CBP Headquarters are to be sent to the attention of the Executive Director, Regulations and Rulings, Office of International Trade.
- Clarify § 113.64(b)(1) and (2) to state, in positive terms, that the principal (carrier) must pay processing fees to CBP ''within'' the prescribed number of ''calendar'' days after the close of the calendar quarter in which they were due.
- Clarify § 133.25(c), relating to the terms of the IPR sample bond, by adding in the second sentence the phrase ''. . ., conditioned to indemnify the importer or owner of the imported article against any loss or damage resulting from the furnishing of the sample by CBP to the owner of the mark.'' This language is added to eliminate confusion and make clear that the IPR sample bond is posted to protect the importer or owner of the sample.

Proposals Not Adopted

As noted above, this final rule adopts changes suggested by commenters in response to the proposed rulemaking, including recommendations to not proceed with certain proposed amendments. In this document, CBP has also determined not to adopt as final certain regulatory proposals that are the subject of other CBP rulemakings that are currently in formal inter-departmental review. In addition, CBP is not finalizing certain proposals in light of ongoing efforts concerning the development and deployment of eBonds in the ACE environment. In this regard, it is noted that CBP has announced a deployment schedule that will include electronic filing of STBs. This schedule is available for viewing at: *http://www.cbp.gov/sites/default/files/documents/Product%20Backlog%20as%20of%2003-31-14.pdf.* As many of the regulatory changes offered in the proposed rule may not be consistent with the deployment of eBonds in the ACE, or have otherwise been overtaken by events, the following proposed changes are not being adopted as final, in whole or in part (notwithstanding non-substantive editorial changes that are retained in this document), as described below:

- Proposed changes to 19 CFR 113.11 relating to bond applications, with the exception that this section is amended to specify that both STBs and continuous bonds may be scanned and submitted to CBP as an email attachment or by fax, paper STBs may be filed at the Revenue Division or with the port director, and continuous bonds must be filed with the Director, Revenue Division.
- Proposed changes to 19 CFR 113.12 regarding bond approval, with the exception that paragraphs (a) and (b) are respectively amended to state that STBs may be approved by either the Revenue Division or by the director of the port where filed, and continuous bonds will be approved by the Director, Revenue Division.
- Proposed changes to 19 CFR 113.13(c) which would remove the 30-day time period from date of notification within which a principal must remedy a bond deficiency. Upon further review, and in response to commenters' suggestions, CBP has decided to reinstate a prescribed time period within which a principal must remedy the bond insufficiency. CBP views a 30-day response period as too lengthy to adequately protect the revenue and ensure compliance with applicable law and regulations, and therefore this provision is amended to prescribe a 15-day period.
- Proposed changes to 19 CFR 113.21 relating to information required on the bond.
- Proposed changes to 19 CFR 113.22 relating to witnesses required on the bond.
- Proposed changes to 19 CFR 113.23 relating to changes made on the bond.
- Proposed changes to 19 CFR 113.24 relating to riders, with the exception

that this section is amended to reflect that riders must be filed with the Revenue Division and may be scanned and submitted to CBP as an email attachment or by fax. In addition, this section clarifies that riders must be attached to their related bond if submitted in a paper format and sets forth a reference to the CBP Web site containing a comprehensive listing of acceptable riders. In addition, this section sets forth a reference to the CBP Web site containing a comprehensive listing of acceptable riders.

• Proposed changes to 19 CFR 113.25 relating to seals on the bond.

• Proposed changes to 19 CFR 113.26 relating to riders, with the exception that this section is amended to allow the filing of riders up to sixty days prior to the effective date rather than thirty days.

• Proposed changes to 19 CFR 113.27 relating to termination of bonds, with the exception that this section is amended to reflect that termination notices must be sent to the Revenue Division.

• Proposed changes to 19 CFR 113.33 relating to bond execution requirements of corporations, with the exception that paragraph (c) is amended to include a reference to the Revenue Division.

• Proposed changes to 19 CFR 113.37 relating to signature and seal requirements of corporate sureties, with the exception that the outdated existing reference to the ''Bureau of Government Financial Operations'' is replaced with an updated reference to ''Bureau of the Fiscal Service'' to reflect current administrative and legal authorities. Also, as noted above, CBP is adopting as final the proposed amendments to paragraph (d) whereby agents or attorneys acting for a corporate surety may identify themselves to CBP by submitting a surety-generated 9-digit alphanumeric identification number as a substitute for submission of a social security number.

• Proposed changes to 19 CFR 113.39 to reflect a generalized reference to ''authorized CBP officer'' as to who may recommend the removal of a surety company from Treasury Department Circular 570, with the exception that this section is amended by adding references to the Revenue Division and also to replace the outdated existing reference to the ''Bureau of Government Financial Operations'' with an updated reference to ''Bureau of the Fiscal Service''.

• Proposed changes to § 113.40, which provides for acceptance of cash deposits or obligations of the United States in lieu of sureties on bonds, with the exception that this section is amended to provide that the Secretary of Homeland Security is among those who may authorize the enforcement of bond laws and regulations and the Director, Revenue Division, and not the Port Director, is authorized to accept cash deposits in lieu of sureties on bonds.

• Proposed changes to 19 CFR 113.62(a)(1)(i) to include a reference to the ''periodic monthly statement'' inasmuch as this type of payment is made pursuant to a test program that has not been provided by regulation.

• Proposed changes to the title of the bond set forth in Appendix A to Part 113 from ''Airport Customs Security Area'' to ''Airport CBP Security Area'' in that the term ''CBP'' is improperly restrictive in this context. Here, CBP uses ''Customs'' in the generic sense of the word rather than as a continued reference to the legacy component of CBP, the U.S. Customs Service, previously referred to throughout title 19 CFR as ''Customs.'' It is noted, however, that CBP adopts in this final rule the proposal to convert this bond from a term bond to a continuous bond.

• Proposed changes to Appendices A and D to part 113 which would remove the witness requirements.

• Proposed changes to 19 CFR 133.21(d) and 19 CFR 133.42(e), as the proposed amendments to these intellectual property rights sample bond provisions are the subject of existing rulemakings which are in formal inter-departmental review.

Discussion of Comments

Eight commenters responded to CBP's solicitation of public comment in the proposed rule. A description of the comments received, together with CBP's analyses, is set forth below.

Comment:

One commenter requested confirmation that the proposed substitution of the reference to the Department of the Treasury in 19 CFR 113.1, with a reference to the

Department of Homeland Security (DHS), does not create a deficiency in authority for CBP to require bonds or other security.

CBP Response:

The proposed substitution does not create a deficiency in authority. First, in view of the authority transferred by the Homeland Security Act of 2002 and delegated by Treasury Department Order No. 100–16 (May 23, 2003), Appendix to part 0 of title 19 of the Code of Federal Regulations (19 CFR part 0), all of the Secretary of the Treasury's authority pursuant to 19 U.S.C. 1623(a) was transferred and/or delegated to the DHS Secretary who then appropriately delegated it to the Commissioner of CBP, who may re-delegate it further within CBP. Second, any authority outside the scope of 19 U.S.C. 1623(a) is encompassed within the dependent clause of the sentence which begins 19 CFR 113.1.

Comment:

Six commenters provided submissions regarding various aspects of the bond application process as set forth in proposed § 113.11. The bond application comments are summarized as follows:

• The level of continuous bond application detail specified in proposed § 113.11(c) is much greater than the amount of information currently collected in bond applications and constitutes a new ''collection of information'' pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). This contradicts CBP's statement in the proposed rule that ''[T]here are no new collections of information proposed in this document.''

• The requirement to submit an application for a STB, as set forth in proposed § 113.11(a), should be removed. The commenters noted that STBs are rarely, if ever, accompanied by bond applications and the transaction that the bond secures serves to provide CBP with the necessary information.

• In the alternative, if CBP elects to retain applications for STBs, as is required in proposed § 113.11(a), CBP should modify the provision to state that STB applications may be filed at either the Revenue Division or the port, and either of those locales may review and approve the bond.

• Requiring applications for any type of customs bonds is an outmoded concept as the preponderance of bond sufficiency decisions rendered by the Revenue Division are not based on the application, but on the Revenue Division's analysis of data that is readily and routinely extracted from CBP's own data systems. In this regard, it is noted that CBP's data processing and analysis capabilities are vastly more comprehensive today than those that were in existence in 1985 when the current bond application regulatory requirements were promulgated. CBP should handle its request for more specific information collection through utilization of CBP Directives.

• The detail set forth in the proposed bond application involves certain information which is pertinent only in the case of Activity Code 1 continuous bonds, even though the requirements of proposed § 113.11(c) purport to apply to all activity codes.

• Proposed § 113.11(d) requires updates to application information in the event of a ''material change.''

Commenters note CBP has not enforced this provision for 25 years. In addition, the term ''material change'' is undefined and therefore subjective, vague, and difficult to enforce. CBP has the ability to determine for itself whether any information has changed materially enough to warrant a new bond and, as the bond obligee, it is good risk management practice to continually review all bonds for adequacy.

• References in § 113.11 to CBP Form 301 should be deleted inasmuch as certain bonds filed with CBP (*e.g.,* Importer Security Filing (ISF) ''Appendix D'' Bonds, Airport Customs Security Area ''Appendix A'' Bonds) are not filed on the CBP Form 301.

• Proposed § 113.11(c)(1)(v) requires that the bond applicant provide information relating to the nature of the relationship between principal, co-principals, or unincorporated divisions or trade names appearing on the bond. This new requirement does not have any relation to protection of revenue and/or setting bond amounts.

• Proposed § 113.11(c)(1)(viii) requires the applicant to report ''anticipated'' material changes to the nature of the merchandise that will be imported over the subsequent 12 months. This new requirement does not have any relation to protection of revenue.

• Proposed § 113.11(c)(1)(xii) and (xiii) duplicate the information requested in paragraph (e).

• It is not necessary that a bond application be executed under seal and this requirement should be removed from proposed § 113.11(e)(1). By waiving this requirement, proposed paragraphs (e)(1) and (e)(2) can be combined and require the same certification language for everyone and every situation.

• As proposed, § 113.11 pertains to bond applications, paragraph (e)(1) should be amended by adding the word ''applications'' to clarify that the provision pertains to paper bond applications.

• The last sentence in the certification language set forth in proposed § 113.11(e)(2) presumes that every bond application submitted electronically will be submitted by a corporate applicant. Non-corporate applicants will not be able to make such a certification.

• The term ''continuous transaction bond'' in proposed § 113.11(c)(1) should read ''continuous bonds.''

• In the proposed rule, CBP would permit certain documentation to be submitted to the Revenue Division in a non-paper format. As such submissions will not contain a written signature or seal, CBP proposes to add alternative certification language stating that the bonds are legally binding ''to the same extent as if signed and under seal.'' CBP should not permit certification in lieu of requiring a signature on non-paper bonds without developing appropriate safeguards to verify and authenticate the intent of the parties to be bound without the evidence of signatures. Part 113 should be limited to bonds submitted by mail, fax or other electronic imagery where the signature and seal will be visible (*i.e.,* as a .pdf or .tif email attachment). CBP should engage the surety industry and trade in discussions to establish the proper regulatory language. Self-certification of one's own authority is susceptible to fraud. In a related submission, another commenter noted that if an electronic bond transmission to CBP is not pursuant to an ''authorized electronic interchange system,'' as required by 19 U.S.C. 1623(e), a signature is required. To remedy these problems, the commenters suggest amending proposed § 113.11 by: (1) Deleting the introductory paragraph and all references to CBP Form 301; (2) deleting the requirement to submit a bond application for STBs set forth in proposed paragraph (a); (3) removing the specific bond information set forth in proposed paragraph (c); (4) deleting the requirement to submit bond application updates in the event of material change; (5) stating that CBP *may* require a prospective or existing continuous or term bond principal to file a written bond application and, when required, the application must include the information specified by the Revenue Division in order to properly evaluate bond sufficiency; (6) changing the reference to ''paper bond'' in proposed § 113.11(e)(1) to read, ''paper bond application'', and; (7) adding the words, ''where applicable'' to the certification language in § 113.11(e)(2) to reflect that not all non-paper bond applications will be from corporate applicants. The commenters maintain that such amendments to the bond application procedures will result in true paperwork reduction without sacrificing CBP's ability to obtain and review the information it needs to make sound bond sufficiency decisions.

CBP Response:

For reasons discussed elsewhere in this preamble, CBP has determined not to proceed with most of the proposed changes to 19 CFR 113.11. It is noted, however, that this final rule amends the CBP regulations to reflect the proposal to set forth CBP's bond application procedures in § 113.11 (which are currently prescribed in § 113.12) and to set forth the bond approval regulations in § 113.12 (which are currently prescribed in § 113.11) as this non-substantive change reflects the proper chronological order of bond processing events. It is further noted that CBP is amending the STB bond application process set forth in § 113.11(a) to provide that the STB bond application may be in the form of a letter and filed with the Director, Revenue Division or the port director, or the STB may be scanned and submitted to CBP as an email attachment or by fax. Similarly, CBP is amending § 113.11(b) to provide that continuous bonds must be submitted to the Director, Revenue Division and may be scanned and submitted to CBP as an email attachment or by fax. Lastly, this final rule removes references to CBP Form 301 in § 113.11.

Comment:

Several commenters noted that a reference to term bonds should be added to proposed § 113.11 to encompass Airport Customs Security Area Bonds or, in the alternative, term bonds should be converted into a continuous bond format.

CBP Response:

CBP agrees with the commenters' suggestion that Airport Customs Security Area Bonds, which are currently term bonds that lapse at the end of a specified period,

should be converted to a continuous bond type. This change will allow CBP to avoid lapses in coverage and thereby enhance security. The conversion poses no economic burden on the public and is a logical outgrowth of the proposed rulemaking in that it serves to ensure a uniform approach to bond approval, maintenance, and periodic review. Accordingly, this document amends Appendix A to 19 CFR part 113 by removing the bond text pertaining to specific duration of the bond and to locality.

Comment:

Several commenters provided submissions regarding various aspects of the bond approval process as set forth in proposed § 113.12. The bond approval comments are summarized as follows:

• Paragraph (a) should reflect that the Revenue Division already accepts emailed STB versions of the ISF Bond (Appendix D to part 113).

• The last sentence of proposed § 113.12(b) should be changed to state that ''only one continuous bond for a particular activity 'code' will be authorized for each principal.'' This is necessary because the unqualified reference to ''a particular activity,'' as is currently proposed, is too broad and susceptible to an unintended

interpretation that would require a principal to obtain more continuous bonds than are needed to cover all of its activities.

CBP Response:

CBP agrees that additional clarification as to who may approve bonds is beneficial. Accordingly, this document amends § 113.12(a) to state that STBs may be approved by the Revenue Division or by the director of the port where the STB is filed, and amends § 113.12(b) to state that continuous bonds must be approved by the Revenue Division. As CBP has determined not to proceed with the remainder of the proposed amendments to § 113.12, it is not necessary to address other comments concerning this section.

Comment:

Several commenters noted that CBP has apparently launched a new electronic single transaction bond program (''e-STB''). The program appears to be unauthorized and violative of the NPRM which repeatedly indicates that STBs will continue to be filed and approved by port directors. The final rule should authorize, but not require, the centralization of e-STBs at the Revenue Division.

CBP Response:

This comment predates deployment of the eBond test on January 3, 2015, and prior to this date CBP had not launched a formal e-STB program; rather, based on individual program requirements, such as Importer Security Filing (ISF) and Automated Commercial Environment (ACE) entries, CBP has accepted and processed scanned images of bonds transmitted via email. Nevertheless, as noted above, CBP is in agreement with the commenters' suggestion to liberalize the manner by which STBs may be submitted to CBP. To that end, this final rule amends the CBP regulations to permit STBs to be scanned and submitted to CBP as an email attachment or by fax. For purposes of uniformity, this document also amends § 113.11(b) to clarify that continuous bonds may be scanned and submitted to CBP as an email attachment or by fax.

Comment:

Several commenters provided comments regarding the proposed amendments to § 113.13(c), which pertain to CBP's periodic review to determine bond sufficiency. The comments are summarized as follows:

- Six commenters objected to the proposed amendments to § 113.13(c) which state that CBP will periodically review each bond on file to determine whether the bond is adequate to protect the revenue and ensure compliance with applicable law and regulations, and that, if CBP determines a bond to be inadequate, the principal will be promptly notified in writing and additional security for any and all of the principal's transactions covered by the bond may be required until the deficiency is remedied. The commenters state that the proposed changes would permit CBP to deactivate a bond and/or require additional collateralization almost immediately, regardless of the reason for the insufficiency. Although 19 CFR 113.13(c), as it is currently proposed to be amended, suggests that a bond insufficiency is determined by whether ''the bond is adequate to protect the revenue and ensure compliance with the law and regulations,'' the commenters note that CBP finds insufficiency and deactivates bonds for a variety of reasons, not all of them involving threats to compliance or the revenue. The commenters request that CBP maintain the 30 days written notice to the principal as is currently provided in the regulations.
- Several commenters object to CBP's ability to render a bond insufficient in situations where a bond has been identified as ''inadequate,'' but the inadequacy is not significant enough to rise to the level of jeopardizing compliance or revenue.
- One commenter suggests replacing the word ''immediate'' in paragraph (d), with a word connoting a more reasonable period of time.
- The bond is an agreement between the principal, CBP, and the surety, and any notice given by CBP to the principal should also be given to the surety.
- Several commenters suggest the language in proposed paragraphs (c) and (d) pertaining to ''additional securities'' is duplicative and need only be stated once in paragraph (d).

CBP Response:

When circumstances require, CBP must be able to act quickly to protect the revenue and ensure compliance with law and regulation. There have been situations where the passage of time between CBP's decision finding a bond to be insufficient and the principal increasing the bond in response to such a finding has resulted in the agency having to write off millions of dollars in uncollectible revenue. It is noted that even in situations where the continuous bond is rendered insufficient ''immediately,'' the trade retains the ability to move cargo without excessive delay by using STBs. In an effort to alleviate concern that CBP will improperly render a bond insufficient in situations where the bond inadequacy is not significant enough to rise to the level of jeopardizing compliance or revenue, CBP will reinstate a prescribed time period within which a principal is given the opportunity to remedy the bond insufficiency. As noted above in this document, CBP views the existing 30-day response period as too lengthy to adequately protect the revenue and ensure compliance with applicable law and regulations; therefore, § 113.13(c) is amended to prescribe a 15-day period within which a principal must remedy a deficiency and to state that where CBP has determined that a bond is insufficient to adequately protect the revenue and ensure compliance with applicable law and regulations, CBP may provide written notice to the principal and surety that additional security in the form of cash deposit or STB may be required for any and all of the principal's transactions until the deficiency is remedied. CBP will provide notice of any insufficiency to both the principal and the surety.

Comment:

Several commenters expressed concern with the ISF implications of CBP's proposed amendments to § 113.13 which would allow CBP to deactivate a bond and/or require additional collateralization almost immediately. Before introduction of the ISF requirement, this action would cause delays in filing an entry for release as the cargo arrives at terminals in the U.S. Under ISF, the immediate inactivation of a bond for any insufficiency takes on troubling implications in that cargo will be held back from being sent to the U.S. by the carrier overseas. If the cargo is not laden aboard the vessel at the foreign port, it may cause significant shipping delays.

CBP response:

CBP disagrees and notes that even in situations where the continuous bond is rendered insufficient ''immediately,'' the trade retains the ability to move cargo without excessive delay by using STBs. This includes using a STB to satisfy the ISF bonding requirement.

Comment:

Seven commenters disagree that CBP is ''entitled to presume, without verification, that submitted bond applications and related documentation, which include the bond, are properly executed, complete, accurate, and in full compliance with all applicable laws.'' This language, or substantially similar variations thereof, was proposed to be added to various provisions throughout part 113. The commenters state that, as CBP is the obligee of the bond and a party to it, CBP has a duty to exercise due diligence to ensure that the bond meets the regulations and requirements CBP establishes. The explicit elimination of CBP's accountability indicates a radical, unnecessary and

inappropriate change in CBP's approach to the bond process and protection of the revenue and such change was not adequately discussed in the proposed rule's preamble. It was also suggested that, as a matter of law, it is inconceivable that the courts would allow CBP to collect against sureties on bonds which were produced fraudulently, or are deficient on their face, or are inconsistent with CBP regulations and statutory requirements. One commenter noted that the presumption of validity, authority and accuracy may attach to the filer, but not to the surety unless the filer's authority is specifically verified. If a bond is submitted and accepted by CBP, then CBP must also take responsibility for the problems, errors or deficiencies in the bond which it has accepted.

CBP Response:

As CBP has determined not to proceed with the proposed regulatory provisions containing this language, it is not necessary to address these comments.

Comment:

One commenter suggests that the requirement to ''line out'' unused portions of the CBP Form 301 should be retained in § 113.21 as it helps reduce ambiguity or uncertainty as to the intent of the principal or the surety when completing the bond.

CBP response:

As CBP has determined not to proceed with the proposed changes to 19 CFR 113.21, it is not necessary to address this comment.

Comment:

One commenter agrees with CBP's proposal to remove § 113.22, which pertains to bond witness requirements, and suggests that all references to witnesses should be removed from §§ 113.24(d), 113.40(b), and Appendices A, B, C, and D to part 113.

CBP Response:

As CBP has determined not to proceed with the proposed changes to 19 CFR 113.22, it is not necessary to address this comment.

Comment:

Four comments were received regarding § 113.23, which describes the types of changes that may be made to a bond and the process by which to effect such changes. The comments are summarized below:

- This section should be amended to read that changes may be made to the bond ''filing'' and not the actual bond because the bond has not been approved yet.
- One commenter suggests that the last sentence in § 113.23(c) be amended to read, ''[W]hen a modification or interlineation is desired, the principal or surety will withdraw the bond filing if submitted to CBP and a new bond will be executed.''

CBP response:

As CBP has determined not to proceed with the proposed changes to 19 CFR 113.23, it is not necessary to address these comments.

Comment:

Four commenters made submissions regarding the proposed amendments to riders in § 113.24. The comments are summarized as follows:

- Any future riders should be able to be submitted to the Revenue Division.
- Proposed § 113.24(e) requires that all riders submitted on paper be signed by both the principal and co-principals. This requirement deviates from the existing requirement to have a rider signed by only the affected principal and, as such, is overly burdensome and unnecessary. In the alternative, if this revision is retained in the final, the requirement should also apply to each surety and co-surety. Section 113.24(e) does not provide the format for all acceptable riders, and the final rule should either list all acceptable riders or refer the reader to the CBP Web site for a complete listing.
- As § 113.26 states that the riders in §§ 113.24(e)(2) and (3) are effective on the ''date in the rider,'' CBP needs to include an effective date in these riders.
- CBP should remove the requirement that the rider must be executed under seal inasmuch as the only approved riders are those intended to correct information that does not rise to the level of materially altering the bond itself (*i.e.,* address change, name change, *etc.*).
- One commenter noted that the riders named in proposed § 113.24, which are to be filed at the Revenue Division, are for a change to the principal's name or address, as well as addition and deletion riders for unincorporated divisions on a bond. The commenter suggests that reconciliation riders, which are currently filed at CBP Headquarters, should also be filed at the Revenue Division to avoid situations where a bond is terminated, but the rider is not. If a new bond is filed with a new surety, the rider is deemed unavailable as it indicates the surety on the terminated bond. Any entry flagged for reconciliation under the new bond is not valid because there is no reconciliation rider for the new bond. This is a CBP system issue and it would be advisable for the Revenue Division to control the filing and termination of reconciliation riders.

CBP Response:

CBP is not proceeding with the finalization of most of the proposed amendments to § 113.24. One exception is the amendment that provides that riders must be filed with the Revenue Division and that they may be scanned and filed as an email attachment or by fax. Other exceptions are the amendment of paragraph (c) to clarify that riders must be attached to their related bond if submitted in a paper format and the amendment of § 113.24 to include a reference to the CBP Web site containing a listing of all acceptable riders. As CBP has determined not to proceed with the remainder of the proposed changes to 19 CFR 113.24, it is not necessary to address the rest of the comments pertaining to this section. In response to the commenter's concern that there may be situations where a bond is terminated but the rider is not, CBP wishes to clarify that termination of the bond also terminates any and all riders to the bond.

Comment:

Five commenters noted the following regarding the seal requirements set forth in proposed § 113.25.

- CBP should add language to this provision stating that seal requirements apply only to bonds directly executed by principals (*e.g.,* corporate officers), and that bonds executed by a duly empowered attorney-in-fact acting for the principal are exempt from seal requirements.
- As bonds are produced in a variety of ways, the regulations should specify whether the requirements imposed on the party executing the bond apply to the principal, surety or both.
- Paragraph (a), which requires that the party executing a bond submitted electronically to CBP ''must retain a copy of the paper seal and make such seal available to CBP for inspection upon request,'' should be amended to apply to the party ''filing'' the electronic bond inasmuch as this more accurately reflects the typical business practice and makes a necessary distinction.
- CBP should specify whether the requirement to retain a copy of the paper bond, and provide it to CBP upon request, is imposed upon the principal, the surety, or both.

CBP Response:

As CBP has determined not to proceed with the proposed changes to 19 CFR 113.25, it is not necessary to address these comments.

Comment:

Several commenters made recommendations pertaining to the effective dates of bonds and bond riders set forth in § 113.26. The comments follow:

• One commenter requested that CBP clarify, in paragraph (e), that the applicable time frame is 15 business days.

• CBP should make the rule more flexible with respect to the effective date of riders that are filed to correct an initial rejection.

CBP Response:

As CBP has determined not to proceed with the proposed changes to 19 CFR 113.26, with the exception that this document amends this section to allow the filing of riders up to 60 days prior to their effective dates, it is not necessary to address these comments.

Comment:

Several commenters submitted the following comments regarding bond termination procedures set forth in § 113.27:

• Proposed § 113.27 should be amended to provide CBP with the discretion to permit a withdrawal of a termination if it would be in the interest of CBP, the principal, and the surety.

• A commenter expressed dissatisfaction with the proposed amendments to § 113.27(b) which eliminate the current authority for sureties to terminate a bond in less than 30 days upon a showing ''that a lesser time is reasonable under the circumstances,'' and recommends that the authority be reinstated.

• The trade supports the proposed procedures set forth in paragraph (c) which avoid gaps in bond coverage.

• One commenter noted that pursuant to § 113.27(c)(1), a new bond must be filed after termination has taken effect and the bond must contain the conditions in Subpart G, regardless of whether the new bond is on CBP Form 301 or some other form in the regulations. As the conditions in Subpart G are only found on the CBP Form 301 and not on the other forms, the regulation should be amended accordingly.

• One commenter stated that the proposed language in § 113.27(c)(2) permits a termination to be conditioned on the approval of a new bond intended to replace the one being terminated. The commenter supports the concept, but not the way it is expressed (''. . . terminated pursuant to this *section* . . .'') as this could circumvent a surety's decision to terminate a bond when that surety does not desire any delay or extension as to when termination becomes effective. A surety does not need a principal's consent to terminate the bond, so the principal should not be able to delay that decision once the surety has given notice of termination under § 113.27(b). Further, this language should apply only when the principal has given notice of termination under § 113.27(a), and it should be moved there with some minor changes. A surety does not have a need to avail itself of the method outlined in proposed § 113.27(c)(2).

• Several commenters recommended removing the reference to ''sureties'' in § 113.27(c)(2) as this provision pertains to actions initiated by principals (usually importers), and by moving the regulatory text set forth in paragraph (c)(2) to paragraph (a). This restructuring will clarify that proposed paragraph (c)(2) does not apply to § 113.27(b).

CBP Response:

As CBP has determined not to proceed with the proposed changes to 19 CFR 113.27, with the exception that termination notices must be filed at the Revenue Division and they may be submitted to CBP via email or by fax, it is not necessary to address these comments.

Comment:

Several comments were submitted regarding corporations and Limited Liability Corporations (LLC) in § 113.33:

• One commenter suggested that CBP should amend proposed § 113.33 to include a definition of ''corporation.''

• One commenter noted that proposed § 113.33(b) states that where the continuous bond of a corporate principal or LLC principal is submitted to CBP in an electronic format, the bond must contain the certification language set forth in § 113.11(e)(2). The commenter continued to note that the CBP Form 301 is subject to OMB approval and, as this certification is not required under the existing regulations, the addition of any language must be approved by OMB. The commenter also expresses concern that there is no physical room on the CBP Form 301 to place this certification.

CBP Response:

As CBP has determined not to proceed with most of the proposed changes to 19 CFR 113.33, with the exception that § 133.33(c) is amended to add a reference to the Revenue Division, it is not necessary to address these comments.

Comment:

One commenter stated that the use of individual sureties is outmoded and therefore § 113.35 should be removed from title 19 of the CFR. However, another commenter suggested that this section should be revised to set forth the specific types of property that can be posted by individual sureties (*e.g.,* such assets should be liquid and be able to be readily valued).

CBP Response:

Although this provision is not commonly used, CBP opts to retain it and does not deem further specification as to the types of property that may be posted by individual sureties as necessary.

Comment:

One commenter noted that CBP should amend § 113.37(d) to remove the requirement that an agent or attorney on the bond must provide his or her social security number (SSN), as this requirement is counter to the protections afforded by the Privacy Act of 1974 (5 U.S.C. 552a). The commenter noted that CBP no longer uses the importer number (*i.e.,* Employee Identification Number, whether CBP-assigned or SSN) of the bond principal on the CBP Form 5955a. Additionally, the commenter noted that the Department of Commerce's Bureau of Census abolished the use of SSNs in its Automated Export System, citing 5 U.S.C. 552a, and suggested that CBP allow a surety attorney-in-fact to obtain and use a CBP-assigned importer number.

CBP Response:

In this final rule CBP is not adopting most of the proposed changes to § 113.37, with the following exceptions:

• Sections 113.37(d) and (g)(ii) are amended to allow an agent or attorney to place either his/her social security number or a surety-generated 9-digit alphanumeric identification number on the bond.

• Sections 113.37(a) and (f) are amended by removing the outdated reference to ''Bureau of Government Financial Operations'' and replacing it with a reference to ''Bureau of the Fiscal Service'' in order to conform to current administrative and legal authorities.

• Section 113.37(g)(1) is amended to allow corporate surety powers of attorney to be scanned and submitted to CBP as an email attachment, or by fax or mail.

Comment:

Two commenters suggested that CBP should amend proposed § 113.37(g) to reflect that the ACE permits a surety to manage its powers of attorney without the need to prepare and submit CBP Form 5297 on paper to CBP. Another commenter stated that CBP should authorize the electronic filing of CBP Form 5297.

CBP Response:

As noted above, CBP is amending § 113.37(g) to allow for the corporate surety powers of attorney to be scanned and submitted to CBP as an email attachment, or by fax or by mail.

Comment:

One commenter recommended that a change is needed to the language set

forth in proposed § 113.38, which pertains to delinquent sureties, in order to harmonize the provision with the goal of bond centralization. Specifically, paragraph (c)(4) proposes to include a port director, along with the Commissioner of CBP and the Director, Revenue Division, as a person with the authority to determine that CBP will no longer accept the bonds of a particular surety. The commenter notes that this is troubling because the opinion of an individual port director may set policy based upon his or her criteria, instead of upon criteria developed and administered centrally. Further, such language is inconsistent with current § 113.38(c)(1) and (2) which distinguish between decisions as to non-acceptance of bonds by a port director and decisions as to non-acceptance of bonds by the Commissioner which are issued to port directors. It is also inconsistent with proposed § 113.39(a) which states that the role of any authorized CBP officer in determinations relating to the removal of a surety from Treasury Department Circular 570 status is that of fact gathering and reporting, with the ultimate determination as to whether to refer a matter to Treasury to be made by CBP Headquarters.

CBP Response:

We agree with the commenter. CBP will revert back to the existing language in § 113.38(c)(4) which states that ''an appropriate CBP officer'' will make these decisions. This final rule also amends § 113.38(c)(4) to no longer require that notice to the surety be provided in person or by certified mail.

Comment:

One commenter requested that CBP extend the effective date of the final rule to 180 days from date of publication in the **Federal Register**.

CBP Response:

CBP does not view an extension beyond the stated effective date to be necessary as the amendments to part 113 promulgated in this document do not require the trade to adopt different procedures.

Comment:

Several commenters noted that the substantive changes proposed in the notice were never the subject of a pre-publication dialogue with the trade, despite the fact that CBP meets regularly with the trade.

CBP Response:

CBP engaged in pre-publication dialogue of these issues with the trade on numerous occasions during the development of this rulemaking. CBP believes that the agency met its trade outreach obligations regarding the content and development of these regulations.

Comment:

Several commenters noted that the proposed changes to § 113.39 would allow an ''authorized CBP officer'' to initiate a procedure to remove a surety from Treasury Department Circular 570. The commenters note that this is an extremely serious action as the Treasury Department Circular 570 is the basis for the surety to secure all types of federal government obligations, not merely customs obligations. Accordingly, it is recommended that CBP delegate the authority to initiate this action to the Commissioner of CBP or the Director, Revenue Division (the same individuals authorized to refuse to accept bonds of significantly delinquent sureties).

CBP Response:

CBP shares the commenters' concern, and this document does not adopt the proposed amendments to 19 CFR 113.39 which would have had the effect of replacing the existing references to ''port director or Fines, Penalties, and Forfeitures Officer'' with a more generalized reference to ''CBP.'' However, in order to reflect the centralization of the continuous bond program at the Revenue Division, this provision is amended to include ''authorized Revenue Division personnel,'' in addition to port directors and Fine, Penalties and Forfeitures Officers, as among those who may recommend that a surety company be removed from Treasury Department Circular 570.

Comment:

Section 113.40 prescribes the terms by which cash deposits or other types of U.S. obligations may be accepted by CBP in lieu of sureties on bonds. Paragraph (a) of this section requires that the party execute CBP Form 301 with the appropriate activity designated. A commenter noted that, as CBP bonds exist in formats other than the CBP Form 301, this paragraph should be amended to reflect that fact. A commenter also inquired whether the proposed amendments to § 113.40 authorize port directors to accept cash deposits or other obligations to secure single transactions.

CBP Response:

As a completed CBP Form 301 is not required for every type of cash-in-lieu of surety bond, § 113.40 is amended accordingly. This document also reverts to the original procedure set forth in paragraph (a) which provides that a port director retains the authority to accept cash deposits or obligations of the United States in lieu of sureties on STBs.

Comment:

One commenter recommended that CBP make a technical change to current § 113.52, which requires that CBP report a bonded debt to the Department of Justice for prosecution if unpaid for 90 days. The commenter notes that as a party has 180 days to submit a protest to CBP, the 90-day period should be changed to 180 days to reflect that fact.

CBP Response:

CBP agrees. Section 2103 of the Miscellaneous Trade and Technical Corrections Act of 2004 amended 19 U.S.C. 1514 by extending the time to file and amend a protest from 90 days to 180 days after the date of liquidation or reliquidation, or date of the decision, order, or finding being protested for entries made on or after December 18, 2004. This document makes a technical correction to 19 CFR 113.52 to reflect the statutory amendment.

Comment:

One commenter requested that CBP clarify what is meant by the term ''paper bond'' as used in proposed §§ 113.11 and 113.25(a). Until CBP adopts the paperless eBond concept, every bond is a paper bond and every bond application is a paper bond application. It appears the defining element as to which rules for signatures and certification apply is to be determined by the means of delivery to CBP, and CBP should be more precise in its language. CBP should define the term ''electronic bond'' as that term is used in § 113.25(b) to mean a paper bond that is transmitted electronically.

CBP Response:

As discussed above, CBP has further clarified the text of §§ 113.11, and of other provisions within part 113 as appropriate, to reflect that bonds and related documents may be scanned and submitted to CBP as an email attachment or by fax. Scanned or faxed documents will contain the requisite signatures and certifications.

Conclusion

After review of the comments and further consideration, CBP has decided to adopt as final, with the changes discussed above in the preamble and with additional non-substantive editorial changes, the proposed rule published in the **Federal Register** (75 FR 266) on January 5, 2010.

Executive Orders 13563 And 12866

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563

emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is not a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed this regulation.

Regulatory Flexibility Act

This section examines the impact on small entities as required by the Regulatory Flexibility Act (5 U.S.C. 601 *et. seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996. A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people).

The entities affected by this rule are importers and various other parties who file bonds with CBP as required by the CBP regulations. ''Importers'' are not defined as a ''major industry'' by the Small Business Administration (SBA) and do not have a unique North American Industry Classification System (NAICS) code; rather, virtually all industries classified by SBA include entities that import goods and services into the United States. Thus, entities affected by this rule would likely consist of a broad range of large, medium, and small businesses operating under the customs laws and other laws that CBP administers and enforces. These entities include, but are not limited to, importers, brokers, and freight forwarders, as well as other businesses that conduct various activities under continuous bonds.

The amendments set forth in this rule align the CBP regulations with current common practice and improve efficiency by requiring importers to file continuous bonds at the Revenue Division, requiring STBs to be filed at either the Revenue Division or with the port director, and permitting both continuous bonds and STBs to be scanned and submitted to CBP via email as an attachment or by fax.

Because these amendments affect such a wide-ranging group of entities involved in the importation of goods to the United States, the number of entities subject to this rule is considered ''substantial.'' It is not anticipated that there will be additional costs associated with filing continuous or single transaction bonds with the Revenue Division instead of the local port, and many importers already file these types of bonds directly with the Revenue Division. Additionally, these changes to the regulations confer a benefit to the entities as a result of increased efficiencies and harmonized standards in bond processing. The effects of these amendments, however, do not rise to the level of being considered a ''significant'' economic impact.

In the proposed rulemaking, CBP solicited comments on this conclusion. As we did not receive any comments contradicting our findings, CBP certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

The information collections contained in this rule have been previously submitted and approved by the Office of Management and Budget (OMB) and assigned OMB control numbers 1651–0050 and 1515–0144. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

Signing Authority

This document is being issued in accordance with 19 CFR 0.1(a)(1).

List of Subjects

19 CFR Part 101

Administrative practice and procedure, Customs duties and inspections, Organization and functions (Government agencies).

19 CFR Part 113

Bonds, Customs duties and inspection, Imports, Reporting and recordkeeping requirements, Surety bonds.

19 CFR Part 133

Bonds, Copyrights, Counterfeit goods, Customs duties and inspection, Imports, Reporting and recordkeeping requirements, Restricted merchandise, Seizures and forfeitures.

Amendments to the CBP Regulations

For the reasons stated above, parts 101, 113 and 133 of title 19 of the Code of Federal Regulations (19 CFR parts 101, 113 and 133) are amended as follows:

PART 101—GENERAL PROVISIONS

■ 1. The general authority citation for part 101 is revised to read as follows:

Authority: 5 U.S.C. 301; 6 U.S.C. 101, *et. seq.;* 19 U.S.C. 2, 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1623, 1624, 1646a.

* * * * *

■ 2. Section 101.1 is amended by adding definitions for ''CBP,'' ''*Commissioner or Commissioner of Customs*,'' ''*Customs or U.S. Customs Service*,'' and ''*Customs regulations or CBP regulations*'' in alphabetical order to read as follows:

§ 101.1 Definitions.

* * * * *

CBP. The term ''CBP'' means U.S. Customs and Border Protection.

Commissioner or *Commissioner of Customs.* The terms ''Commissioner'' or ''Commissioner of Customs'' mean Commissioner of U.S. Customs and Border Protection.

Customs or *U.S. Customs Service.* The terms ''Customs'' or ''U.S. Customs Service'' mean U.S. Customs and Border Protection.

Customs regulations or CBP regulations. The terms ''Customs regulations'' or ''CBP regulations'' mean Chapter 1 of title 19 of the Code of Federal Regulations (19 CFR Chapter 1).

* * * * *

PART 113—CBP BONDS

■ 3. The general authority citation for part 113 is revised to read as follows:

Authority: 6 U.S.C. 101, *et. seq.;* 19 U.S.C. 66, 1623, 1624.

* * * * *

■ 4. The part 113 heading is revised to read as set forth above.

§ 113.0 [Amended]

■ 5. Section 113.0 is amended by removing the word ''Customs'' and adding in its place the term ''CBP''.

■ 6. Section 113.1 is revised to read as follows:

§ 113.1 Authority to require security or execution of bond.

Where a bond or other security is not specifically required by law or regulation, the Commissioner of CBP may by specific instruction require, or authorize the Director, Revenue Division or the port director to require, such bonds or other security considered necessary for the protection of the revenue or to assure compliance with any pertinent law, regulation, or instruction.

§ 113.2 [Amended]

■ 7. In § 113.2:

■ a. The heading is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ b. The introductory text is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ c. Paragraph (c) is amended by removing the word ''shall'' and adding

in its place the word ''will'', and by adding the word ''as'' before the word ''he''; and

■ d. In paragraph (d), the first sentence is amended by removing the word ''entry'' and adding in its place the word ''transaction'', the second sentence is amended by removing the word ''shall'' and adding in its place the word ''will'', and the third sentence is amended by removing the word ''Customs'' and adding in its place the term ''CBP''.

■ 8. Section 113.4 is amended by revising paragraph (a) and amending paragraph (b) by removing the words ''Customs laws or regulations'' and adding in their place the words ''customs laws or CBP regulations''.

The revision reads as follows:

§ 113.4 Bonds and carnets.

(a) *Bonds.* All bonds required to be given under the customs laws or CBP regulations will be known as CBP bonds.

* * * * *

■ 9. Section 113.11 is revised to read as follows:

§ 113.11 Bond application.

(a) *Single transaction bond application.* In order to insure that the revenue is adequately protected, the port director may require a person who will be engaged in a single customs transaction relating to the importation or entry of merchandise to file a bond application. The single transaction bond application may be in the form of a letter filed with the Director, Revenue Division or the port director, or the application may be scanned and submitted to CBP as an email attachment or by fax. The application must identify the value and nature of the merchandise involved in the transaction to be secured. When the proper bond in a sufficient amount is filed with the entry summary or with the entry, or when the entry summary is filed at the time of entry, an application will not be required.

(b) *Continuous bond application.* To secure multiple transactions relating to the importation or entry of merchandise or the operation of a bonded smelting or refining warehouse, a continuous bond application must be submitted to the Director, Revenue Division. The continuous bond application may be in the form of a letter or it may be scanned and submitted to CBP as an email attachment or by facsimile (fax).

(1) *Information required.* The application must contain the following information:

(i) The general character of the merchandise to be entered; and

(ii) The total amount of ordinary customs duties (including any taxes required by law to be treated as duties), plus the estimated amount of any other tax or taxes on the merchandise to be collected by CBP, accruing on all merchandise imported by the principal during the calendar year preceding the date of the application. The total amount of duties and taxes will be that which would have been required to be deposited had the merchandise been entered for consumption even though some or all of the merchandise may have been entered under bond. If the value or nature of the merchandise to be imported will change in any material respect during the next year the change must be identified. If no imports were made during the calendar year prior to the application, a statement of the duties and taxes it is estimated will accrue on all importations during the current year shall be submitted.

(2) *Application updates.* If the Director, Revenue Division approves a bond based upon the application, whenever there is a significant change in the information provided under this paragraph, the principal on the bond must submit a new application containing an update of the information required by paragraph (b)(1) of this section. The new application must be filed no later than 30 days after the new facts become known to the principal.

(c) *Certification.* Any application submitted under this section must be signed by the applicant and contain the following certification:

> I certify that the factual information contained in this application is true and accurate and any information provided which is based upon estimates is based upon the best information available on the date of this application.

■ 10. Section 113.12 is revised to read as follows:

§ 113.12 Bond approval.

(a) *Single transaction bonds.* Single transaction bonds will be approved by the Revenue Division or the director of the port where filed.

(b) *Continuous bonds.* Continuous bonds must be approved by the Revenue Division. Only one continuous bond for a particular activity will be authorized for each principal.

■ 11. In § 113.13:

■ a. The first sentence in paragraph (a) is amended by removing the words ''Customs bond shall'' and adding in their place the words ''CBP bond must'', and the second and third sentences in paragraph (a) are amended by removing the word ''shall'' each place that it appears and adding the word ''will'';

■ b. Paragraph (b) introductory text is amended by removing the words ''the port director or drawback office in the case of a bond relating to repayment of erroneous drawback payment (*see* § 113.11) should at least'' and adding in their place the words ''CBP will'';

■ c. Paragraph (b)(2) is revised;

■ d. Paragraph (b)(4) is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ e. Paragraph (c) is revised; and

■ f. Paragraph (d) is amended by removing the words ''a port director or drawback office'' and adding in their place the term ''CBP''; by removing the word ''Customs'' and adding in its place the words ''all applicable''; and by removing the words ''he shall'' and adding in their place the words ''CBP may immediately''.

The revisions read as follows:

§ 113.13 Amount of bond.

* * * * *

(b) * * *

(2) The prior record of the principal in complying with CBP demands for redelivery, the obligation to hold unexamined merchandise intact, and other requirements relating to enforcement and administration of customs and other laws and CBP regulations;

* * * * *

(c) *Periodic review of bond sufficiency.* CBP will periodically review each bond on file to determine whether the bond is adequate to protect the revenue and ensure compliance with applicable law and regulations. If CBP determines that a bond is inadequate, the principal and surety will be promptly notified in writing. The principal will have 15 days from the date of notification to remedy the deficiency. Notwithstanding the foregoing, where CBP determines that a bond is insufficient to adequately protect the revenue and ensure compliance with applicable law and regulations, CBP may provide written notice to the principal and surety that, upon receipt thereof, additional security in the form of cash deposit or single transaction bond may be required for any and all of the principal's transactions until the deficiency is remedied.

* * * * *

■ 12. Section 113.14 is revised to read as follows:

§ 113.14 Approved form of bond inadequate.

If CBP determines that none of the conditions contained in subpart G of this part is applicable to a transaction sought to be secured, the Director,

Revenue Division, or the port director, as CBP deems appropriate, will draft conditions that cover the transaction. Before execution of the bond, the conditions must be submitted to Headquarters, Attention: Executive Director, Regulations and Rulings, Office of International Trade, for approval.

■ 13. Section 113.15 is revised to read as follows:

§ 113.15 Retention of approved bonds.

Except for bonds containing an agreement to pay court costs (condemned goods) (*see* § 113.72), and except as may otherwise be deemed appropriate by CBP, bonds that are approved by the port director will be retained at the port office and bonds that are approved by the Revenue Division (including bonds relating to repayment of erroneous drawback payments containing the conditions set forth in § 113.65) will be retained at the Revenue Division. The bond containing the agreement to pay court costs (condemned goods), will be transmitted to the United States attorney, as required by section 608, Tariff Act of 1930, as amended (19 U.S.C. 1608).

§ 113.21 [Amended]

■ 14. In § 113.21:

■ a. Paragraphs (a)(1), (b), (c), and (e) are amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must''; and

■ b. Paragraph (d) is amended by removing the word ''shall'' and adding in its place the word ''may''.

§ 113.22 [Amended]

■ 15. Section 113.22 is amended in paragraphs (a) and (b) by removing the word ''shall'' each place it appears and adding in its place the word ''must''.

§ 113.23 [Amended]

■ 16. In § 113.23:

■ a. Paragraph (b) is amended by removing the word ''shall'' and adding in its place the word ''must'';

■ b. Paragraph (c) is amended, in the first sentence, by removing the word ''Customs'' and adding in its place the term ''CBP'' and by removing the word ''shall'' and adding in its place the word ''must'' and, in the second sentence, by removing the word ''shall'' and adding in its place the word ''may''; and

■ c. Paragraph (d) is amended: by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP''; by removing, in the first sentence, the word ''shall'' and adding in its place the word ''may'', and; in the second sentence, be removing the word ''shall'' and adding in its place the word ''will''.

■ 17. In § 113.24:

■ a. Paragraphs (a), (b) and (c) are revised; and

■ b. Paragraph (d) is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must'', and by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP''.

The revisions read as follows:

§ 113.24 Riders.

(a) *Types of riders.* The Revenue Division will accept all types of authorized bond riders. For a comprehensive listing, see the CBP Web site located at *www.cbp.gov.*

(b) *Location and method of filing.* A bond rider must be filed at the Revenue Division, and may be submitted in paper or scanned and submitted to the Revenue Division as an email attachment or by facsimile (fax).

(c) *Attachment of rider to paper bond.* A rider submitted to CBP in paper format must be securely attached to the related bond to prevent their loss or misplacement.

* * * * *

§ 113.25 [Amended]

■ 18. Section 113.25 is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must''.

■ 19. In § 113.26:

■ a. Paragraph (a) is revised;

■ b. Paragraph (b) is amended by removing the words ''the Customs Bond, Customs'' and adding in their place the term ''CBP''; and

■ c. Paragraph (c) is amended by removing the words ''the Customs Bond, Customs'' and adding in their place the term ''CBP''.

The revision reads as follows:

§ 113.26 Effective dates of bonds and riders.

(a) *General.* A continuous bond, and any associated application required by § 113.11 or a rider, must be filed at least 60 days prior to the effective date requested for the continuous bond or rider.

* * * * *

■ 20. Section 113.27 is revised to read as follows:

§ 113.27 Effective dates of termination of bond.

(a) *Termination by principal/co-principal.* A written request by a principal or co-principal to terminate a bond must be mailed, faxed, or emailed to the Revenue Division or, in the case of a bond relating to repayment of erroneous drawback payment, to the drawback office where the bond was approved. The termination will take effect on the date requested if that date is at least 10 business days after the date CBP receives the request. If no termination date is requested, the termination will take effect on the tenth business day following the date CBP receives the request.

(b) *Termination by surety.* A surety may not disavow already incurred obligations but may, with or without the consent of the principal, terminate its agreement to accept future obligations on a bond. The surety must provide reasonable notice of termination, made pursuant to the methods set forth in paragraph (a) of this section, to both the Revenue Division or a drawback office, as appropriate, and to the principal. The notice must state the date on which the termination will be effective. Thirty days will constitute reasonable notice unless the surety can show to the satisfaction of CBP that a shorter time frame is reasonable under the facts and circumstances.

(c) *Effect of termination.* If a bond is terminated, no new customs transactions may be charged against the bond. A new bond in an appropriate amount on CBP Form 301, containing the appropriate bond conditions set forth in subpart G of this part, must be filed before further customs activity may be transacted.

■ 21. In § 113.32:

■ a. Introductory text is added;

■ b. Paragraph (a) is removed;

■ c. Paragraph (b) is redesignated as paragraph (a) and is amended by removing the word ''shall'' and adding in its place the word ''must''; and

■ d. Paragraph (c) is redesignated as paragraph (b) and is amended, in the first sentence, by removing the word ''shall'' and adding in its place the word ''will'', and by removing the second sentence.

The addition reads as follows:

§ 113.32 Partnerships as principals.

A partnership, including a limited partnership, means any business association recognized as such under the laws of the State where the association is organized.

* * * * *

■ 22. Section 113.33 is amended:

■ a. In paragraph (a), by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ b. In paragraph (b), be removing the word ''shall'' each place that it appears

and adding in its place the word ''must'';

■ c. By revising paragraph (c);

■ d. In paragraph (d), by removing the words ''port director'' and adding in their place the words ''Revenue Division'', and removing the word ''shall'' each place that it appears and adding in its place the word ''must''; and

■ e. In paragraph (e), removing the words ''shall be'' and adding in their place the word ''are''.

The revision reads as follows:

§ 113.33 Corporations (including Limited Liability Corporations) as principals.

* * * * *

(c) *Bond executed by an officer of corporation.* When a bond is executed by an officer of a corporation, a power of attorney will not be required if the person signing the bond on behalf of the corporation is known to the Revenue Division, port director, or drawback office to be the president, vice president, treasurer, or secretary of the corporation. The officer's signature is prima facie evidence of that officer's authority to bind the corporation. When a power of attorney is required, it must conform to the requirements of subpart C, part 141, of this chapter.

* * * * *

§ 113.34 [Amended]

■ 23. Section 113.34 is amended by removing the word ''shall'' in the second sentence and adding in its place the word ''may''.

■ 24. Section 113.35 is revised to read as follows:

§ 113.35 Individual sureties.

(a) *Number required.* If individuals sign as sureties, there must be two sureties on the bond unless CBP is satisfied that one surety is sufficient to protect the revenue and ensure compliance with the law and regulations.

(b) *Qualifications to act as surety*—(1) *Residency and citizenship.* Each individual surety on a CBP bond must be both a resident and citizen of the United States.

(2) *Granting of power of attorney.* Any individual, unless prohibited by law, may grant a power of attorney to sign as surety on CBP bonds. Unless the power is unlimited, all persons to whom the power relates must be named.

(3) *Property requirements.* For both single transaction and continuous bonds, each individual surety must have property available as security within the customs territory of the United States. The current market value of the property, less any encumbrance, must be equal to or greater than the amount of the bond. If one individual surety is accepted, the individual surety must have property the value of which, less any encumbrance, is equal to or greater than twice the amount of the bond.

(c) *Oath and evidence of solvency.* Before being accepted as a surety, the individual must:

(1) Take an oath on CBP Form 3579, setting forth:

(i) The amount of assets over and above all debts and liabilities and such exemptions as may be allowed by law; and

(ii) The general description and location of one or more pieces of real estate owned within the customs territory of the United States, and the value thereof, less any encumbrance.

(2) Produce such evidence of solvency and financial responsibility as CBP may require.

(d) *Determination of financial responsibility.* An individual will not be accepted as surety on a bond until CBP is satisfied as to the financial responsibility of the individual. CBP may request Immigration and Customs Enforcement (ICE) to conduct an immediate investigation to verify a surety's financial responsibility.

(e) *Continuancy of financial responsibility.* In order to ascertain the continued solvency and financial responsibility of individual sureties, CBP will require a new oath and determine the financial responsibility of each individual surety as prescribed in paragraphs (c) and (d) of this section at least once every six months, and more often if deemed advisable.

§ 113.36 [Amended]

■ 25. Section 113.36 is amended by removing the word ''shall'' and adding in its place the word ''will''.

■ 26. In § 113.37:

■ a. The second sentence in paragraph (a) is amended by removing the word ''Customs'' and adding in its place the term ''CBP''; removing the word ''shall'' where it appears after the word ''corporation'' and adding in its place the word ''will''; removing the words ''shall be for a greater amount than'' and adding in their place the words ''may exceed'', and; removing the phrase ''Bureau of Government Financial Operations'' and adding in its place the phrase, ''Bureau of the Fiscal Service''.

■ b. Paragraph (b) is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ c. Paragraph (c) is amended by removing the word ''shall'' and adding in its place the word ''must'';

■ d. Paragraph (d) is revised;

■ e. Paragraph (e) is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must'';

■ f. Paragraph (f) is amended by removing the words ''Bureau of Government Financial Operations'' and adding in their place the words, ''Bureau of the Fiscal Service''; removing the word ''shall'' and adding in its place the word ''must''; removing, in the last paragraph of the ''Corporate Sureties Agreement for Limitation of Liability'' set forth under paragraph (f), the number ''19__'' and adding in its place ''20__''; and removing in the signature block the words ''Port Director (Drawback Office)'' and adding in their place the words ''Authorized CBP officer'';

■ g. Paragraph (g)(1) introductory text and (g)(1)(ii) are revised;

■ h. Paragraph (g)(2) is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must'' and by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP'';

■ i. Paragraph (g)(3) is amended by removing the word ''Customs'' each place it appears and adding in its place the term ''CBP''; in the first, second and third sentences by removing the word ''shall'' each place that it appears and adding in its place the word ''must', and; in the fourth sentence, by removing the word ''shall'' and adding in its place the word ''will'';

■ j. Paragraph (g)(4) is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''will'' and by removing the word ''Customs'' and adding in its place the term ''CBP''; and

■ k. Paragraph (g)(5) is revised.

The revisions read as follows:

§ 113.37 Corporate sureties.

* * * * *

(d) *Social security or other surety-generated identification number of agent or attorney on the bond.* In the appropriate place on each bond executed by the agent or attorney acting for a corporate surety, the agent or attorney must place his/her social security number or other surety-generated 9-digit alphanumeric identification number, as it appears on the corporate surety power of attorney.

* * * * *

(g) * * *

(1) *Execution and contents.* Corporate surety powers of attorney may be submitted to CBP on the CBP Form 5297 and may be scanned and submitted as

an email attachment, or submitted by facsimile (fax) or mail.

* * * * *

(ii) Name and address of agent or attorney, and social security number or other surety-generated 9-digit alphanumeric identification number for the agent or attorney.

* * * * *

(5) *Change on the power of attorney.* (i) No change may be made on the CBP Form 5297 after it has been approved by CBP except the following:

(A) Grantee name change;

(B) Grantee address change; and

(C) The addition of port(s) to the corporate surety power of attorney on file.

(ii) To make any other change to the power of attorney two separate CBP Forms 5297 must be submitted, one revoking the previous power of attorney, and one containing a new grant of authority.

■ 27. In § 113.38:

■ a. The heading and text of paragraph (a) are amended by removing the word ''Customs'' each place it appears and adding the term ''CBP'' in its place; and the text of paragraph (a) is further amended by removing the word, ''shall'' and adding in its place the word, ''will'';

■ b. The heading and text of paragraph (b) are amended by removing the word ''Customs'' each place it appears and adding the term ''CBP'' in its place;

■ c. Paragraph (c)(1) is amended in the heading and first sentence by adding the words ''single transaction'' before the word ''bond'' each place that it appears and, in the second sentence, by removing the language, ''Director, Border Security and Trade Compliance Division'' and adding in its place, ''Executive Director, Regulations and Rulings, Office of International Trade,'';

■ d. Paragraph (c)(2) is revised;

■ e. Paragraph (c)(3) is amended by removing the word ''Customs'' and adding in its place the term ''CBP''; and

■ f. Paragraph (c)(4) is revised.

The revisions read as follows:

§ 113.38 Delinquent sureties.

* * * * *

(c) * * *

(2) *Non-acceptance of bond upon instruction by Commissioner of CBP or Director, Revenue Division.* The Commissioner of CBP, or the Director, Revenue Division, may issue instructions to CBP officers not to accept a bond secured by an individual or corporate surety who, without just cause, is significantly delinquent with respect to either the number or dollar amounts of outstanding bills.

* * * * *

(4) *Review and final decision.* After a review of any submission made by a surety under paragraph (c)(3) of this section, if an appropriate CBP officer is still of the opinion that bonds secured by the surety should not be accepted, written notice of the decision will be provided to the surety at least five days before the date that CBP will no longer accept the bonds of the surety. Copies of the notice will also be provided to the Executive Director, Regulations and Rulings, Office of International Trade and, if the notice does not originate from the Revenue Director, to the Director, Revenue Director. Notice will be given to the public by publishing the decision in the *Customs Bulletin.*

* * * * *

■ 28. In § 113.39:

■ a. The introductory text is revised;

■ b. Paragraph (a) introductory text is revised;

■ c. Paragraph (a)(5) is amended by removing the words the ''port director or Fines, Penalties, and Forfeitures Officer'' and adding in their place the words ''port director, Fines, Penalties, and Forfeitures Officer, or authorized Revenue Director personnel''; and

■ d. Paragraph (b) is amended in the first sentence, by removing the words ''The Director, Border Security and Trade Compliance Division, shall'' and adding in their place the words ''CBP Headquarters will''; in the second sentence, by removing the words ''Bureau of Government Financial Operations'' and adding in their place the words, ''Bureau of the Fiscal Service''; and, in the last sentence, by removing the words ''port director and Fines, Penalties, and Forfeitures Officer'' and adding in their place the words ''port director, Fines, Penalties, and Forfeitures Officer, and Director, Revenue Division''.

The revisions read as follows:

§ 113.39 Procedure to remove a surety from Treasury Department Circular 570.

If a port director, Fines, Penalties, and Forfeitures Officer, or authorized Revenue Division officer is dissatisfied with a surety company because the company has neglected or refused to pay a valid demand made on the surety company's bond or otherwise has failed to honor an obligation on that bond, the port director, Fines, Penalties, and Forfeitures Officer, or authorized Revenue Division personnel may take the following steps to recommend that the surety company be removed from Treasury Department Circular 570.

(a) *Report to Headquarters.* A port director, Fines, Penalties, and Forfeitures Officer, or authorized Revenue Division officer will send the following evidence to CBP Headquarters, Attention: Executive Director, Regulations and Rulings, Office of International Trade:

* * * * *

■ 29. In § 113.40:

■ a. Paragraph (a) is revised;

■ b. Paragraph (b) introductory text is revised and the ''Power of Attorney and Agreement (For Corporation)'' form is amended by removing the designation ''19__'' each place that it appears and adding ''20__'' in its place; and

■ c. Paragraph (c) is revised.

The revisions read as follows:

§ 113.40 Acceptance of cash deposits or obligations of the United States in lieu of sureties on bonds.

(a) *General provisions.* In lieu of sureties on any bond required or authorized by any law, regulation, or instruction which the Secretary of the Treasury, the Secretary of Homeland Security, or the Commissioner of CBP are authorized to enforce, the Director, Revenue Division or, in the case of single transaction bonds, a port director, may accept United States money, United States bonds (except for savings bonds), United States certificates of indebtedness, Treasury notes, or Treasury bills in an amount equal to the face amount of the bond that would be required. The option to deposit cash or U.S. obligations in lieu of sureties is at the option of the importer, and a CBP Form 301 or other CBP-approved bond designating the appropriate activity for the cash deposits or U.S. obligations in lieu of surety must be filed. When cash or obligations in lieu of surety are accepted, it must be for a term of no more than one year. Additional cash deposits or obligations in lieu of surety may be required.

(b) *Authority to sell United States obligations on default.* At the time of deposit with the Director, Revenue Division, of any U.S. obligation (other than U.S. money), the obligor must deliver a duly executed power of attorney and agreement authorizing the Director, Revenue Division, in the case of any default in the performance of any of the conditions of the bond, to sell the obligation so deposited and to apply the proceeds of the sale, in whole or in part, to the satisfaction of any damages, demands, or deficiency arising by reason of default. The format of the power of attorney and agreement, when the obligor is a corporation, is set forth below and must be appropriately modified when the obligor is either an individual or a partnership:

* * * * *

(c) *Application of United States money or obligations on default.* If

United States cash or obligations are deposited in lieu of surety on any bond, the appropriate CBP officer is authorized to apply the cash or money received from the deposited obligation to satisfy any damages, demand, or deficiency arising from a default under the bond.

§ 113.41 [Amended]

■ 30. Section 113.41 is amended by removing the word ''shall'' and adding in its place the word ''must'', and removing the word ''Customs'' and adding in its place the term ''CBP''.

§ 113.42 [Amended]

■ 31. Section 113.42 is amended by removing from the first sentence the word ''shall'' and adding in its place the word ''must''; removing the word ''Customs'' and adding in its place the term ''CBP''; and removing in the second sentence the word ''shall'' and adding in its place the word ''will''.

■ 32. In § 113.43:

■ a. Paragraph (a) is revised;

■ b. Paragraph (b) is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''will'' and removing the words ''2 months'' each place that they appear and adding in their place the words ''60 days''; and

■ c. Paragraph (c) is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''will''.

The revision reads as follows:

§ 113.43 Extension of time period.

(a) *Application received within time period.* If a document referred to in § 113.42 is not produced within 120 days from the date of the transaction in connection with which the bond was given, the port director or an appropriate CBP officer, in his or her discretion, and upon written application of the importer, may extend the period for one further period not to exceed 60 days.

* * * * *

§ 113.44 [Amended]

■ 33. In § 113.44, paragraph (b) is amended by removing the word ''shall'' and adding in its place the word ''must''.

§ 113.45 [Amended]

■ 34. Section 113.45 is amended by removing the word ''shall'' and adding in its place the word ''must'' and removing the word ''entry'' each place that it appears and adding in its place the word ''transaction''.

§ 113.51 [Amended]

■ 35. Section 113.51 is amended by removing the word ''Customs'' and adding in its place the term ''CBP''.

■ 36. Section 113.52 is revised to read as follows:

§ 113.52 Failure to satisfy the bond.

If any CBP bond, except one given only for the production of free-entry or reduced-duty documents (*see* § 113.43(c) of this chapter) has not been satisfied upon the expiration of 180 days after liability has accrued under the bond, the matter will be reported to the Department of Justice for prosecution unless measures have been taken to file an application for relief or protest in accordance with the provisions of this chapter or to satisfactorily settle this matter.

§ 113.53 [Amended]

■ 37. In § 113.53:

■ a. The section heading is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ b. Paragraph (a) introductory text is amended by removing in the paragraph heading the word ''Customs'' and adding in its place the term ''CBP'' and removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP'';

■ c. Paragraph (a)(3) is amended by adding after the word ''Commissioner'' the words ''of CBP''; and

■ d. Paragraph (b) is amended by adding in the paragraph heading, after the word ''director'', the words ''or other authorized CBP officer''; removing, in the text, the word ''Customs'' and adding in its place the term ''CBP''; adding after the word ''director'' the words ''or other authorized CBP officer''; and removing the word ''shall'' and adding in its place the word ''will''.

§ 113.55 [Amended]

■ 38. In § 113.55:

■ a. Paragraph (c) introductory text is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must'' and removing the word ''Customs'' and adding in its place the word ''customs'';

■ b. Paragraph (c)(1) is amended by removing the word ''shall'' and adding in its place the word ''will'';

■ c. Paragraph (c)(3) is amended by removing the word ''Customs'' and adding in its place the term ''CBP''; and

■ d. Paragraph (d) is removed.

Subpart G—CBP Bond Conditions

■ 39. The subpart G heading is revised to read as set forth above.

§ 113.61 [Amended]

■ 40. Section 113.61 is amended in the first sentence by removing the word ''Customs'' and adding in its place the word ''customs'' and in the second sentence by removing the word ''Customs'' and adding in its place the term ''CBP''.

■ 41. In § 113.62:

■ a. The introductory text is amended by removing the word ''shall'' and adding in its place the word ''must'' and by removing the words ''single entry'' and adding in their place the words ''single transaction'';

■ b. Paragraphs (a)(1) introductory text, (a)(1)(ii), and (a)(2) introductory text are amended by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP'';

■ c. Paragraph (a)(3) is amended by removing the words ''the port director'' and adding in their place the term ''CBP'';

■ d. Paragraph (b) introductory text and paragraph (b)(1) are amended by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP'';

■ e. Paragraph (c) is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ f. Paragraph (d) introductory text is amended by removing the word ''Customs'' wherever it appears and adding in its place the term ''CBP'';

■ g. Paragraph (f) introductory text and paragraph (f)(2) are amended by removing the word ''Customs'' wherever it appears and adding in its place the term ''CBP'';

■ h. Paragraph (f)(3) is revised;

■ i. Paragraph (g)(1) is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ j. Paragraph (h)(2) is revised;

■ k. Paragraphs (h)(3) and (4) are amended by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP'';

■ l. The heading and text of paragraph (i) are amended by removing the words ''Customs Regulations'' each place that they appear and adding in their place the words ''CBP regulations''; and by removing the words ''Customs security'' each place that they appear and adding in their place the words ''customs security'';

■ m. Paragraph (j) is amended by removing the words ''Customs and Border Protection'' and adding in their place the term ''CBP'';

■ n. Paragraph (k)(2) is amended by removing the words ''Customs and Border Protection (CBP)'' and adding in their place the term ''CBP''; and

■ o. Paragraphs (m)(2) and (4) are amended by removing the word

''Customs'' each place that it appears and adding in its place the term ''CBP'' and removing the word ''shall'' each place that it appears and adding in its place the word ''will''.

The revisions to § 113.62 read as follows:

§ 113.62 Basic importation and entry bond conditions.

* * * * *

(f) * * *

(3) Keep any customs seal or cording on the merchandise intact until the merchandise is examined by CBP.

* * * * *

(h) * * *

(2) If a fishing vessel, to present the original approved application to CBP within 24 hours on each arrival of the vessel in the customs territory of the United States from a fishing voyage;

* * * * *

§ 113.63 [Amended]

■ 42. In § 113.63:

■ a. The introductory text is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must'';

■ b. Paragraph (a)(2) is amended by removing the words ''Customs Regulations'' and adding in their place the words ''CBP regulations'';

■ c. Paragraph (a)(3) is amended by adding the term ''CBP'' before the word ''regulations'' and removing the word ''Customs'' and adding in its place the term ''CBP'';

■ d. Paragraph (a)(5) is amended by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP'' and removing the word ''Regulations'' and adding in its place the word ''regulations'';

■ e. Paragraph (b)(2) is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ f. Paragraph (b)(3) is amended by removing the words ''Customs Regulations'' and adding in their place the words ''CBP regulations'';

■ g. Paragraphs (c)(1) and (2) are amended by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP'';

■ h. Paragraph (c)(3) is amended by removing the words ''Customs Regulations'' and adding in its place the words ''CBP regulations'';

■ i. Paragraph (c)(4) is amended by removing the word ''Customs'' and adding in its place the term ''CBP'' and removing the words ''Customs Regulations'' and adding in their place the words ''CBP regulations'';

■ j. Paragraph (d) is amended by removing in the paragraph heading and text the word ''Customs'' each place that it appears and adding in their place the term ''CBP'';

■ k. Paragraph (e) is amended by removing the words ''Customs laws and regulations'' and adding in their place the words ''customs laws and CBP regulations'';

■ l. The heading and text of paragraph (f) are amended by removing the words ''Customs Regulations'' each place that they appear and adding in their place the words ''CBP regulations'' and by removing the words ''Customs security'' each place that they appear and adding in their place the words ''customs security'';

■ m. Paragraph (g) is amended by removing the words ''Customs and Border Protection'' and adding in their place the term ''CBP'';

■ n. Paragraph (h)(1) is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ o. Paragraph (h)(2) is amended by removing the words ''Customs Regulations'' and adding in their place the words ''CBP regulations'';

■ p. Paragraph (h)(5) is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ q. Paragraph (i)(2) is amended by removing the word ''shall'' and adding in its place the word ''will'' and by removing the word ''Customs'' and adding in its place the term ''CBP''; and

■ r. Paragraph (i)(3) is amended by removing the word ''Customs'' and adding in its place the term ''CBP''.

■ 43. In § 113.64:

■ a. The introductory text is amended by removing the word ''shall'' and adding in its place the word ''must'' and by removing the word ''entry'' and adding in its place the word ''transaction'';

■ b. Paragraph (a) is amended by removing the words ''Customs and Border Protection (CBP)'' and adding in their place the term ''CBP'' and by removing the second sentence;

■ c. Paragraphs (b) through (k) are redesignated as paragraphs (c) through (l);

■ d. A new paragraph (b) is added;

■ e. Newly redesignated paragraph (c) is amended by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP''; by removing the word ''Regulations'' each place it appears and adding in its place the word ''regulations'', and; in the third sentence, by removing the word ''shall'' and adding in its place the word ''will'';

■ f. The heading and text of newly redesignated (j) are amended by removing the words ''Customs Regulations'' each place they appear and adding in their place the words ''CBP regulations''; and by removing the words ''Customs security'' each place that they appear and adding in their place the words ''customs security''; and

■ g. Newly redesignated paragraphs (l)(1) and (2) are amended by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP''.

The addition reads as follows:

§ 113.64 International carrier bond conditions.

* * * * *

(b) *Agreement to pay liquidated damages*—(1) *Passenger processing fees:* If the principal (carrier) fails to pay passenger processing fees to CBP within 31 calendar days after the close of the calendar quarter in which they were required to be collected pursuant to § 24.22(g) of this chapter, the obligors (principal and surety, jointly and severally) agree to pay liquidated damages equal to two times the passenger processing fees that were required to be collected but not timely remitted to CBP, regardless of whether such fees were in fact collected from passengers, as prescribed by regulation.

(2) *Railroad car processing fees:* If the principal (carrier) fails to pay railroad car processing fees to CBP within 60 calendar days after the close of the calendar month in which they were collected pursuant to § 24.22(d) of this chapter, the obligors (principal and surety, jointly and severally) agree to pay liquidated damages equal to two times the railroad car processing fees which have not been timely paid to CBP as prescribed by regulation.

(3) *Reimbursement fees payable by express consignment carrier and centralized hub facilities.* If the principal (carrier) fails to timely pay the reimbursement fees payable to CBP by express consignment carrier facilities and centralized carrier facilities pursuant to the terms set forth in § 24.23(b)(4) of this chapter, the obligors (principal and surety, jointly and severally) agree to pay liquidated damages equal to two times the fees which have not been timely paid to CBP as prescribed by that section.

* * * * *

§ 113.65 [Amended]

■ 44. In § 113.65:

■ a. The introductory text is amended by removing the word ''shall'' and adding in its place the word ''must'' and by removing the word ''entry'' and adding in its place the word ''transaction''; and

■ b. Paragraphs (a)(3) and (4) are amended by removing the word

''Customs'' each place that it appears and adding in its place the term ''CBP''.

■ 45. In § 113.66:

■ a. The introductory text is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must'';

■ b. Paragraph (a) introductory text and paragraph (a)(1) are revised;

■ c. Paragraph (b)(3) is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ d. Paragraph (c)(2) is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ e. Paragraph (d)(2) is amended by removing the word ''shall'' and adding in its place the word ''will'' and by removing the word ''Customs'' and adding in its place the term ''CBP''; and

■ f. Paragraph (d)(3) is amended by removing the word ''Customs'' and adding in its place the term ''CBP''.

The revisions read as follows:

§ 113.66 Control of containers and instruments of international traffic bond conditions.

(a) *Agreement to Enter Any Diverted Instrument of International Traffic.* If a principal brings in and takes out of the customs territory of the United States an instrument of international traffic without entry and without payment of duty, as provided by the CBP regulations and section 322(a), Tariff Act of 1930, as amended (19 U.S.C. 1322(a)) the principal agrees to:

(1) Report promptly to CBP when the instrument is diverted to point-to-point local traffic in the customs territory of the United States or when the instrument is otherwise withdrawn in the customs territory of the United States from its use as an instrument of international traffic.

* * * * *

§ 113.67 [Amended]

■ 46. In § 113.67:

■ a. Paragraph (a) introductory text is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must'';

■ b. Paragraph (a)(1) introductory text is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ c. Paragraph (a)(1)(i) is amended by removing the words ''Customs Regulations'' and adding in their place the words ''CBP regulations'';

■ d. Paragraph (a)(1)(iii) is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ e. Paragraph (a)(2)(iii) is amended by removing the word ''shall'' and adding in its place the word ''will''; and by removing the word ''Customs'' each place it appears and adding in its place the term ''CBP'';

■ f. Paragraph (b) introductory text is amended by removing the word ''shall'' each place it appears and adding in its place the word ''must'';

■ g. Paragraph (b)(1) introductory text is amended by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ h. Paragraph (b)(1)(i) is amended by removing the words ''Customs Regulations'' and adding in their place the words ''CBP regulations''; and

■ i. Paragraphs (b)(1)(iii) and (b)(2)(iii) are amended by removing the word ''Customs'' each place it appears and adding in its place the term ''CBP''.

§ 113.68 [Amended]

■ 47. In § 113.68:

■ a. The introductory text is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must''; and by removing the word ''entry'' and adding in its place the word ''transaction'';

■ b. Paragraph (a) is amended by removing the word ''Customs'' and adding in its place the term ''CBP''; and

■ c. The second sentence of paragraph (b) is amended by removing the word ''shall'' and adding in its place the word ''will''; and by removing the word ''Customs'' and adding in its place the term ''CBP''.

§ 113.69 [Amended]

■ 48. In § 113.69:

■ a. The introductory text is amended by removing the word ''shall'' each place it appears and adding in its place the word ''must'' and by removing the word ''entry'' and adding in its place the word ''transaction''; and

■ b. The introductory text of the ''Production of Bill of Lading Bond Conditions'' is amended by removing the word ''Customs'' and adding in its place the term ''CBP''.

§ 113.70 [Amended]

■ 49. In § 113.70:

■ a. The introductory text is amended by removing the word ''shall'' each place it appears and adding in its place the word ''must'' and by removing the word ''entry'' and adding in its place the word ''transaction''; and

■ b. The first sentence in the ''Bond Condition to Indemnify United States for Detention of Copyrighted Material'' is amended by removing the word ''Customs'' and adding in its place the term ''CBP''.

§ 113.71 [Amended]

■ 50. In § 113.71, the introductory text is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must'' and by removing the word ''entry'' and adding in its place the word ''transaction''.

§ 113.72 [Amended]

■ 51. In § 113.72, the introductory text is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must'' and by removing the word ''entry'' and adding in its place the word ''transaction''.

§ 113.73 [Amended]

■ 52. In § 113.73:

■ a. The introductory text is amended by removing the word ''shall'' each place that it appears and adding in its place the word ''must'';

■ b. Paragraph (a)(1) is amended by removing the words ''Customs Regulations'' and adding in their place the words ''CBP regulations'';

■ c. Paragraph (a)(2) is amended by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP'' by removing the word ''Regulations'' and adding in its place the word ''regulations'' and by removing the word ''shall'' in the third sentence and adding in its place the word ''will'';

■ d. Paragraph (b) is amended by removing the word ''shall'' and adding in its place the word ''will'' and by removing the word ''Customs'' and adding in its place the term ''CBP'';

■ e. Paragraph (c) is amended by removing the words ''Customs and Border Protection (CBP)'' and adding in their place the term ''CBP'';

■ f. Paragraph (d)(2) is amended by removing the words ''Customs officer'' and adding in its place the words ''CBP Officer''; and

■ g. Paragraph (e) is amended by removing the words ''Customs Regulations'' and adding in their place the words ''CBP regulations''.

§ 113.74 [Amended]

■ 53. Section 113.74 is amended by removing the word ''entry'' and adding in its place the word ''transaction''.

■ 54. Appendix A to Part 113 is revised to read as follows:

Appendix A to Part 113—Airport Customs Security Area Bond

AIRPORT CUSTOMS SECURITY AREA BOND

_____(name of principal) of _____(address) and _____(name of surety) of _____(address) are held and firmly bound unto the United States of America in the sum of ____dollars ($____), for the payment of

which we bind ourselves, our heirs, executors, administrators, successors, and assigns, jointly and severally, by these conditions.

WITNESS our hands and seals this __day of ____, 20__. WHEREAS, the principal (including the principal's employees, agents, and contractors) desires access to airport customs security areas;

Now, Therefore, the Condition of this Obligation is Such That—

The principal agrees to comply with the CBP regulations applicable to customs security areas at airports. If the principal defaults on the condition of this obligation, the principal and surety, jointly and severally, agree to pay liquidated damages of $1,000 for each default; or such other amount as may be authorized by law or regulation. This bond is effective ___, 20____, and remains in force for one year beginning with the effective date and for each succeeding annual period, or until terminated. This bond constitutes a separate bond for each annual period in the amount listed above for liabilities that accrue in each annual period.

Signed, Sealed, and Delivered in the Presence of —

Name
Address

Name
Address
Principal (SEAL)

Name
Address

Name
Address

Name
Address
Surety (SEAL)

Name
Address

Appendix B to Part 113 [Amended]

■ 55. Appendix B to Part 113 is amended by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP''.

Appendix C to Part 113 [Amended]

■ 56. Appendix C to Part 113 is amended by removing the word ''Customs'' each place that it appears and adding in its place the term ''CBP''.

PART 133—TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

■ 57. The general and specific authority citations for part 133 continue to read as follows:

Authority: 15 U.S.C. 1124, 1125, 1127; 17 U.S.C. 101, 601, 602, 603; 19 U.S.C. 66, 1202, 1499, 1526, 1624; 31 U.S.C. 9701;

* * * * *

Sections 133.21 through 133.25 also issued under 18 U.S.C. 1905; Sec. 818(g), Pub. L. 112–81.

* * * * *

■ 58. In § 133.25, paragraph (c) is revised to read as follows:

§ 133.25 Procedure on detention of articles subject to restriction.

* * * * *

(c) Disclosure *to the trademark or trade name owner.* At any time following presentation of the merchandise for CBP's examination, but prior to seizure, CBP may release a sample of the suspect merchandise to the owner of the trademark or trade name for examination or testing to assist in determining whether the article imported bears an infringing trademark or trade name. To obtain a sample under this paragraph, the owner of the mark must furnish to CBP a bond in the form and amount specified by CBP, conditioned to indemnify the importer or owner of the imported article against any loss or damage resulting from the furnishing of the sample by CBP to the owner of the mark. CBP may demand the return of the sample at any time. The owner must return the sample to CBP upon demand or at the conclusion of the examination or testing, whichever occurs sooner. In the event that the sample is damaged, destroyed, or lost while in the possession of the trademark or trade name owner, the owner must, in lieu of returning the sample, certify to CBP that: ''The sample described as [insert description] and provided pursuant to 19 CFR 133.25(c) was (damaged/destroyed/lost) during examination or testing for trademark infringement.''

* * * * *

R. Gil Kerlikowske,

Commissioner.

Approved: November 4, 2015.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 2015–28503 Filed 11–12–15; 8:45 am]

BILLING CODE 9111–14–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in December 2015. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective December 1, 2015.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (*Klion.Catherine@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's Web site (*http://www.pbgc.gov*).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the

benefit payments interest assumptions for December 2015.[1]

The December 2015 interest assumptions under the benefit payments regulation will be 1.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for November 2015, these interest assumptions are unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during December 2015, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 266, as set forth below, is added to the table.

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*	*	*		*	*		*
266	12–1–15	1–1–16	1.25	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, Rate Set 266, as set forth below, is added to the table.

Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*	*		*	*	*		*
266	12–1–15	1–1–16	1.25	4.00	4.00	4.00	7	8

Issued in Washington, DC, on this 6th day of November 2015.

Judith Starr,

General Counsel, Pension Benefit Guaranty Corporation.

[FR Doc. 2015–28763 Filed 11–12–15; 8:45 am]

BILLING CODE 7709–02–P

[1] Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2014–0649; FRL–9935–43]

RIN 2070–AB27

Modification of Significant New Uses of Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending the significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for five chemical substances which were the subject of premanufacture notices (PMNs). This action amends the SNURs to allow certain uses without requiring a significant new use notice (SNUN), and extends SNUN requirements to certain additional uses. EPA is amending these SNURs based on review of new data for each chemical substance. This action requires persons who intend to manufacture (including import) or process any of these chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to

prohibit or limit that activity before it occurs.

DATES: This final rule is effective January 12, 2016.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2014–0649, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 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 OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

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

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

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. 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:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

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

II. Background

A. What action is the agency taking?

In the **Federal Register** of April 9, 2015 (80 FR 19307) (FRL–9924–10), EPA proposed amendments to the SNURs for 24 chemical substances in 40 CFR part 721 subpart E. This action would require persons who intend to manufacture or process these chemical substances for an activity that is designated as a significant new use by these amended rules to notify EPA at least 90 days before commencing that activity. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. The proposed rule included 23 chemical substances where EPA determined, based on new information, there is no need to require additional notice from persons who propose to engage in identical or similar activities, or a rational basis no longer exists for the findings that activities involving the substance may present an unreasonable risk of injury to human health or the environment required under section 5(e)(1)(A) of the Act. The proposed rule also included a chemical substance, P–01–781, where EPA is modifying the chemical identity information. In the **Federal Register** of June 30, 2015 (80 FR 37161) (FRL–9928–93), EPA issued amendments to the SNURs for 19 of those chemical substances in 40 CFR part 721 subpart E. EPA is now issuing a final SNUR amendment for the other five chemical substances. EPA received public comments for the proposed SNUR amendments for the remaining five chemical substances of the 24 included in the proposed rule subject to SNURs at 40 CFR 721.5575, 721.9675, and 721.10515. As described in Unit III., EPA is finalizing the SNURs as proposed for the SNURs at 40 CFR 721.9675, and 721.10515 and is finalizing the SNUR at 40 CFR 721.5575 with one change. EPA is now amending the SNURs of these five chemical substances pursuant to 40 CFR 721.185.

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

Upon conclusion of the review of the five chemical substances in this SNUR amendment, EPA designated certain activities as significant new uses. Under § 721.185, EPA may at any time amend a SNUR for a chemical substance which has been added to subpart E of 40 CFR part 721 if EPA makes one of the determinations set forth in § 721.185. Amendments may occur on EPA's initiative or in response to a written request. Under § 721.185(b)(3), if EPA concludes that a SNUR should be amended, the Agency will propose the changes in the **Federal Register**, briefly describe the grounds for the action, and provide interested parties an opportunity to comment. Pursuant to § 721.185 and as described in Unit IV. of the proposed rule for the five chemical substances, EPA determined, based on new information, that there is no need to require additional notice from persons who propose to engage in identical or similar activities, or a rational basis no longer exists for the findings that activities involving the substance may present an unreasonable risk of injury to human health or the environment required under section 5(e)(1)(A) of the Act.

III. Response to Comments on Proposed SNURs

Comment 1: One commenter stated that for the chemical substance subject to 40 CFR 721.5575 SNUR requirements should be excluded when the substance is incorporated or encapsulated in plastic as there would no longer be exposure.

Response: EPA reviewed uses of the chemical substance during PMN/SNUN reviews where it was incorporated or encapsulated into plastic. EPA estimated limited human and environmental exposures that were not expected to cause an unreasonable risk. Therefore, the final SNUR will remove from the scope of the SNUR any use where the chemical substance is incorporated or encapsulated into plastic.

Comment 2: One commenter stated that, for the chemical substance subject to 40 CFR 721.9675, one of the SNUN submitters cited in the proposed rule was actually manufacturing a different chemical substance, which was instead the subject of P–06–0149 and a SNUR at 40 CFR 721.10553.

Response: Each of the SNUNs cited in the proposed SNUR modification were

submitted to EPA pertained to the chemical substance titanate [Ti_6O_{13} (2-)], dipotassium, which is the chemical substance subject to 40 CFR 721.9675. But regardless of whether any of the SNUN submitters are manufacturing or processing a different chemical substance, any manufacturer and processor who is manufacturing potassium titanium oxide (which was the chemical substance submitted for P–06–149 and subject to the SNUR at 40 CFR 721.10553) is subject to the requirements of the SNUR at 40 CFR 721.10553.

Comment 3: EPA proposed to modify the SNUR at 40 CFR 721.10515 to include P–10–184, because P–10–184 pertains to the same chemical substance as P–10–60, which is already the subject of 40 CFR 721.10515. A commenter asked EPA to clarify if the SNUR would require the PMN submitter of P–10–184 to conduct the same triggered testing required in the consent order for P–10–60.

Response: The consent order for P–10–60 requires certain fate and physical property testing to be conducted at five different aggregate production volume limits. The consent order for P–10–184 does not require any testing to be conducted by production volume limits. The SNUR, however, requires *notification* before exceeding the manufacture of the five aggregate production volume limits. While the SNUR does not require the submitter of P–10–184, or any other manufacturer, to conduct testing, the SNUR does require that a SNUN be submitted before exceeding the aggregate production volume limit. If EPA receives a SNUN from the submitter of P–10–184, or any other manufacturer, EPA will then determine what testing, if any, would be required. This could be the testing required in the consent order for P–10–60 or other appropriate testing. This is the same procedure EPA uses for SNURs of consent orders with testing requirements at certain production volume or time limits.

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

To establish a significant ''new'' use, EPA must determine that the use is not ongoing. As discussed in the **Federal Register** issue of April 24, 1990 (55 FR 17376) (FRL–3658–5), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed SNUR rather than as of the effective date of the final rule. If uses begun after publication were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became effective, and then argue that the use was ongoing as of the effective date of the final rule.

Thus, any persons who begin commercial manufacture or processing activities with the chemical substances that are not currently a significant new use under the current rule but which would be regulated as a ''significant new use'' when this rule is finalized, must cease any such activity as of the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

EPA has promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person were to meet the conditions of advance compliance under § 721.45(h), the person would be considered to have met the requirements of the final SNUR for those activities.

V. Test Data and Other Information

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

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).

2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In this case, EPA recommends persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.'' The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at *http://www.oecdbookshop.org* or SourceOECD at *http://www.sourceoecd.org.* ASTM International standards are available at *http://www.astm.org/Standard/index.shtml.*

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

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

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

VI. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 721.25 and 720.40. E–PMN software is available electronically at *http://www.epa.gov/opptintr/newchems.*

VII. Economic Analysis

EPA evaluated the potential costs of SNUN requirements for potential manufacturers and processors of the chemical substances in the rule. The Agency's complete Economic Analysis is available in the docket under docket ID number EPA–HQ–OPPT–2014–0649.

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866

This action will modify SNURs for five chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

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

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

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

2. The SNUN submitted by any small entity would not cost significantly more than $8,300.

A copy of that certification is available in the docket for this rule.

This rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit VI and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than $8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this final rule. As such, EPA has determined that this rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

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

F. Executive Order 13175

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

G. Executive Order 13045

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

H. Executive Order 13211

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

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

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

IX. Congressional Review Act (CRA)

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 721

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

Dated: November 2, 2015.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR chapter I is amended as follows:

PART 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

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

■ 2. Amend § 721.5575 by revising paragraphs (a)(1) and (a)(2)(iii) to read as follows:

§ 721.5575 Oxirane, 2,2′-(1,6-hexanediylbis (oxymethylene)) bis-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as oxirane, 2,2′-(1,6-hexanediylbis(oxymethylene))bis- (PMN P–88–2179; PMN P–89–539; and SNUN S–08–3; CAS No. 16096–31–4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The reporting requirements of this rule do not apply once the chemical substance has been incorporated or encapsulated into plastic.

(2) * * *

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(q). A significant new use of the chemical substance is any commercial use other than the commercial use described in S–08–3.

* * * * *

■ 3. Amend § 721.9675 by revising paragraphs (a)(1) and (a)(2)(i), remove and reserve paragraph (a)(2)(ii), and revise paragraph (b)(1).

The revisionso read as follows:

§ 721.9675 Titanate [Ti_6O_{13} (2-)], dipotassium.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as titanate [Ti_6O_{13} (2-)], dipotassium (PMN P–90–226; SNUNs P–96–1408, S–08–6, S–09–4, and S–13–49; CAS No. 12056–51–8)) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) * * *

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f) and (l). In addition, a significant new use of the substance is importation of the chemical substance if:

(A) Manufactured by other than the method described in premanufacture notice P–90–226 and significant new use notices P–96–1408, S–08–6, S–09–4, and S–13–49.

(B) Manufactured producing respirable, acicular fibers with an average aspect ratio of greater than 5. The average aspect ratio is defined as the ratio of average length to average diameter.

* * * * *

(b) * * *

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

* * * * *

■ 4. Amend § 721.10515 by revising paragraphs (a)(1) and (a)(2)(i) to read as follows:

§ 721.10515 Partially fluorinated alcohol substituted glycols (generic).

(a) * * *

(1) The chemical substances identified generically as partially fluorinated alcohol substituted glycols (PMNs P–10–58, P–10–59, P–10–60, and P–10–184) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) * * *

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (manufacture of the PMN substances according to the chemical synthesis and composition section of the TSCA section 5(e) consent order, including analysis, reporting, and limitations of maximum impurity levels of certain fluorinated impurities; manufacture and import of P–10–60 and P–10–184 other than when the mean number of moles of the ethoxy group is between 3 and 11 or the average number molecular weight is between 496 and 848 daltons based on the amounts of raw materials charged to the reactor; manufacture and import of P–10–58 and P–10–59 only as intermediates for the manufacture of P–10–60), and (q).

* * * * *

[FR Doc. 2015–28844 Filed 11–12–15; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 80, No. 219
Friday, November 13, 2015

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–3674; Airspace Docket No. 15–ANM–18]

Proposed Amendment of Class E Airspace; Boise, ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class E surface area airspace designated as an extension to Class C airspace, and Class E airspace extending upward from 700 feet above the surface at Boise Air Terminal/Gowen Field Airport, formerly Boise Air Terminal (Gowen Field), Boise, ID. After reviewing the airspace, the FAA found standard instrument approach procedures are not fully contained in controlled airspace, thereby necessitating airspace redesign for the safety and management of Instrument Flight Rules (IFR) operations at the airport. This proposal also would update the name of the airport to match the FAAs aeronautical database.

DATES: Comments must be received on or before December 28, 2015.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2015–3674; Airspace Docket No. 15–ANM–18, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy and ATC Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 29591; telephone: 202–267–8783. The Order is also available for inspection at 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.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Steve Haga, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4500.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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 airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class E airspace at Boise Air Terminal/Gowen Field Airport, Boise, ID.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2015–3674; Airspace Docket No. 15–ANM–18.'' The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

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

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in

the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying Class E airspace designated as an extension to Class C airspace at Boise Air Terminal/Gowen Field Airport, Boise, ID. Two segments would be expanded from the 5-mile radius of the airport and extend to 12.8 miles southeast, and 11 miles northwest of the airport. Class E airspace extending upward from 700 feet above the surface at Boise Air Terminal/Gowen Field Airport would be amended to accommodate standard instrument approach procedures for IFR operations at the airport. A review of the airspace found modification of the airspace necessary for the safety and management of standard instrument approach procedures for IFR operations at the airport. Also, the name of the airport would be updated from Boise Air Terminal (Gowen Field), to Boise Air Terminal/Gowen Field Airport, to coincide with the FAA's aeronautical database.

Class E airspace extending upward from 700 feet above the surface would be modified to within an 8.6-mile radius north of Boise Air Terminal/Gowen Field Airport, extending to 11.4 miles to the south, 17 miles to the east and 30 miles to the west.

Class E airspace designations are published in paragraph 6003 and 6005, respectively, of FAA Order 7400.9Z, dated August 6, 2015 and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

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 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.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

Authority: 49 U.S.C. 106(f), 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 FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 6003 Class E Airspace Areas Designated as an Extension.

* * * * *

ANM ID E3 Boise, ID [Modified]

Boise Air Terminal/Gowen Field Airport, ID
(Lat. 43°33′52″ N., long. 116°13′22″ W.)

That airspace extending upward from the surface within 5 miles each side of the Boise Air Terminal/Gowen Field Airport 114° bearing extending from the 5-mile radius of the airport to 12.8 miles southeast of the airport; and within 5 miles each side of the Boise Air Terminal/Gowen Field Airport 295° bearing extending from the 5-mile radius of the airport to 11 miles northwest of the airport.

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

* * * * *

ANM ID E5 Boise, ID [Modified]

Boise Air Terminal/Gowen Field Airport, ID
(Lat. 43°33′52″ N., long. 116°13′22″ W.)

That airspace extending upward from 700 feet above the surface bounded by a line beginning at lat. 43°44′51″ N., long. 116°52′05″ W.; to lat. 43°52′31″ N., long. 116°38′57″ W.; to lat. 43°51′24″ N., long. 116°24′16″ W.; to lat. 43°31′33″ N., long. 115°50′14″ W.; to lat. 43°19′45″ N., long. 115°56′41″ W.; to lat. 43°25′11″ N., long. 116°32′39″ W.; to lat. 43°35′39″ N., long. 116°47′51″ W., thence to the point of beginning. That airspace extending upward from 1,200 feet above the surface within the 30.5-mile radius of the airport beginning at the 122° bearing of the airport, thence via a line to the intersection of the 34.8-mile radius of the airport and the 224° bearing of the airport, thence clockwise along the 34.8-mile radius of the airport to that airspace 7 miles each side of the 269° bearing of the airport extending from the 34.8-mile radius to 49.6 miles west of the airport, and within 7 miles northeast and 9.6 miles southwest of the 295° bearing of the airport extending from the 34.8-mile radius to 65.3 miles northwest of the airport, to lat. 44°00′27″ N., long. 117°10′58″ W., thence along the 042° bearing to V–253, thence south along V–253, thence along the 30.5-mile radius of the airport to the point of beginning. That airspace southeast of the airport extending upward from 9,000 feet MSL bounded on the north by V–444, on the east by V–293, on the south by V–330 and on the southwest by V–4. That airspace northeast of the airport extending upward from 11,500 feet MSL, bounded on the northeast by V–293, on the south by V–444, on the southwest by the 30.5-mile radius of the airport and on the west by V–253.

Issued in Seattle, Washington, on November 3, 2015.

Christopher Ramirez,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2015–28784 Filed 11–12–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–3899; Airspace Docket No. 15–AWP–14]

Proposed Amendment of Class D and Class E Airspace, Revocation of Class E Airspace; Chico, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class D airspace, Class E airspace extending upward from 700 feet above the surface, and remove Class E surface area airspace designated as an extension at Chico Municipal Airport, Chico, CA. After reviewing the airspace, the FAA found it necessary to amend the airspace area by increasing the Class E airspace extending upward from 700 feet above the surface for the safety and management of Instrument Flight Rules (IFR) operations for arriving and departing aircraft at the airport. The

FAA found no standard instrument approach procedures requiring Class E surface area airspace designated as an extension to Class D airspace. This action would also change from navigation aid to geographic coordinate references in the legal description, in anticipation of the FAA's future navigation aid discontinuance plan. The geographic coordinates of Chico Municipal and Ranchaero Airports also would be updated for the Class D and E airspace areas noted above.

DATES: Comments must be received on or before December 28, 2015.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2015–3899; Airspace Docket No. 15–AWP–14, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy and ATC Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 29591; telephone: 202–267–8783. The Order is also available for inspection at 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.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Steve Haga, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4563.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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 airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class D and Class E airspace at Chico Municipal Airport, Chico, CA.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2015–3899; Airspace Docket No. 15–AWP–14.'' The postcard will be date/time stamped and returned to the commenter.

Availability of NPRMs

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

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

Availability and Summary of Documents Proposed for Incorporation by Reference

This document would amend FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying Class D airspace, Class E airspace extending upward from 700 feet above the surface, and removing Class E surface area airspace as an extension as this airspace is no longer needed, at Chico Municipal Airport, Chico, CA. Class E airspace extending upward from 700 feet above the surface would be modified to within a 4.1-mile radius east of Chico Municipal, extending to 6 miles from the southeast to the north, excluding that airspace within 1 NM of Ranchaero Airport, CA. Also, this action would remove reference to navigation aids and use instead geographic coordinate references in the legal descriptions. The geographic coordinates of the Chico Municipal and Ranchaero Airports would be amended for the Class D and E airspace areas to coincide with the FAA's aeronautical database.

Class D and Class E airspace designations are published in paragraph 5000, 6004, and 6005, respectively, of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

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 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.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

Authority: 49 U.S.C. 106(f), 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 FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AWP CA D Chico, CA [Modified]

Chico Municipal Airport, CA
(Lat. 39°47′43″ N., long. 121°51′30″ W.)
Ranchaero Airport, Chico, CA
(Lat. 39°43′10″ N., long. 121°52′14″ W.)

That airspace extending upward from the surface to and including 2,700 feet MSL within a 4.1-mile radius of Chico Municipal Airport, excluding the portion within a 1-mile radius of Ranchaero Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

AWP CA E4 Chico, CA [Removed]

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

* * * * *

AWP CA E5 Chico, CA [Modified]

Chico Municipal Airport, CA
(Lat. 39°47′43″ N., long. 121°51′30″ W.)
Ranchaero Airport, Chico, CA
(Lat. 39°43′10″ N., long. 121°52′14″ W.)

That airspace extending upward from 700 feet above the surface bounded by a line beginning at lat. 39°43′57″ N., long. 121°45′28″ W. clockwise along the Chico Municipal Airport 6-mile radius to lat. 39°41′45″ N., long. 121°50′42″ W.; thence along the 174° bearing from the Chico Municipal Airport to intersect the 1-mile radius of the Ranchaero Airport, thence counter-clockwise along the Ranchaero Airport 1-mile radius to intersect the 200° bearing from the Chico Municipal Airport, thence along the 200° bearing to the Chico Municipal Airport 6-mile radius, thence clockwise to lat. 39°53′31″ N., long. 121°53′31″ W.; thence to lat. 39°51′48″ N., long. 121°52′04″ W. clockwise along the Chico Municipal Airport 4.1-mile radius to lat. 39°45′40″ N., long. 121°46′54″ W.; thence to the point of beginning.

Issued in Seattle, Washington, on November 5, 2015.

Christopher Ramirez,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2015–28793 Filed 11–12–15; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 49, 51, 52, 60, 70, and 71

[EPA–HQ–OAR–2013–0685; EPA–HQ–OAR–2010–0505; EPA–HQ–OAR–2014–0606; EPA–HQ–OAR–2015–0216; FRL–9937–01–OAR]

Source Determination for Certain Emission Units in the Oil and Natural Gas Sector; Oil and Natural Gas Sector: Emission Standards for New and Modified Sources; Review of New Sources and Modifications in Indian Country: Federal Implementation Plan for Managing Air Emissions From True Minor Sources Engaged in Oil and Natural Gas Production in Indian Country

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: On September 18, 2015, the Environmental Protection Agency (EPA) proposed three rules titled, ''Source Determination for Certain Emission Units in the Oil and Natural Gas Sector,'' ''Oil and Natural Gas Sector: Emission Standards for New and Modified Sources,'' and ''Review of New Sources and Modifications in Indian Country: Federal Implementation Plan for Managing Air Emissions from True Minor Sources Engaged in Oil and Natural Gas Production in Indian Country.'' The EPA is extending the comment period on the three proposed rules that was scheduled to close on November 17, 2015. The EPA has received several letters from trade and business organizations, states and tribes requesting additional time to review and comment on the three proposed rule revisions.

DATES: The public comment period for the three proposed rules published in the **Federal Register** on September 18, 2015 (80 FR 56579, 80 FR 56593, and 80 FR 56553), is being extended. Written comments must be received on or before December 4, 2015.

ADDRESSES: The EPA has established separate dockets for each of the three proposed rulemakings (available at *http://www.regulations.gov*). For the proposed rulemaking titled, ''Source Determination for Certain Emission Units in the Oil and Natural Gas Sector,'' the Docket ID No. is EPA–HQ–OAR–2013–0685. For the proposed rulemaking titled, ''Oil and Natural Gas Sector: Emission Standards for New and Modified Sources,'' the Docket ID No. is EPA–HQ–OAR–2010–0505. For the proposed rulemaking titled, ''Review of

New Sources and Modifications in Indian Country: Federal Implementation Plan for Managing Air Emissions from True Minor Sources Engaged in Oil and Natural Gas Production in Indian Country,'' the Docket ID No. is EPA–HQ–OAR–2014–0606. Information on all of these actions is posted at *http://www.epa.gov/airquality/oilandgas/actions.html.* Submit your comments, identified by the appropriate Docket ID, to the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If you need to include CBI as part of your comment, please visit *http://www.epa.gov/dockets/comments.html* for instructions. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make.

For additional submission methods, the full EPA public comment policy, and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/comments.html.*

FOR FURTHER INFORMATION CONTACT: For additional information on this action, contact Cheryl Vetter, Office of Air Quality Planning and Standards, Environmental Protection Agency (C504–03), Research Triangle Park, North Carolina 27711; telephone number (919) 541–4391; fax number (919) 541–5509; email address: *vetter.cheryl@epa.gov.*

SUPPLEMENTARY INFORMATION: After considering the requests to extend the public comment period received from various trade and business organizations, states and tribes, the EPA has decided to extend the public comment period until December 4, 2015. This extension will ensure that the public has additional time to review the three proposed rules.

Dated: November 3, 2015.

Stephen D. Page,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 2015–28764 Filed 11–12–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 258

[EPA–HQ–RCRA–2015–0126; FRL–9936–10–OSWER]

RIN–2050–AG75

Revision to the Research, Development and Demonstration Permits Rule for Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to revise the maximum permit term for Municipal Solid Waste Landfill (MSWLF) units operating under Research, Development and Demonstration (RD&D) permits. The RD&D permit program, which began in 2004, allows landfill facilities to utilize innovative and new methods that vary from the prescribed run-on control systems, liquids restrictions, and final cover criteria if these systems are determined by the Director of states with EPA-approved RD&D programs, as defined in 40 CFR 258.2, to meet the criteria in 40 CFR 258.4. The current rule limits permits for these units to 3 years each, renewable 3 times for a total permit term of 12 years. If finalized, this rule will allow the Director of an approved State to increase the number of permit renewals to 6, for a total permit term of up to 21 years. The EPA is not proposing any other changes to the existing MSWLF RD&D permit program at this time.

DATES: Comments on this proposed rule must be received on or before December 14, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–RCRA–2015–0126 to the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Craig Dufficy, Materials Recovery and Waste Management Division of the Office of Resource Conservation and Recovery (mail code 5304P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: 703–308–9037; email: *Dufficy.craig@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Entities potentially affected by this proposal are public or private owners or operators of MSWLFs. These entities include:

Category	Example of affected entities
State Governments	Regulatory agencies and agencies operating landfills.
Industry	Owners or operators of municipal solid waste landfills.
Municipalities, including Tribal Governments	Owners or operators of municipal solid waste landfills.

The affected entities may also fall under the North American Industry Classification System (NAICS) code 924110, Sanitation engineering agencies, government; or 562212, Solid Waste Landfill. This list of sectors is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that the EPA believes could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in 40 CFR part 258 and

the Research, Development, and Demonstration Permits for Municipal Solid Waste Landfills final rule published in the **Federal Register** at 69 FR 13242, March 22, 2004, (''2004 RD&D rule''). If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is the agency taking?

The EPA is proposing to revise the maximum permit term for MSWLF units operating under RD&D permits. In effect, this proposed rule, if finalized, would allow the Directors of a states with EPA-approved RD&D programs to increase the number of 3-year permit renewals from 3 to 6, for a total permit term of 21 years.

The basis for the proposed extension of the permit period to up to 21 years is to provide more time to support research into the performance of bioreactors, alternative covers and run-on systems. The EPA believes the period of 21 years strikes a balance between providing more time for projects to continue operations as research facilities, while providing enough time for the EPA to consider making permanent changes to the Part 258 MSWLF regulations.

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

The authority for this proposal is sections 1008, 2002(a), 4004, 4005(c), 4010 and 8001(a) of the Resource Conservation and Recovery Act of 1976 (RCRA), as amended, 42 U.S.C. 6907, 6912(a), 6944, 6945(c), 6949a, 6981(a).

D. What are the anticipated effects and benefits of this action?

The anticipated effect of this proposed action, when final, is to provide the Director of an approved State the ability to issue renewals to existing RD&D permits, as well as new RD&D permits, for up to 21 years instead of 12 years. During this time, the EPA will continue to evaluate data from these facilities. The universe of facilities presently covered by this action is approximately 30 facilities currently operating with RD&D permits, and one on tribal lands. Additional facilities may also continue to seek an RD&D permit after this action is finalized. The EPA has no information with which to estimate whether or not, nor how many, new facilities will seek RD&D permits. Owners/operators operating under existing RD&D permits are not expected to incur any new costs as a result of this proposed rule. The annual costs for ongoing recordkeeping and annual reporting requirements are estimated at $2,410 per facility.

It is important to note that applying for a RD&D permit is voluntary. This proposed action would merely allow the Director of an approved State to increase the number of extensions of the permit period for existing facilities, or offer more extensions of the permit term for new facilities, for those owners and operators who choose to participate in this research program; it would not impose any new regulatory burden. Increasing the possible number of extensions of the RD&D permit term may benefit current owners and operators of RD&D units by providing additional time to recover their costs, if the Director of an approved State chooses to extend existing permits. For example, data from one RD&D permitted facility shows a projected increase of 3% in the rate of return for 20 years compared to 12 years.[1]

Increasing the possible number of extensions of RD&D permit terms will provide more time for the EPA to collect additional data on the potential benefits of the approaches being taken under these RD&D permits. These potential benefits include: Decreased costs for leachate treatment due to leachate recirculation in bioreactors; increased revenue from the sale of landfill gas for use as a renewable source of fuel; decreased risk due to a reduction in the transportation of leachate for treatment; accelerated production and capture of landfill gas for use as a renewable fuel; and, accelerated stabilization, and corresponding decreased post-closure care activities, for facilities as a result of the accelerated decomposition of waste.

II. Background

Under Subchapter IV of RCRA, 42 U.S.C. 6941–6949a, the EPA has promulgated minimum national standards for MSWLFs at 40 CFR part 258. See 56 FR 50978 (October 9, 1991). RCRA also directs the EPA to encourage research and development for, among other things, the development and application of new and improved methods of collecting and disposing of solid waste. 42 U.S.C. 6981(a).

The initial MSWLF regulations addressed seven basic areas: Location restrictions; operation; design; groundwater monitoring; corrective action; closure and post-closure care; and financial assurance. These MSWLF landfill regulations focused on dry-tomb landfills to minimize the possibility of groundwater contamination from the production and subsequent leakage of leachate. After the promulgation of those standards, the EPA became aware that landfill technology had advanced sufficiently that some alternative designs and operations could benefit from further study through research and demonstration projects. For example, some of these methods, particularly the addition of liquids and leachate recirculation, could accelerate biodegradation and provide additional potential benefits. These include:

—Acceleration of landfill gas generation which can be collected as a source of renewable fuel.
—Minimization of leachate treatment requirements during the operational life of the landfill.
—More rapid reduction in concentration of leachate constituents of concern, thereby limiting the corresponding post-closure activities for leachate control.
—An increase in the rate of landfill settlement resulting in the more efficient use of permitted landfill capacity.

As a means to advance innovation in landfill design, in 2000 the EPA selected four landfills to participate in its Project XL program. The landfills are located in Buncombe County, North Carolina; Yolo County, California; King George County, Virginia; and the Maplewood facility in Amelia Country, Virginia.

In addition to Project XL, in 2001 the EPA began using Cooperative Research and Development Agreements (CRADAs) to promote collaborative research between federal and non-federal scientists as an additional means to explore the addition of liquids to landfills to promote faster biodegradation and stabilization. Bioreactor landfill sites operating with CRADAs include the Outer Loop landfill in Louisville, Kentucky; and the Polk County landfill in Florida.

Subsequently, in 2004, the EPA amended 40 CFR part 258 MSWLF regulations to create a broader RD&D research program. The 2004 RD&D rule, which amended § 258.4 enabled the Director of an approved State to allow RD&D projects with variances to specific provisions of the MSWLF criteria, including variances from operating criteria in part 258 subpart C with respect to run-on controls (§ 258.26(a)(1)) and the liquids restrictions in § 258.28(a). In addition, the rule allows an additional variance for the final cover requirements set forth in the closure criteria in §§ 258.60(a)(1), (a)(2) and (b)(1). The 2004 RD&D rule limits the duration of the initial permit to 3 years. The permit can be renewed for up to three additional 3-year terms,

[1] See docket # EPA–HQ–RCRA–2015–0126 for supporting documentation.

for a total of 12 years. More information on the RD&D rule can be found in the final rule preamble. See 69 FR 13242, March 22, 2004.

As of March 2014, there were 30 active RD&D projects in 11 approved states and one project on tribal lands.[2] The maximum permit period for the first of these bioreactors is coming to an end, and the EPA proposes to allow the Director of an approved State to continue to extend the permit period for up to a total of 21 years to allow for continued research.

A. What the EPA Is Proposing

The EPA is proposing to allow Directors of states with EPA-approved RD&D programs to increase the maximum term for RD&D permits from 12 to 21 years at 40 CFR 258.4(e)(1), to provide more time to support research into the performance of bioreactors, alternative covers and run-on systems. In effect, this proposed rule, if finalized, would allow the Director of an approved State to increase the number of permit renewals from three to six. The EPA is not proposing any other changes to the RD&D permit program at this time. The EPA is not reopening, nor will it respond to comments on, any other provision of the existing RD&D rule or MSWLF criteria in 40 CFR part 258.

Separately from this proposal, the EPA expects to publish an Advanced Notice of Proposed Rulemaking (ANPRM) seeking comment on revising other sections of the MSWLF (40 CFR part 258) criteria to authorize bioreactor operation (and other changes to the national criteria) on a permanent basis. Interested parties will have an opportunity to comment on broader issues relating to bioreactor operation during the public comment period on that ANPRM.

B. Basis for This Proposal

In the 2004 RD&D final rule, the EPA made clear its intention that MSWLF RD&D permits be of limited duration, yet also provide data to support future rulemaking. This proposal is intended to further these dual goals. Although the EPA does not expect that all RD&D permits will necessarily extend to the full permit term, the EPA has since learned that the 12-year time limit may not be sufficient to realize potential benefits in all cases. Thus, extending the permit period for up to 21 years will provide more time to collect data on potential benefits and any problems without making the permit period so long as to be open-ended.

Extending the maximum permit term will help continuing efforts to collect data at existing RD&D units. If the EPA does not take this action, owners and operators using existing RD&D permits would need to make significant modifications to their disposal units or cease operation altogether, before reaching the end of their normal operations or closure. Because of the potential environmental benefits that may be derived from bioreactors, alternative cover designs, and run-on systems, the EPA believes that it is important to extend the maximum permit period to 21 years to provide more time to characterize the performance of RD&D projects without making the permit period so long as to be open-ended.

The EPA also wishes to enhance the economic feasibility to build and operate bioreactors or final cover variances in the future, and to thereby provide additional sources of data. In addition, the EPA has heard from stakeholders that the current 12-year maximum permit period is an insufficient length of time for potential owners and operators of bioreactors to recoup their initial investment. These stakeholders have indicated limiting the permit period to 12 years has the unintended consequence of discouraging the development of bioreactors.

C. Implementation of This Proposal

This proposal does not require states with EPA-approved RD&D programs to modify their solid waste permit programs. Since this proposed change to the RD&D rule provides more flexibility than existing federal criteria, states are not required to amend existing solid waste permit programs that have been determined by the EPA to be adequate under 40 CFR part 239. States will have the option to amend their programs once this proposal is finalized. At the same time, the RD&D rule (including this proposed revision of the maximum permit term) is not self-implementing and states are required to adopt the RD&D rule and obtain EPA approval for their RD&D program in order to issue a RD&D permit. States previously approved to issue RD&D permits that wish to increase the total length of time for which RD&D permits can be issued will need to notify the EPA in accordance with 40 CFR part 239. States with EPA-approved solid waste permit programs that have not previously sought approval for an RD&D program and now wish to do so will need to apply to EPA for approval of an RD&D program, including approval of the longer time period allowed by this proposal. Any state without an EPA-approved solid waste permit program may submit an application to the EPA for a determination of adequacy under 40 CFR part 239 and may include a request for approval of the RD&D permit provisions reflecting the longer time period allowed by this proposal. For municipal solid waste landfill units located in Indian Country, the EPA intends to consider the longer maximum permit term in this proposal when issuing or modifying any site-specific RD&D rule. The EPA has previously issued draft guidance on the site-specific flexibility request process in Indian Country. *See* Site-specific Flexibility Requests for Municipal Solid Waste Landfills in Indian Country, EPA 530–R–97–016, August 1997.

III. 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 and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new Information Collection Request (ICR) burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control numbers 2050–0152 and 2050–0122. The purpose of this action is to extend the maximum allowable permit period for this program and this change to the RD&D program itself does not impose any additional reporting requirements. The OMB has previously approved the information collection activities contained in the existing regulations in two different, applicable ICRs. The ICRs affected by this proposal are for 40 CFR part 239, Requirements for State Permit Program Determination of Adequacy and part 258, MSWLF Criteria. The OMB has reviewed the ICR for part 239 (ICR# 1608.07, OMB# 2050–0152.) The EPA will request comments under the ICR review process from states that plan to make these revisions so that the EPA can better understand the expected burden that would be incurred by states who wish to make these changes. In addition, the EPA will also be requesting information from MSWLF owners/operators on the reporting burden that they would incur under an extended permit term

[2] Permitting of Landfill Bioreactor Operations: Ten years After the RD&D Rule, EPA document number EPA/600/R–14/335.

provided in accordance with this proposal under the part 258, MSWLF criteria ICR (ICR# 1381.09, OMB# 2050–0122) when that review process begins. This process is scheduled to be completed in June 2016.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. 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, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. This proposed rule will not create any additional burden for small entities. Small entities are not required to take any action as a consequence of this proposed rule, and this action will not have a significant impact on a substantial number of small entities. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector. The costs involved in this action are imposed only by voluntary participation in a federal program.

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. Although Executive Order 13132 does not apply to this proposal, the EPA has consulted with states through the Association of State and Territorial Solid Waste Management Officials during the development of this proposal.

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

This action does not have tribal implications as specified in Executive Order 13175. The EPA has concluded that this proposal will have no new tribal implications, nor would it present any additional burden on the tribes. It will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law. Accordingly, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations.

The underlying RD&D rule requires any RD&D permit to include such terms and conditions at least as protective as the criteria for municipal solid waste landfills to assure protection of human health and the environment, and this proposal does not reopen or otherwise change that requirement. Therefore, the EPA finds that the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations.

List of Subjects in 40 CFR Part 258

Environmental protection, Municipal landfills, Reporting and recordkeeping requirements, Waste treatment and disposal.

Dated: October 30, 2015.

Gina McCarthy,

Administrator.

For the reasons set forth in the preamble, the EPA proposes to amend 40 CFR part 258 as follows:

PART 258—CRITERIA FOR MUNICIPAL SOLID WASTE LANDFILLS

■ 1. The authority citation for part 258 continues to read as follows:

Authority: 33 U.S.C. 1345(d) and (e); 42 U.S.C. 6902(a), 6907, 6912(a), 6944, 6945(c) and 6949a(c), 6981(a).

Subpart A—General

■ 2. Revise § 258.4(e)(1) to read as follows:

§ 258.4 Research, development, and demonstration permits.

* * * * *

(e) * * *

(1) The total term for a permit for a project including renewals may not exceed twenty-one (21) years; and

* * * * *

[FR Doc. 2015–28666 Filed 11–12–15; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 80, No. 219

Friday, November 13, 2015

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Media Outlets for Publication of Legal and Action Notices in the Southern Region

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: This notice lists the newspapers that will be used by all U.S. Forest Service Ranger Districts, Forests, and the Regional Office of the Southern Region to publish legal notices required under 36 CFR 214, 218, and 219. The intended effect of this action is to inform interested members of the public which newspapers the Forest Service will use to publish notices of proposed actions, notices of decision, and notices of opportunity to file an appeal/objection. This will provide the public with constructive notice of Forest Service proposals and decisions, provide information on the procedures to comment, appeal, or object and establish the date that the Forest Service will use to determine if comments, appeals, or objections were timely.

DATES: Publication of legal notices in the listed newspapers will begin on the date of this publication and remain in effect until another notice is published in the **Federal Register**.

ADDRESSES: USDA Forest Service, Southern Region; ATTN: Regional Administrative Review Coordinator; 1720 Peachtree Road NW., Atlanta, Georgia 30309.

FOR FURTHER INFORMATION CONTACT: David Harris, Regional Environmental Coordinator, Southern Region, 1720 Peachtree Road NW., Atlanta, Georgia 30309, Phone: 404/347–5292.

SUPPLEMENTARY INFORMATION: In addition to the primary newspaper listed for each unit, some Forest Supervisors and District Rangers have listed newspapers providing additional notice of their decisions. The timeframe for filing comment, appeal or an objection shall be based on the date of publication of the notice in the first (primary) newspaper listed for each unit.

Southern Region

Regional Forester Decisions

Affecting National Forest System lands in more than one Administrative unit of the 15 in the Southern Region, *Atlanta Journal-Constitution,* published daily in Atlanta, GA.

Affecting National Forest System lands in only one Administrative unit or only one Ranger District will appear in the newspaper of record elected by the National Forest, National Grassland, National Recreation Area, or Ranger District as listed below.

National Forests in Alabama, Alabama

Forest Supervisor Decisions

Affecting National Forest System lands in more than one Ranger District of the 6 in the National Forests in Alabama, *Montgomery Advertiser,* published daily in Montgomery, AL. Affecting National Forest System lands in only one Ranger District will appear in the newspaper of record elected by the Ranger District as listed below.

District Ranger Decisions

Bankhead Ranger District: *Northwest Alabamian,* published bi-weekly (Wednesday & Saturday) in Haleyville, AL

Conecuh Ranger District: *The Andalusia Star News,* published daily (Tuesday through Saturday) in Andalusia, AL

Oakmulgee Ranger District: *The Tuscaloosa News,* published daily in Tuscaloosa, AL

Shoal Creek Ranger District: *The Anniston Star,* published daily in Anniston, AL

Talladega Division: *The Anniston Star,* published daily in Anniston, AL

Talladega Ranger District: *The Daily Home,* published daily in Talladega, AL

Tuskegee Ranger District: *Tuskegee News,* published weekly (Thursday) in Tuskegee, AL

Chattahoochee-Oconee National Forest, Georgia

Forest Supervisor Decisions

The Times, published daily in Gainesville, GA

District Ranger Decisions

Blue Ridge Ranger District: *The News Observer* (newspaper of record) published bi-weekly (Tuesday & Friday) in Blue Ridge, GA

North Georgia News, (newspaper of record) published weekly (Wednesday) in Blairsville, GA

Conasauga Ranger District: *Daily Citizen*, published daily in Dalton, GA

Chattooga River Ranger District: *The Northeast Georgian*, (newspaper of record) published bi-weekly (Wednesday & Friday) in Cornelia, GA

Clayton Tribune, (newspaper of record) published weekly (Thursday) in Clayton, GA

The Toccoa Record, (secondary) published weekly (Thursday) in Toccoa, GA

White County News, (secondary) published weekly (Thursday) in Cleveland, GA

Oconee Ranger District: *Eatonton Messenger*, published weekly (Thursday) in Eatonton, GA

Cherokee National Forest, Tennessee

Forest Supervisor Decisions

Knoxville News Sentinel, published daily in Knoxville, TN

District Ranger Decisions

Unaka Ranger District: *Greeneville Sun*, published daily (except Sunday) in Greeneville, TN

Ocoee-Hiwassee Ranger District: *Polk County News*, published weekly (Wednesday) in Benton, TN

Tellico Ranger District: *Monroe County Advocate & Democrat*, published tri-weekly (Wednesday, Friday, and Sunday) in Sweetwater, TN

Watauga Ranger District: *Johnson City Press*, published daily in Johnson City, TN

Daniel Boone National Forest, Kentucky

Forest Supervisor Decisions

Lexington Herald-Leader, published daily in Lexington, KY

District Ranger Decisions

Cumberland Ranger District: *The Morehead News*, published bi-weekly (Tuesday and Friday) in Morehead, KY

London Ranger District: *The Sentinel-Echo*, published tri-weekly (Monday, Wednesday, and Friday) in London, KY

Redbird Ranger District: *Manchester Enterprise*, published weekly (Thursday) in Manchester, KY

Stearns Ranger District: *The McCreary Voice*, published weekly (Thursday) in Whitley City, KY

El Yunque National Forest, Puerto Rico

Forest Supervisor Decisions

El Nuevo Dia, published daily in Spanish in San Juan, PR

Puerto Rico Daily Sun, published daily in English in San Juan, PR

National Forests in Florida, Florida

Forest Supervisor Decisions

The Tallahassee Democrat, published daily in Tallahassee, FL

District Ranger Decisions

Apalachicola Ranger District: *Calhoun-Liberty Journal*, published weekly (Wednesday) in Bristol, FL

Lake George Ranger District: *The Ocala Star Banner*, published daily in Ocala, FL

Osceola Ranger District: *The Lake City Reporter*, published daily (Monday-Saturday) in Lake City, FL

Seminole Ranger District: *The Daily Commercial*, published daily in Leesburg, FL

Wakulla Ranger District: *The Tallahassee Democrat*, published daily in Tallahassee, FL

Francis Marion & Sumter National Forests, South Carolina

Forest Supervisor Decisions

The State, published daily in Columbia, SC

District Ranger Decisions

Andrew Pickens Ranger District: *The Daily Journal*, published daily (Tuesday through Saturday) in Seneca, SC

Enoree Ranger District: *Newberry Observer*, published tri-weekly (Monday, Wednesday, and Friday) in Newberry, SC

Long Cane Ranger District: I*ndex-Journal*, published daily in Greenwood, SC

Wambaw Ranger District: *Post and Courier*, published daily in Charleston, SC

Witherbee Ranger District: *Post and Courier*, published daily in Charleston, SC

George Washington and Jefferson National Forests, Virginia and West Virginia

Forest Supervisor Decisions

Roanoke Times, published daily in Roanoke, VA

District Ranger Decisions

Clinch Ranger District: *Coalfield Progress*, published bi-weekly (Tuesday and Friday) in Norton, VA

North River Ranger District: *Daily News Record*, published daily (except Sunday) in Harrisonburg, VA

Glenwood-Pedlar Ranger District: *Roanoke Times*, published daily in Roanoke, VA

James River Ranger District: *Virginian Review*, published on Tuesday, Thursday and Saturday in Covington, VA

Lee Ranger District: *Shenandoah Valley Herald*, published weekly (Wednesday) in Woodstock, VA

Mount Rogers National Recreation Area: *Bristol Herald Courier*, published daily in Bristol, VA

Eastern Divide Ranger District: *Roanoke Times*, published daily in Roanoke, VA

Warm Springs Ranger District: *The Recorder*, published weekly (Thursday) in Monterey, VA

Kisatchie National Forest, Louisiana

Forest Supervisor Decisions

The Town Talk, published daily in Alexandria, LA

District Ranger Decisions

Calcasieu Ranger District: *The Town Talk*, (newspaper of record) published daily in Alexandria, LA

The Leesville Daily Leader, (secondary) published daily in Leesville, LA

Caney Ranger District: *Minden Press Herald*, (newspaper of record) published daily in Minden, LA

Homer Guardian Journal, (secondary) published weekly (Wednesday) in Homer, LA

Catahoula Ranger District: *The Town Talk*, published daily in Alexandria, LA

Kisatchie Ranger District: *Natchitoches Times*, published daily (Tuesday thru Friday and on Sunday) in Natchitoches, LA

Winn Ranger District: *Winn Parish Enterprise*, published weekly (Wednesday) in Winnfield, LA

Land Between The Lakes National Recreation Area, Kentucky and Tennessee

Area Supervisor Decisions

The Paducah Sun, published daily in Paducah, KY

National Forests in Mississippi, Mississippi

Forest Supervisor Decisions

Clarion-Ledger, published daily in Jackson, MS

District Ranger Decisions

Bienville Ranger District: *Clarion-Ledger*, published daily in Jackson, MS

Chickasawhay Ranger District: *Clarion-Ledger*, published daily in Jackson, MS

Delta Ranger District: *Clarion-Ledger*, published daily in Jackson, MS

De Soto Ranger District: *Clarion Ledger*, published daily in Jackson, MS

Holly Springs Ranger District: *Clarion-Ledger*, published daily in Jackson, MS

Homochitto Ranger District: *Clarion-Ledger*, published daily in Jackson, MS

Tombigbee Ranger District: *Clarion-Ledger*, published daily in Jackson, MS

National Forests in North Carolina, North Carolina

Forest Supervisor Decisions

The Asheville Citizen-Times, published Wednesday thru Sunday, in Asheville, NC

District Ranger Decisions

Appalachian Ranger District: *The Asheville Citizen-Times*, published Wednesday thru Sunday, in Asheville, NC

Cheoah Ranger District: *Graham Star*, published weekly (Thursday) in Robbinsville, NC

Croatan Ranger District: *The Sun Journal*, published daily in New Bern, NC

Grandfather Ranger District: *McDowell News*, published daily in Marion, NC

Nantahala Ranger District: *The Franklin Press*, published bi-weekly (Tuesday and Friday) in Franklin, NC

Pisgah Ranger District: *The Asheville Citizen-Times*, published Wednesday thru Sunday, in Asheville, NC

Tusquitee Ranger District: *Cherokee Scout*, published weekly (Wednesday) in Murphy, NC

Uwharrie Ranger District: *Montgomery Herald*, published weekly (Wednesday) in Troy, NC

Ouachita National Forest, Arkansas and Oklahoma

Forest Supervisor Decisions

Arkansas Democrat-Gazette, published daily in Little Rock, AR

District Ranger Decisions

Caddo-Womble Ranger District: *Arkansas Democrat-Gazette*, published daily in Little Rock, AR

Jessieville-Winona-Fourche Ranger District: *Arkansas Democrat-Gazette*,published daily in Little Rock, AR

Mena-Oden Ranger District: *Arkansas Democrat-Gazette*, published daily in Little Rock, AR

Oklahoma Ranger District (Choctaw; Kiamichi; and Tiak): *McCurtain Daily Gazette*, published daily in Idabel, OK

Poteau-Cold Springs Ranger District: *Arkansas Democrat-Gazette*, published daily in Little Rock, AR

Ozark-St. Francis National Forests, Arkansas

Forest Supervisor Decisions

The Courier, published daily (Tuesday through Sunday) in Russellville, AR

District Ranger Decisions

Bayou Ranger District: *The Courier*, published daily (Tuesday through Sunday) in Russellville, AR

Boston Mountain Ranger District: *Southwest Times Record*, published daily in Fort Smith, AR

Buffalo Ranger District: *The Courier*, published daily (Tuesday through Sunday) in Russellville, AR

Magazine Ranger District: *Southwest Times Record*, published daily in Fort Smith, AR

Pleasant Hill Ranger District: *Johnson County Graphic*, published weekly (Wednesday) in Clarksville, AR

St. Francis National Forest: *The Daily World*, published daily (Sunday through Friday) in Helena, AR

Sylamore Ranger District: *Stone County Leader*, published weekly (Wednesday) in Mountain View, AR

National Forests and Grasslands in Texas, Texas

Forest Supervisor Decisions

The Lufkin Daily News, published daily in Lufkin, TX

District Ranger Decisions

Angelina National Forest: *The Lufkin Daily News*, published daily in Lufkin, TX

Caddo & LBJ National Grasslands: *Denton Record-Chronicle*, published daily in Denton, TX

Davy Crockett National Forest: *The Lufkin Daily News*, published daily in Lufkin, TX

Sabine National Forest: *The Lufkin Daily News*, published daily in Lufkin, TX

Sam Houston National Forest: *The Courier*, published daily in Conroe, TX

Dated: November 5, 2015.

Jerome Thomas,

Deputy Regional Forester.

[FR Doc. 2015–28900 Filed 11–12–15; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–489–502]

Certain Welded Carbon Steel Pipes and Tubes From Turkey: Amended Final Results of Countervailing Duty Administrative Review, 2013

AGENCY: Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce.

SUMMARY: The Department of Commerce (''Department'') is amending the *Final Results* [1] of the administrative review of the countervailing duty order on certain welded carbon steel pipe and tube from Turkey to correct ministerial errors. The period of review (''POR'') is January 1, 2013, through December 31, 2013.

DATES: *Effective date:* November 13, 2015

FOR FURTHER INFORMATION CONTACT: Jolanta Lawska, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington DC 20230; telephone 202–482–8362.

SUPPLEMENTARY INFORMATION:

Background

On October 9, 2015, the Department disclosed to interested parties its calculations for the *Final Results*.[2] On October 13, 2015, we received a timely filed ministerial error allegation from Borusan Mannesmann Boru Sanayi ve Ticaret A.S. (BMB), Borusan Istikbal Ticaret T.A.S. (Istikbal), and Borusan Lojistik Dagitim Pepolama Tasimacilik ve Tic A.S. (Borusan Lojistik) (collectively, the Borusan Companies) regarding the Department's final margin calculations.[3]

Period of Review

The POR covered by this review is January 1, 2013, through December 31, 2013.

Scope of Order

The products covered by this order are certain welded carbon steel pipe and tube with an outside diameter of 0.375 inch or more, but not over 16 inches, of any wall thickness (pipe and tube) from Turkey. These products are currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings as 7306.30.10, 7306.30.50, and 7306.90.10. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Ministerial Errors

Section 751(h) of the Tariff Act of 1930, as amended (''the Act''), and 19 CFR 351.224(f) define a ''ministerial error'' as an error ''in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any similar type of unintentional error which the Secretary considers ministerial.'' We analyzed the Borusan Companies' ministerial error comments and determined, in accordance with section 751(h) of the Act and 19 CFR 351.224(e), that there was a ministerial error in our calculation of the Borusan Companies net subsidy rate for the *Final Results.* For a complete discussion of the alleged error, *see* the Department's Ministerial Error Memorandum.[4]

In accordance with section 751(h) of the Act and 19 CFR 351.224(e), we are amending the *Final Results.* Specifically, we are amending the net subsidy rate for the Borusan Companies as well as the net subsidy rate for those companies that were not selected for individual examination, who were assigned the rate determined for the Borusan Companies.[5] The revised net subsidy rates are detailed below.

Amended Final Results

As a result of correcting for the ministerial error, we determine the following amended net subsidy rates for the period January 1, 2013, through December 31, 2013:

[1] *See Circular Welded Carbon Steel Pipes and Tubes from Turkey: Final Results of Countervailing Duty Administrative Review; Calendar Year 2013 and Rescission of Countervailing Duty Administrative Review, in Part,* 80 FR 61361 (Dep't Commerce Oct. 13, 2015) (''*Final Results*''), and accompanying Decision Memorandum for the Final Results of Countervailing Duty Administrative Review: Circular Welded Carbon Steel Pipes and Tubes from Turkey (Oct. 5, 2015).

[2] *See* Memorandum to Eric Greynolds, Program Manager, AD/CVD Operations, Office III from Jolanta Lawska, Case Analyst, AD/CVD Operations, Office III, ''Final Calculations for the Borusan Group, Borusan Mannesmann Boru Sanayi ve Ticaret A.S. (BMB), and Borusan Istikbal Ticaret T.A.S. (Istikbal), (collectively, the Borusan Companies),'' dated October 5, 2015 (''Final Results Calculations'').

[3] *See* Letter from Borusan Companies, dated October 13, 2015.

[4] *See* ''2013 Certain Welded Carbon Steel Pipe and Tube from Turkey: Amended Final Results of Countervailing Duty Administrative Review, 2013: Final Results Ministerial Error Allegation'' dated concurrently with this notice (''Ministerial Error Memorandum'').

[5] *See Final Results,* 80 FR at 61362.

Company	Net subsidy rate (percent)
Borusan Group, Borusan Holding, A.S. (Borusan Holding), Borusan Mannesmann Boru Sanayi ve Ticaret A.S. (Borusan), Borusan Istikbal Ticaret T.A.S. (Istikbal), and Borusan Lojistik Dagitim Pepolama Tasimacilik ve Tic A.S. (Borusan Lojistik) (collectively, the Borusan Companies).	0.88 *ad valorem.*
Umran Celik Born Sanayii A.S. (also known as Umran Steel Pipe Inc.) (Umran)	0.88 *ad valorem.*
Guven Steel Pipe (also known as Guven Celik Born San. Ve Tic. Ltd.) (Guven)	0.88 *ad valorem.*
Toscelik Profil ve Sac Endustrisi A.S. (Toscelik Profil), Toscelik Metal Ticaret AS., and Tosyali Dis Ticaret AS. (Tosyali) (collectively, the Toscelik Companies).	0.88 *ad valorem.*

Assessment Rates/Cash Deposits

The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these amended final results to liquidate shipments of subject merchandise produced and/or exported by respondents listed above entered, or withdrawn form warehouse, for consumption on or after January 1, 2013, through December 31, 2013.

Pursuant to section 751(a)(2)(C) of the Act, the Department also intends to instruct CBP to collect cash deposits of estimated countervailing duties, in the amounts shown above for each of the respective companies shown above, on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after October 13, 2015, the date of publication of the *Final Results.* For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most-recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective orders (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Disclosure

We will disclose the calculations performed for these amended final results to interested parties within five business days of the date of the publication of this notice in accordance with 19 CFR 351.224(b).

We are issuing and publishing this notice in accordance with sections 751(h) and 777(i)(1) of the Act and 19 CFR 351.224(e).

Dated: November 5, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–28887 Filed 11–12–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE273

Pacific Whiting; Advisory Panel

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

ACTION: Notice; call for nominations.

SUMMARY: NMFS is soliciting nominations for appointments to the United States Advisory Panel (AP) established in the Agreement between the Government of the United States of America and the Government of Canada on Pacific Hake/Whiting (Pacific Whiting Treaty). Nominations are being sought to fill two positions on the AP for terms that begin on January 23, 2016 and end September 15, 2019.

DATES: Nominations must be received by December 18, 2015.

ADDRESSES: You may submit nominations by any of the following methods:

- Email: *whiting.nominations.wcr@noaa.gov.*
- Fax: 206–526–6736, Attn: Frank Lockhart.
- Mail: William W. Stelle, Jr., Regional Administrator, West Coast Region, NMFS, 7600 Sand Point Way NE., Seattle, WA 98115–0070.

FOR FURTHER INFORMATION CONTACT: Frank Lockhart, (206) 526–6142 or Miako Ushio, (206) 526–4644.

SUPPLEMENTARY INFORMATION:

Pacific Whiting Treaty Committees Background

The Pacific Whiting Act of 2006 (Pacific Whiting Act), 16 U.S.C. 7001–10, implements the 2003 Agreement between the Government of the United States of America and the Government of Canada on Pacific Hake/Whiting. Among other provisions, the Pacific Whiting Act provides for the establishment of an Advisory Panel (AP). The AP advises the Joint Management Committee on bilateral Pacific whiting management issues. AP members must be knowledgeable or experienced in the harvesting, processing, marketing, management, conservation, or research of the offshore Pacific whiting resource. Eight individuals represent the United States on the AP, and nominations for two of those positions (id. at § 7005) are solicited through this notice.

Members appointed to the U.S. sections of the AP will be reimbursed for necessary travel expenses in accordance with Federal Travel Regulations and sections 5701, 5702, 5704 through 5708, and 5731 of Title 5. (Id. at § 7008). NMFS anticipates that 1–2 meetings of the AP will be held annually, and these meetings will be held in the United States or Canada. AP members will need a valid U.S. passport.

The Pacific Whiting Act also states that while performing their appointed duties, members ''other than officers or employees of the United States Government, shall not be considered to be Federal employees while performing such service, except for purposes of injury compensation or tort claims liability as provided in chapter 81 of title 5 and chapter 171 of title 28.'' (Id.)

Information on the Pacific Whiting Treaty, including current committee members can be found at: *www.westcoast.fisheries.noaa.gov/fisheries/management/whiting/pacific_whiting_treaty.html.*

Advisory Panel Qualifications

AP member nominees must be knowledgeable or experienced in the harvesting, processing, marketing, management, conservation, or research of the offshore Pacific whiting resource; and must not be employees of the United States government. Nomination

packages for appointments should include:

1. The name of the applicant or nominee, position they are being nominated for and a description of his/her interest in Pacific whiting; and

2. A statement of background and/or description of how the nominee is knowledgeable or experienced in the harvesting, processing, marketing, management, conservation, or research of the offshore Pacific whiting resource. Letters of support for nominees will also be considered.

Authority: 16 U.S.C. 7001 *et seq.*

Dated: November 6, 2015.

Emily H. Menashes,

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

[FR Doc. 2015–28775 Filed 11–12–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE311

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a one-day meeting of its Coastal Migratory Pelagics (CMP) Advisory Panel (AP).

DATES: The meeting will be held on Monday, November 30, 2015, from 8:30 a.m. until 5 p.m.

ADDRESSES: The meeting will be held at the Hilton Tampa Airport Westshore hotel, located at 2225 N. Lois Avenue, Tampa, FL 33607; telephone: (813) 877–6688.

Council address: Gulf of Mexico Fishery Management Council, 2203 N. Lois Avenue, Suite 1100, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Ryan Rindone, Fishery Biologist, Gulf of Mexico Fishery Management Council; *ryan.rindone@gulfcouncil.org,* telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Agenda

Monday, November 30, 2015

The Chairman will begin the meeting with introductions, adoption of the agenda, and review and approval of the CMP Advisory Panel (AP) minutes from the March 3–4, 2015 meeting; followed by an election of a new chair and vice-chair. The Committee will then review the CMP Amendment 26 Public Hearing Draft—Gulf and Atlantic King Mackerel reallocation, stock boundary, and sale provisions; including the review of the CMP 26 Decision Document and the AP's recommendations. The AP will discuss Other Business; Modifications to Electronic Seafood Dealer Report, and additional items, if any.

Meeting Adjourns

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on the Council's file server. To access the file server, go to the Council's Web site (*http://www.gulfcouncil.org*) and click on the ''File Server'' link at the lower left corner of the Web site. The username and password are both ''gulfguest''. Click on the ''Library Folder'', then scroll down to ''Mackerel AP Meeting—November 30, 2015''.

The meeting will be webcast over the internet. A link to the webcast will be available on the Council's Web site, *http://www.gulfcouncil.org.*

Although other non-emergency issues not on the agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the Scientific and Statistical Committee will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Gulf Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

Dated: November 9, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–28816 Filed 11–12–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE313

New England 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 New England Fishery Management Council (Council, NEFMC) will hold a three-day meeting to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Tuesday, Wednesday and Thursday, December 1–3, 2015, starting at 9 a.m. on December 1, and at 8:30 a.m. on both December 2–3.

ADDRESSES: The meeting will be held at the Holiday Inn by the Bay, 88 Spring Street, Portland, ME 04101; telephone: (207) 775.2311, fax: (207) 761.8224, or online at *www.innbythebay.com/.*

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950; telephone 978–465–0492.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492, ext. 113.

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, December 1, 2015

After introductions and any announcements, the Council meeting will open with brief reports from the NEFMC Chairman and Executive Director, the NOAA Regional Administrator for the Greater Atlantic Region, Northeast Fisheries Science Center and Mid-Atlantic Fishery Management Council liaisons, NOAA General Counsel and Office of Law Enforcement representatives, and staff from the Atlantic States Marine Fisheries Commission, the U.S Coast Guard, and the Northeast Regional Ocean Council. These reports will be followed by a Mid-Atlantic Fishery Management Council (MAFMC) staff overview on proposed 2016–17 spiny dogfish fishery specifications. Because it is a joint plan with the MAFMC, the NEFMC is scheduled to vote on the specifications at this meeting.

Following a lunch break, the public will have an opportunity to make brief

comments on items that are relevant to Council business but otherwise not listed on the published agenda. The Northeast Fisheries Science Center director will then provide the Council with a briefing on the Center's Strategic Plan. The Scientific and Statistical Committee (SSC) will present its recommendations for an overfishing limit (OFL) and an acceptable biological catch (ABC) for the following: Atlantic sea scallops for fishing years 2016–17; red hake for 2016–17; and most of the 20 groundfish stocks in the Northeast Multispecies Fishery Management Plan (FMP) for fishing years 2016–18. The Council also will receive the SSC's comments on NOAA's Ecosystem-based Fishery Management (EBFM) Policy. The EBFM Committee will present a progress report on the development of a pilot EBFM Plan and ask for approval of its draft comments on the agency's EBFM policy.

Wednesday, December 2, 2015

Wednesday's session will begin with a report from the Council's Skate Committee. It will recommend final action (approval) of Framework Adjustment 3 to the Northeast Skate Complex Fishery Management Plan (FMP). It will contain next year's fishery specifications, in addition to measures that address possession limits and possible modifications to the seasonal management of the skate wing fishery. This will be followed by an update on NOAA Fisheries' activities concerning a petition to list thorny skates as threatened or endangered. Next, the Greater Atlantic Regional Fisheries Office staff will brief the Council on its Recreational Fishery Implementation Plan and solicit public comments. During the Groundfish Committee's report to follow, the Council will consider recommendations for recreational management measures for stocks of Gulf of Maine haddock and Gulf of Maine cod for fishing year 2016. They will be further considered by NOAA Fisheries and announced prior to the beginning of the upcoming fishing year. The Council also plans to approve Framework 55 to the Northeast Multispecies FMP, including specifications for its groundfish stocks for fishing years 2016–18, plus three U.S./Canada stocks for 2016 only. At-sea monitoring alternatives and other management measures are being proposed for inclusion in the framework.

Thursday, December 3, 2015

The final meeting day will begin with consideration and approval of the NEFMC's management priorities for 2016, followed by a briefing about the collection of fisheries data through the Atlantic Coastal Cooperative Statistics Program, and a report by the Council's Research Steering Committee regarding work on sea scallops and monkfish. The Scallop Committee will ask the Council to approve final action on Amendment 19 to the Sea Scallop FMP. The action is intended to expedite the implementation date of the sea scallop fishery specifications each year. Final approval is also expected on Framework Adjustment 29 to the Scallop FMP, which includes fishing year 2016 fishery specifications and default measures for fishing year 2017.

Although other non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided that the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: November 9, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–28817 Filed 11–12–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Commerce Spectrum Management Advisory Committee Meeting

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a public meeting of the Commerce Spectrum Management Advisory Committee (Committee). The Committee provides advice to the Assistant Secretary for Communications and Information and the National Telecommunications and Information Administration (NTIA) on spectrum management policy matters.

DATES: The meeting will be held on December 2, 2015, from 1 p.m. to 4 p.m., Eastern Standard Time.

ADDRESSES: The meeting will be held at Wilkinson Barker and Knauer, LLP, 1800 M Street NW., Suite 800N, Washington, DC 20036. Public comments may be mailed to Commerce Spectrum Management Advisory Committee, National Telecommunications and Information Administration, 1401 Constitution Avenue NW., Room 4099, Washington, DC 20230 or emailed to *BWashington@ntia.doc.gov.*

FOR FURTHER INFORMATION CONTACT: Bruce M. Washington, Designated Federal Officer, at (202) 482–6415 or *BWashington@ntia.doc.gov;* and/or visit NTIA's Web site at *http://www.ntia.doc.gov/category/csmac.*

SUPPLEMENTARY INFORMATION: *Background:* The Committee provides advice to the Assistant Secretary for Communications and Information on needed reforms to domestic spectrum policies and management in order to: License radio frequencies in a way that maximizes their public benefits; keep wireless networks as open to innovation as possible; and make wireless services available to all Americans. *See* Charter at *http://www.ntia.doc.gov/files/ntia/publications/csmac_2015_charter_renewal_2-26-15.pdf.*

This Committee is subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, and is consistent with the National Telecommunications and Information Administration Act, 47 U.S.C. 904(b). The Committee functions solely as an advisory body in compliance with the FACA. For more information about the Committee visit: *http://www.ntia.doc.gov/category/csmac.*

Matters To Be Considered: The Committee provides advice to the Assistant Secretary to assist in developing and maintaining spectrum management policies that enable the United States to maintain or strengthen its global leadership role in the introduction of communications technology and services and innovation. This helps in expanding the economy, adding jobs, and increasing international trade, while at the same time providing for the expansion of existing technologies and supporting the country's homeland security, national defense, and other critical government needs. The Committee will hear reports of the following Subcommittees:

1. Federal Access to Non-Federal Bands (Bi-directional Sharing)

2. Government and Industry Collaboration
3. Measurement and Sensing in 5 GHz
4. Spectrum Access System (SAS)/ Spectrum Database International Extension
5. Fifth Generation (5G) Wireless

NTIA will post a detailed agenda on its Web site, *http://www.ntia.doc.gov/category/csmac,* prior to the meeting. To the extent that the meeting time and agenda permit, any member of the public may speak to or otherwise address the Committee regarding the agenda items. *See Open Meeting and Public Participation Policy,* available at *http://www.ntia.doc.gov/category/csmac.*

Time and Date: The meeting will be held on December 2, 2015, from 1 p.m. to 4 p.m., Eastern Standard Time. The times and the agenda topics are subject to change. The meeting will be available via two-way audio link and may be webcast. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/category/csmac,* for the most up-to-date meeting agenda and access information.

Place: The meeting will be held at Wilkinson Barker and Knauer, LLP, 1800 M Street NW., Suite 800N, Washington, DC 20036. Public comments may be mailed to Commerce Spectrum Management Advisory Committee, National Telecommunications and Information Administration, 1401 Constitution Avenue NW., Room 4099, Washington, DC 20230. The meeting will be open to the public and press on a first-come, first-served basis. Space is limited. The public meeting is physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Mr. Washington at (202) 482–6415 or *BWashington@ntia.doc.gov* at least ten (10) business days before the meeting.

Status: Interested parties are invited to attend and to submit written comments to the Committee at any time before or after the meeting. Parties wishing to submit written comments for consideration by the Committee in advance of a meeting must send them to NTIA's Washington, DC office at the above-listed address and comments must be received five (5) business days before the scheduled meeting date, to provide sufficient time for review. Comments received after this date will be distributed to the Committee, but may not be reviewed prior to the meeting. It would be helpful if paper submissions also include a compact disc (CD) in Word or PDF format. CDs should be labeled with the name and organizational affiliation of the filer. Alternatively, comments may be submitted electronically to *BWashington@ntia.doc.gov.* Comments provided via electronic mail also may be submitted in one or more of the formats specified above.

Records: NTIA maintains records of all Committee proceedings. Committee records are available for public inspection at NTIA's Washington, DC office at the address above. Documents including the Committee's charter, member list, agendas, minutes, and any reports are available on NTIA's Committee Web page at *http://www.ntia.doc.gov/category/csmac.*

Dated: November 9, 2015.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2015–28878 Filed 11–12–15; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2014–HA–0025]

Proposed Collection; Comment Request

AGENCY: Defense Health Agency (DHA), Defense Health Clinical Systems, Data Sharing Program Office, DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Health Agency, Defense Health Clinical Systems, Data Sharing Program Office, announces a proposed public information collection and seeks public comment on the provisions thereof. 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 12, 2016.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.

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.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Health Information Management System (DHIMS), ATTN: Alvaro Rodriguez, 5109 Leesburg Pike, Skyline 6, Suite 508, Falls Church, VA 22041, or call DHIMS, at 703–882–3867.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Health Artifact and Image Management Solution (HAIMS); 0720–TBD.

Needs and Uses: The information collection requirement is necessary for HAIMS to provide the departments of Defense and Veterans Affairs health care providers with global visibility and access to artifacts (documents) and images generated during the health care delivery process. HAIMS will provide a single enterprise-wide data sharing capability for all types of artifacts and images (also known as A&I), including radiographs, clinical photographs, electrocardiographs, waveforms, audio files, video and scanned documents.

Affected Public: Individuals and Households; specifically, beneficiaries with access to the Military Healthcare system.

Annual Burden Hours: 500,000.

Number of Respondents: 8,333,333.

Responses per Respondent: 1.2.

Annual Responses: 10,000,000.

Average Burden per Response: 3 minutes.

Frequency: On occasion.

The Health Artifact and Image Management Solution (HAIMS) will provide the departments of Defense and Veterans Affairs health care providers with global visibility and access to artifacts (documents) and images generated during the health care delivery process. HAIMS, a Wounded Warrior strategic project, will provide a single enterprise-wide data sharing capability for all types of artifacts and images (also known as A&I), including radiographs, clinical photographs, electrocardiographs, waveforms, audio files, video and scanned documents.

HAIMS will provide an enterprise solution utilizing a Service Oriented Architecture (SOA) based application with a federated infrastructure. The required solution to satisfy the scope of HAIMS will consist of industry standard COTS, as well as government off the shelf (GOTS). The expected business outcomes have been defined and constraints/dependencies have been identified in satisfying the functional, technical and system requirements to develop, field and support HAIMS throughout the life cycle.

HAIMS interfaces with external repositories to register and access patient A&I. Patient demographic information from the Clinical Data Repository (CDR) is used to associate A&I with the patient. Another method of collecting data is through bulk scanning of patient artifacts into HAIMS. The user will first select the patient for which the artifact is associated with, and then enters in relevant metadata of the artifacts.

The information in HAIMS is sensitive; therefore, it contains built-in safeguards to limit access and visibility of this information. HAIMS uses role-based security so a user sees only the information for which permission has been granted. It uses encryption security for transactions. It is DIACAP certified having been subjected to and passed thorough security testing and evaluation by independent parties. It meets safeguards specified by the Privacy Act of 1974 in that it maintains a published Department of Defense (DoD) Privacy Impact Assessment and System of Record covering Active Duty Military, Reserve, National Guard, and government civilian employees, to include non-appropriated fund employees and foreign nationals, DoD contractors, and volunteers. HAIMS servers are hosted at Military Treatment Facilities (MTFs) and physically secured by the Services and within the MHS enclave, Enterprise Infrastructure maintains information security.

Dated: November 9, 2015.

Aaron Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2015–28829 Filed 11–12–15; 8:45 am]

BILLING CODE 5001–06–P

DELAWARE RIVER BASIN COMMISSION

Notice of Public Hearing and Business Meeting November 10 and December 9, 2015

Correction

In notice document 2015–26837 appearing on pages 63973 through 63974 in the issue of Thursday, October 22, 2015 make the following correction:

1. Beginning page 63973, in the third column, in the final paragraph and continuing on page 63974 in the first paragraph, ''The public business meeting on December 9, 2015 will begin at 1:30 p.m.'' should read ''The public business meeting on December 9, 2015 will begin at 10:30 a.m.''

In notice document C1–2015–26837 appearing on page 66524 in the issue of Thursday, October 29, 2015 make the following correction:

2. On page 66524, in the second column, in lines four through six, ''The public hearing on November 10, 2015 will begin at 10:30 a.m.'' should read ''The public hearing on November 10, 2015 will begin at 1:30 p.m.''

[FR Doc. C2–2015–26837 Filed 11–12–15; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0085]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and approval; Comment Request; Recent Graduates Employment and Earnings Survey (RGEES) Standards and Survey Form

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et se.*), ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before December 14, 2015.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2015–ICCD–0085 Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E105 Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Recent Graduates Employment and Earnings Survey (RGEES) Standards and Survey Form.

OMB Control Number: 1845–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 22,123.

Total Estimated Number of Annual Burden Hours: 7,374.

Abstract: The National Center for Education Statistics (NCES) of the U.S. Department of Education (Department) is required by regulation to develop an earnings survey to support gainful employment (GE) program evaluations. The regulations specify that the Secretary of Education will publish in the **Federal Register** the survey and the standards required for its administration. NCES has developed the Recent Graduates Employment and Earnings Survey (RGEES) Standards and Survey Form. The RGEES can be used in a debt-to-earnings (D/E) ratio appeal under the GE regulations as an alternative to the Social Security administration earnings data.

Institutions that choose to submit alternate earnings appeal information will survey all Title IV funded students who graduated from GE programs during the same period that the Department used to calculate the D/E ratios, or a comparable period as defined in 668.406(b)(3) of the regulations. The survey will provide an additional source of earnings data for the Department to consider before determining final D/E ratios for programs subject to the gainful employment regulations. Programs with final D/E ratios that fail to meet the minimum threshold may face sanctions, including the possible loss of Title IV federal student financial aid program funds.

Dated: November 9, 2015.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–28839 Filed 11–10–15; 11:15 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Notice of Public Meeting to Provide Comments on Draft Materials to Improve FERC–USACE Coordinated Regulatory Processes for Non-Federal Development of Hydropower at USACE Non-Hydropower Dams

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

ACTION: Announcement of meeting.

SUMMARY: This notice announces a meeting to obtain individual public input on new ideas developed collaboratively by the Department of Energy (DOE), Federal Energy Regulatory Commission (FERC) and U.S. Army Corps of Engineers (USACE) aimed at improving coordination of FERC and USACE regulatory processes regarding non-federal development of hydropower at USACE non-powered dams. DOE estimates that there is a potential for 12 gigawatts of new hydropower capacity in the U.S. by adding power at non-powered dams.[1] Adding power at USACE non-powered dams requires federal authorizations, potentially including authorizations via: The FERC licensing process [2], the USACE 408 process [3], and the USACE regulatory 404 process [4] (impacts to waters of the U.S. pursuant to Section 404 of the Clean Water Act). All three of these processes require project proposal identification, information gathering, and environmental and engineering analyses to support licensing, permitting, or agency decisions.

DATES: The meeting will be held on Thursday, December 10th, 2015, from 1:00–5:00 p.m. Eastern Time.

ADDRESSES: The meeting will be held at the Federal Energy Regulatory Commission (FERC), 888 First Street NE., Hearing Room 1, Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT: Patrick Gilman, Department of Energy at (720) 356–1420 or *Patrick.Gilman@ee.doe.gov,* or Hoyt Battey, Department of Energy, at (202) 586–0143 or *Hoyt.Battey@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE with the assistance of Oak Ridge National Laboratory convened a collaborative process with FERC and USACE staff to develop ideas on how FERC and USACE permitting efforts can be more efficiently coordinated to decrease overall process time and avoid duplication of efforts.

The focus of the public meeting will be for agencies to receive public input, questions, and recommendations for areas of potential improvement in the coordination of FERC and USACE regulatory processes regarding non-federal development of hydropower at USACE non-powered dams and provide a forum to exchange information. Attendees will be asked to provide these recommendations and information based on their personal experience, individual advice, information, or facts regarding this topic. The object of the meeting is not to obtain any group position or consensus; rather, the agencies are seeking as many recommendations as possible from all individuals at this meeting. Draft documents outlining preliminary ideas for improving processes can be viewed at the meeting Web site: *http://hydropower.ornl.gov/npd-public-workshop/.* The meeting is open to the public; project developers, those involved in adding power at non-power dams, environmental non-governmental organizations, tribes, and all interested members of the public are encouraged to attend. Pre-registration is required as space is limited. Register at *http://hydropower.ornl.gov/npd-public-workshop/;* or contact Kelsey Rugani at Kearns & West (*krugani@kearnswest.com,* (415) 391–7900) to RSVP.

If you are unable to attend and want to provide written comments, please do so by 11:59 p.m. EST on December 18th. Please send all comments to *Hydropermitting@ee.doe.gov.*

Jim Ahlgrimm,

Supervisory General Engineer, Wind and Water Power Program, Office of Energy Efficiency and Renewable Energy.

[FR Doc. 2015–28875 Filed 11–12–15; 8:45 am]

BILLING CODE 6450–01–P

[1] National Hydropower Asset Assessment Program, Non-Powered Dam Resource Assessment can be found at *http://nhaap.ornl.gov/content/non-powered-dam-potential.*

[2] 18 U.S.C. 4, 5, and 16.

[3] Section 14 of the Rivers and Harbors Act of 1899 (33 U.S.C. 408).

[4] Section 404 of the Clean Water Act (33 U.S.C. 1344).

DEPARTMENT OF ENERGY

Notice of Availability of the Plains & Eastern Clean Line Transmission Project Final Environmental Impact Statement

AGENCY: Department of Energy.

ACTION: Notice of availability.

SUMMARY: The U.S. Department of Energy (DOE) announces the availability of the *Plains & Eastern Clean Line Transmission Project Final Environmental Impact Statement* (DOE/EIS–0486; Final EIS), prepared pursuant to the National Environmental Policy Act (NEPA). This Final EIS considered public comments on the Draft EIS, which was issued in December 2014, reports on the status of consultations under section 106 of the National Historic Preservation Act (NHPA) and under section 7 of the Endangered Species Act (ESA), and identifies DOE's preferred alternative. DOE has not made a decision whether to participate in the proposed Plains & Eastern Clean Line Transmission Project.

DATES: DOE will publish a Record of Decision no sooner than 30 days after publication of the U.S. Environmental

Protection Agency's (EPA) Notice of Availability in the **Federal Register**.

ADDRESSES: The Final EIS is available on the DOE NEPA Web site at *http://energy.gov/nepa* and on the Plains & Eastern EIS Web site at *http://www.plainsandeasterneis.com/*. Copies of the Final EIS also are available in the public reading rooms listed in **SUPPLEMENTARY INFORMATION**.

A printed summary and CD of the complete Final EIS or a complete printed copy of the Final EIS (approximately 5,500 pages) may be requested by sending an email to *info@PlainsandEasternEIS.com*.

FOR FURTHER INFORMATION CONTACT: For information on the Plains & Eastern EIS or the Section 106 process, contact Jane Summerson, Ph.D., DOE NEPA Document Manager on behalf of the Office of Electricity Delivery and Energy Reliability, U.S. Department of Energy, DOE NNSA, Post Office Box 5400 Building 391, Kirtland Air Force Base East, Albuquerque, NM 87185; email at *Jane.Summerson01@nnsa.doe.gov;* or telephone at (505) 845–4091.

For general information regarding the DOE NEPA process, contact Carol Borgstrom, Director, Office of NEPA Policy and Compliance (GC–54), U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585; or phone at (202) 586–4600; voicemail at (800) 472–2756; or email at *askNEPA@hq.doe.gov.* Additional information regarding DOE's NEPA activities is available on the DOE NEPA Web site at *http://energy.gov/nepa*.

Additional information on the Final EIS is also available through the EIS Web site at *http://www.plainsandeasternEIS.com/*.

SUPPLEMENTARY INFORMATION:

Background

In June 2010, DOE, acting through the Southwestern Power Administration and the Western Area Power Administration, both power marketing administrations within DOE, issued *Request for Proposals for New or Upgraded Transmission Line Projects Under Section 1222 of the Energy Policy Act of 2005* (EPAct; 42 United States Code [U.S.C.] 16421; 75 FR 32940; June 10, 2010). In response to the request for proposals, Clean Line Energy Partners LLC of Houston, Texas, the parent company of Plains and Eastern Clean Line LLC and Plains and Eastern Clean Line Oklahoma LLC (collectively referred to as Clean Line or the Applicant) submitted a proposal to DOE in July 2010 for the Plains & Eastern Clean Line Project. In August 2011, Clean Line modified the proposal and subsequently submitted additional information (referred to as the Part 2 Application) in January 2015 at DOE's request.

DOE is the lead federal agency for the preparation of the Plains & Eastern EIS, which examines the potential environmental impacts from Clean Line's proposed Project (also referred to as the Applicant Proposed Project) and the range of reasonable alternatives. DOE has prepared the EIS pursuant to NEPA (42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality NEPA regulations (40 Code of Federal Regulations [CFR] parts 1500 through 1508), and the DOE NEPA implementing regulations (10 CFR part 1021). DOE's purpose and need for agency action is to implement section 1222 of the EPAct. To that end, the Plains & Eastern EIS will inform DOE as it decides whether and under what conditions it would participate in the Project.

The Applicant Proposed Project would include an overhead ± 600-kilovolt (kV) high voltage direct current (HVDC) electric transmission system and associated facilities with the capacity to deliver approximately 3,500 megawatts (MW) primarily from renewable energy generation facilities in the Oklahoma and Texas Panhandle regions to load-serving entities in the Mid-South and Southeast United States via an interconnection with the Tennessee Valley Authority (TVA) in Tennessee. Major facilities associated with the Applicant Proposed Project consist of converter stations in Oklahoma and Tennessee; an approximately 720-mile, ± 600kV HVDC transmission line; an alternating current (AC) collection system; and access roads. Pursuant to NEPA, DOE has identified and analyzed potential environmental impacts for the range of reasonable alternatives to the Applicant Proposed Project. These alternatives include an Arkansas converter station and alternative routes for the HVDC transmission line. The Arkansas Converter Station alternative would increase the capacity of the proposed transmission system and facilities by 500MW (to 4,000MW) to facilitate delivery of electricity to the grid in Arkansas.

DOE has prepared this Final EIS in consultation with the following cooperating agencies: Bureau of Indian Affairs (BIA), Natural Resources Conservation Service (NRCS), TVA, U.S. Army Corps of Engineers (USACE), EPA, and the U.S. Fish and Wildlife Service (USFWS).

BIA, NRCS, TVA, USACE, and USFWS can, to the extent permitted by law, rely on the Plains & Eastern EIS to fulfill their obligations under NEPA for any action, permit, or approval by these agencies for the Project. Upgrades to TVA's transmission system would be necessary to interconnect with the Project while maintaining reliable service to its customers. Additionally, TVA would need to construct a new 500kV transmission line to enable the injection of 3,500MW of power from the Project. TVA would complete its own NEPA review, tiering from this EIS, to assess the impact of the upgrades and the new 500kV line. The USACE may consider the routing alternatives in Oklahoma, Arkansas, Texas, and Tennessee as presented in the Final EIS when making its permit decisions and can use the analysis contained in the Final EIS to inform all of its permit decisions for the Project.

DOE is the lead agency for consultation required under section 106 of the NHPA (54 U.S.C. 300101 *et seq.*) for the Project. DOE is using the NEPA process and documentation required for the Plains & Eastern EIS to comply with section 106 of the NHPA in lieu of the procedures set forth in 36 CFR 800.3 through 800.6. This approach is consistent with the recommendations set forth in the NHPA implementing regulations that section 106 compliance should be coordinated with actions taken to meet NEPA requirements (36 CFR 800.8(a)(1)). Appendix P of the Final EIS includes the draft Programmatic Agreement developed pursuant to 36 CFR 800.14(b). This draft Programmatic Agreement was developed consistent with DOE's obligations under NHPA section 106, including government-to-government consultation with Indian Tribes and Nations on whose tribal lands the undertaking may occur or that may attach religious and cultural significance to historic properties that may be affected by the undertaking, and consultation with the Arkansas, Oklahoma, Tennessee, and Texas State Historic Preservation Officers. DOE intends to execute the Programmatic Agreement prior to issuance of the Record of Decision or otherwise comply with procedures set forth in 36 CFR part 800.

DOE and the Applicant have prepared a Biological Assessment of potential impacts on special status species protected under the Endangered Species Act (ESA) as part of the section 7 consultation between DOE and the USFWS. The section 7 consultation review is a parallel, but separate, process to the NEPA process, conducted

pursuant to the requirements of ESA and the applicable implementing regulations. The Biological Assessment and associated addendum are included as Appendix O to the Final EIS. The Biological Opinion, to be issued by the USFWS, may identify additional protective measures to avoid or minimize impacts to special status species.

In the Final EIS, DOE analyzed the potential environmental impacts of the Applicant Proposed Project, the range of reasonable alternatives, and a No Action Alternative. The potential environmental impacts resulting from connected actions (wind energy generation and substation and transmission upgrades related to the Project) were also analyzed in the Final EIS. The Final EIS considers comments submitted on the Draft EIS, including those submitted during the public comment period that began on December 19, 2014, and ended on April 20, 2015. Late comments have been considered to the extent practicable. During the comment period, DOE held 15 public hearings in Oklahoma, Texas, Arkansas, and Tennessee. Approximately 950 comment documents were received from individuals, interested groups, tribal governments, and federal, state, and local agencies during the public comment period on the Draft EIS. This total includes a single copy of documents that were received as part of 50 email and letter campaigns (*i.e.,* identical letters signed and submitted by more than one commenter). The total number of campaign documents was approximately 1,700 emails or letters. In addition to numerous comments that provided a statement of general opposition or support, the primary topics raised include, but are not limited to concern about electric and magnetic fields from the transmission line; concern about reductions in property value; concern about impacts to agricultural resources such as crop production, irrigation, and aerial spraying; concern about the use of eminent domain; and concern about visual impacts from the transmission line.

As indicated above, DOE's purpose and need for agency action is to implement section 1222 of the EPAct. While developing the Final EIS, DOE considered the alternatives analyzed in the Draft EIS, the comparison of potential impacts for each resource area, and input received on the Draft EIS. Based on the information presented in the Final EIS, DOE has identified participation in the Project as its preferred alternative in the Final EIS. The Project would include the Oklahoma converter station and AC interconnection, the AC collection system, the Applicant Proposed Route for the majority of the HVDC transmission line (with the exception of route variation Region 4, Applicant Proposed Route Link 3, Variation 2), and the Arkansas converter station and AC interconnection.

Consistent with section 1222 of the EPAct, DOE's participation would be limited to states in which Southwestern operates, namely, Oklahoma, Arkansas, and, possibly, Texas, but not Tennessee. Consequently, DOE would not participate in the portions of the Project that would be sited in Tennessee.

Other Regulations

Parallel with the NEPA process, DOE is evaluating Clean Line's application under section 1222 of the EPAct. This non-NEPA evaluation includes, but is not limited to, reviewing the application against statutory criteria and other factors listed in the 2010 request for proposals (75 FR 32940). An outcome of this evaluation could be a Participation Agreement between Clean Line and DOE, which would define under what conditions DOE would participate with Clean Line and, if applicable, would include any stipulations or requirements that resulted from this environmental review under NEPA. The DOE Office of Electricity Delivery and Energy Reliability Web site (*http://www.energy.gov/oe/services/electricity-policy-coordination-and-implementation/transmission-planning/section-1222-0*) provides more information about the section 1222 evaluation.

Public Reading Rooms

Copies of the Final EIS and supporting documents are available for inspection at the following locations:

Oklahoma

- Guymon Public Library—1718 N. Oklahoma St., Guymon, OK 73942
- Beaver County Pioneer Library—201 Douglas Ave., Beaver, OK 73932
- Woodward Public Library—1500 W. Main St., Woodward, OK 73801
- Muskogee Public Library—801 W. Okmulgee Ave., Muskogee, OK 74401
- Enid & Garfield County Public Library—120 W. Maine St., Enid, OK 73701
- Buffalo Public Library—11 E. Turner St., Buffalo, OK 73834
- Fairview City Library—115 S. 6th St., Fairview, OK 73737
- Guthrie Public Library—201 N. Division St., Guthrie, OK 73044
- Stillwater Public Library—1107 S. Duck St., Stillwater, OK 74074
- Chandler Public Library—1021 Manvel Ave., Chandler, OK 74834
- Montfort and Allie B. Jones Memorial Library—111 W. 7th Ave., Bristow, OK 74010
- Bartlett-Carnegie Sapulpa Public Library—27 W. Dewey Ave., Sapulpa, OK 74066
- Cushing Public Library—215 North Steele Ave., Cushing, OK 74023
- Okmulgee Public Library—218 S. Okmulgee Ave., Okmulgee, OK 74447
- Stanley Tubbs Memorial Library—101 E. Cherokee Ave., Sallisaw, OK 74955

Arkansas

- Van Buren Public Library—1409 Main St., Van Buren, AR 72956
- Pope County Library—116 E. 3rd St., Russellville, AR 72801
- Jackson County/W.A. Billingsley Memorial Library—213 Walnut St., Newport, AR 72112
- Searcy Public Library—113 E. Pleasure Ave., Searcy, AR 72143
- Marked Tree Public Library—102 Locust St., Marked Tree, AR 72365
- Franklin County Library—407 W. Market St., Ozark, AR 72949
- Johnson County Library—2 Taylor Cir., Clarksville, AR 72830
- Conway County Library—101 W. Church St., Morrilton, AR 72110
- Conway Public Library—1900 W. Tyler St., Conway, AR 72034
- Mary I. Wold Cleburne County Library—1009 W. Main St., Heber Springs, AR 72543
- Poinsett County Library—200 N. East St., Harrisburg, AR 72432
- Blytheville Public Library—200 N. 5th St., Blytheville, AR 72315
- Osceola Public Library—320 W. Hale Ave., Osceola, AR 72370
- Cross County Library—410 E. Merriman Ave., Wynne, AR 72396

Tennessee

- Munford Memorial Library—1476 Munford Ave., Munford, TN 38058

Texas

- Hansford County Library—122 Main St., Spearman, TX 79081

Issued in Washington, DC, on November 2, 2015.

Patricia A. Hoffman,

Assistant Secretary, Office of Electricity Delivery and Energy Reliability.

[FR Doc. 2015–28574 Filed 11–12–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 5891–009]

Deschutes Valley Water District; Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Comments, Recommendations, Terms and Conditions, and Fishway Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type*: Settlement Agreement, Amendment Application, and Fish Passage Operation Plan.

b. *Project No.*: 5891–009.

c. *Date Filed*: October 8, 2015.

d. *Applicant*: Deschutes Valley Water District (licensee).

e. *Name of Project*: Opal Springs Hydroelectric Project.

f. *Location*: The project is located on the Crooked River in Jefferson County, Oregon.

g. *Filed Pursuant to*: Federal Power Act, 16 U.S.C. 791(a)–825(r) and Rule 602 of the Commission's Rules of Practice and Procedure, 18 CFR 385.602.

h. *Applicant Contact*: Edson Pugh, General Manager, Deschutes Valley Water District, 881 SW Culver Highway, Madras, Oregon 97741; telephone (541) 475–3849; email *edson@dvwd.org.*

i. *FERC Contact*: Jennifer Ambler; telephone: (202) 502–8586; email address: *jennifer.ambler@ferc.gov.*

j. Deadline for filing motions to intervene and protests, comments, recommendations, terms and conditions, and fishway prescriptions is 60 days from the issuance date of this notice by the Commission. Reply comments are due 105 days from the issuance date of this notice by the Commission.

All documents may be filed electronically via the Internet. *See*, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, recommendations, terms and conditions and fishway prescriptions using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–5891–009.

k. *Description of Request*: The licensee filed a settlement agreement, amendment application, and a fish passage operation plan for Commission approval. All three documents address the need for fish passage at the Opal Springs Project. The licensee proposes to construct upstream fish passage facilities on the east bank of the diversion dam and to modify the existing spillway to improve downstream passage. To accommodate the proposed modifications, the licensee would raise the project's normal maximum reservoir elevation by 6 feet and would replace the current flashboard system with a series of five inflatable weirs to attain the proposed higher reservoir elevation. The licensee states that the proposed changes are necessary to facilitate the reintroduction of steelhead trout (*Oncorhynchus mykiss*) and Chinook salmon (*Oncorhynchus tshawytscha*).

l. *Locations of the Application*: A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov*, for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*: Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents*:All filings must (1) bear in all capital letters the title ''PROTEST'', ''MOTION TO INTERVENE'', ''COMMENTS,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' '' TERMS AND CONDITIONS,'' or ''FISHWAY PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, recommendations, terms and conditions or prescriptions should relate to the settlement agreement, proposed amendment application, and fish passage operation plan. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: November 5, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–28773 Filed 11–12–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. Algonquin Gas Transmission, LLC CP16–9–000 Maritimes & Northeast Pipeline, L.L.C. PF15–12–000]

Notice of Application

Take notice that on October 22, 2015, Algonquin Gas Transmission, LLC (Algonquin) and Maritimes & Northeast Pipeline, L.L.C. (Maritimes) (together, the Applicants), 5400 Westheimer Court, Houston, Texas 77056–5310, jointly filed in the above referenced docket an application pursuant to section 7(c) of the Natural Gas Act (NGA), and Part 157 of the Commission's regulations requesting authorization to construct and operate the Atlantic Bridge Project, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application may be directed to Berk Donaldson, General Manager, Rates and Certificates, Algonquin Gas Transmission, LLC and Maritimes & Northeast Pipeline, L.L.C., P.O. Box 1642, Houston, Texas 77251–1642 at (713) 627–4488.

Specifically the applicants propose to: (i) Construct 6.3 miles pipeline facilities and related facilities in New York and Connecticut; (ii) modify three existing compressor stations in Connecticut resulting in the addition of 18,800 horsepower (hp) of compression; (iii) construct and operate a new compressor station in Massachusetts resulting in the addition of 7,700 hp of compression; (iv) modify six existing metering, and regulator stations (M&R) and construct a new M&R Station; and (v) to abandon certain existing facilities. The Atlantic Bridge Project will allow both Algonquin and Maritimes to provide additional firm transportation. The applicants request authorization to charge an initial incremental Atlantic Bridge Project recourse rate and related incremental fuel, and also requested a pre-determination of rolled-in rates treatment for the Project. The cost of the project will be approximately $449.8 million.

On February 20, 2015 the Commission staff granted Columbia's request to utilize the Pre-Filing Process and assigned Docket No. PF15–12–000 to staff activities involved in the Project. Now, as of the filing of the October 22, 2015 application, the Pre-Filing Process for this project has ended. From this time forward, this proceeding will be conducted in Docket No. CP16–9–000, as noted in the caption of this Notice.

Pursuant to section 157.9 of the Commission's rules (18 CFR 157.9), within 90 days of this Notice, the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit seven copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: November 27, 2015.

Dated: November 5, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–28770 Filed 11–12–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–10–000; Docket No. PF15–3–000; Docket No. CP16–13–000; Docket No. PF15–22–000]

Mountain Valley Pipeline, LLC; Equitrans, LP; Notice of Applications

On October 23, 2015, Mountain Valley Pipeline, LLC (Mountain Valley), having its principal place of business at 625 Liberty Avenue, Suite 1700,

Pittsburgh, Pennsylvania 15222–3111, filed an application pursuant to section 7(c) of the Natural Gas Act (NGA) and the Federal Energy Regulatory Commission's (Commission) regulations seeking: (1) A certificate of public convenience and necessity authorizing Mountain Valley to construct, own, and operate the Mountain Valley Pipeline Project; (2) a blanket certificate of public convenience and necessity authorizing Mountain Valley to provide open-access interstate transportation services, with pre-granted abandonment approval; (3) a blanket certificate of public convenience and necessity under Part 157, Subpart F of the Commission's regulations for Mountain Valley to construct, operate, acquire, and abandon certain eligible facilities, and services related thereto; (4) approval for its proposed interim period rates and initial recourse rates for transportation service and for its pro forma tariff; and (5) such other authorizations or waivers as may be deemed necessary to allow for the construction to commence as proposed.

On October 27, 2015, Equitrans, LP (Equitrans), having its principal place of business at 625 Liberty Avenue, Suite 1700, Pittsburgh, Pennsylvania 15222–3111, filed an application pursuant to sections 7(b) and 7(c) of the Natural Gas Act (NGA) and the Federal Energy Regulatory Commission's (Commission) regulations seeking a certificate of public convenience and necessity to construct, own, and operate the Equitrans Expansion Project. Equitrans also seeks authority to abandon an existing compressor station located in Greene County, Pennsylvania.

The proposals of both applicants are more fully described in the applications, which are on file with the Commission and open to public inspection. The filings may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding the Mountain Valley or Equitrans applications should be directed to Matthew Eggerding, Counsel, 625 Liberty Avenue, Suite 1700, Pittsburgh, PA 15222, or call (412) 553–5786, or fax (412) 553–7781, or by email *meggerding@eqt.com.*

Mountain Valley requests authorization to construct facilities that will allow it to provide up to 2.0 million dekatherms per day of firm transportation service. Specifically, Mountain Valley proposes to construct and operate: (1) Approximately 301 miles of 42-inch diameter pipeline in West Virginia and Virginia; (2) three new compressor stations providing approximately 171,600 nominal horsepower (hp) of compression; and (3) other minor facilities.

Equitrans requests authorization to construct, own, and operate: (1) Approximately 7.87 miles of pipeline in Allegheny, Washington, and Greene Counties, Pennsylvania and Wetzel County, West Virginia; (2) a new 31,300 nominal hp compressor station (Redhook Compressor Station) in Greene County, Pennsylvania; (3) a new interconnect in Wetzel County, West Virginia with Mountain Valley's planned pipeline system (Webster Interconnect); and (4) ancillary facilities. Equitrans also seeks authority to abandon an existing 4,800 hp compressor station in Greene County, Pennsylvania (Pratt Compressor Station) following the construction of the new Redhook Compressor Station.

On October 31, 2014, Commission staff granted Mountain Valley's request to use the pre-filing process and assigned Docket No. PF15–3–000 to staff activities involving the Projects. Now, as of the filing of this application on October 23, 2015, the NEPA Pre-Filing Process for this project has ended. From this time forward, this proceeding will be conducted in Docket No. CP16–10–000 as noted in the caption of this Notice. Additionally, Equitrans, LP (Equitrans) filed a related application under CP16–13–000. On April 9, 2015, Commission staff granted Equitrans request to use the pre-filing process and assigned Docket No. PF15–22–000 to staff activities involving the Projects. Now, as of the filing of Equitrans' application on October 27, 2015, the NEPA Pre-Filing Process for this project has ended. From this time forward, Equitrans' proceeding will be conducted in Docket No. CP16–13–000.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 7 copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the

Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on November 26, 2015.

Dated: November 5, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–28771 Filed 11–12–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2246–074]

Yuba County Water Agency; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Application for Temporary Variance of Minimum Flow Requirement.

b. *Project No.:* 2246–074.

c. *Date Filed:* October 30, 2015.

d. *Applicant:* Yuba County Water Agency (licensee).

e. *Name of Project:* Yuba River Project.

f. *Location:* North Yuba River, Middle Yuba River, and Oregon Creek in Yuba, Nevada, and Sierra counties, CA.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Curt Aikens, General Manager, Yuba County Water Agency, 1200 F Street, Marysville, CA 95901–4740, (530) 741–5015.

i. *FERC Contact:* Mr. John Aedo, (415) 369–3335, or *john.aedo@ferc.gov.*

j. Deadline for filing comments, motions to intervene, protests, and recommendations is December 7, 2015. The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, or recommendations using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please include the project number (P–2246–074) on any comments, motions to intervene, protests, or recommendations filed.

k. *Description of Request:* The licensee requests a temporary variance of the minimum flow requirements in the lower Yuba River below Englebright Dam from December 1, 2015 through March 31, 2016, due to low reservoir storage and dry watershed conditions. License Article 33 requires that the licensee provide a minimum flow of: 600 cubic feet per second (cfs) from October 16 through December 31; 1,000 cfs from January 1–15; and 600 cfs from January 16 through March 31. In order to conserve water resources during the current drought, the licensee proposes to instead, release 550 cfs from December 1, 2015 through March 31, 2016. In addition, the licensee requests that the minimum flow compliance criteria during this period be based on a 5-day running average of average daily streamflows, with instantaneous flows never less than 90 percent of the specified 550 cfs minimum flow and never less than 550 cfs for more than 48 hours.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208- 3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the license surrender. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: November 5, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–28772 Filed 11–12–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC09–104–002.
Applicants: Lord, Abbett & Co. LLC.
Description: Request for Reauthorization and Extension of Blanket Authorization to Acquire and Dispose of Securities Under Section 203 of the Federal Power Act and Request for Shortened Comment Period.
Filed Date: 11/4/15.
Accession Number: 20151104–5254.
Comments Due: 5 p.m. ET 11/25/15.

Docket Numbers: EC16–27–000.
Applicants: Carousel Wind Farm, LLC.
Description: Amendment to November 3, 2015 Application for Authorization Under Section 203 of the Federal Power Act and Request for Expedited Action of Carousel Wind Farm, LLC.
Filed Date: 11/4/15.
Accession Number: 20151104–5257.
Comments Due: 5 p.m. ET 11/24/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2579–003.
Applicants: NorthPoint Energy Solutions Inc.
Description: Notification of Non-Material Change in Status of NorthPoint Energy Solutions, Inc.
Filed Date: 11/4/15.
Accession Number: 20151104–5225.
Comments Due: 5 p.m. ET 11/25/15.

Docket Numbers: ER10–2615–006*; ER11–2335–007*
Applicants: Plum Point Energy Associates, LLC, Plum Point Services Company, LLC.
Description: Supplement to June 29, 2015 Triennial MBR Filing of Plum Point Energy Associates, LLC and Plum Point Services Company, LLC.
Filed Date: 10/23/15.
Accession Number: 20151023–5196.
Comments Due: 5 p.m. ET 11/16/15.

Docket Numbers: ER16–263–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: GIA and Distribution Service Agmt Yavi Energy LLC Eastwind Project to be effective 11/1/2015.
Filed Date: 11/5/15.
Accession Number: 20151105–5000.
Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–264–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of WMPA SA No. 3480, Queue No. W1–107 to be effective 10/6/2015.
Filed Date: 11/5/15.
Accession Number: 20151105–5050.
Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–265–000.
Applicants: Exelon Generation Company, LLC.
Description: Tariff Cancellation: Notice of Cancellation of Rate Schedule to be effective 11/6/2015.
Filed Date: 11/5/15.
Accession Number: 20151105–5051.
Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–266–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of WMPA SA No. 3186, Queue No. W4–072 to be effective 12/28/2015.
Filed Date: 11/5/15.
Accession Number: 20151105–5052.
Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–267–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: Haywood Amendment to PPA RS No. 335 to be effective 1/1/2016.
Filed Date: 11/5/15.
Accession Number: 20151105–5113.
Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–268–000.
Applicants: Duke Energy Progress, LLC.
Description: § 205(d) Rate Filing: Haywood 2nd Amended RS No. 180 to be effective 1/1/2016.
Filed Date: 11/5/15.
Accession Number: 20151105–5114.
Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–269–000.
Applicants: San Diego Gas & Electric Company.
Description: § 205(d) Rate Filing: Vista Energy Storage EP, Service Agreement No. 53, Volume 11 to be effective 11/6/2015.
Filed Date: 11/5/15.
Accession Number: 20151105–5147.
Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–270–000.
Applicants: Midcontinent Independent System Operator.
Description: § 205(d) Rate Filing: 2015–11–05_SA 2863 ATC Construction Management Agreement to be effective 10/30/2015.
Filed Date: 11/5/15.
Accession Number: 20151105–5192.
Comments Due: 5 p.m. ET 11/27/15.

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: November 5, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–28769 Filed 11–12–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9937–05–Region 2]

Proposed CERCLA Section 122(h) Cost Recovery Settlements for the Power City Superfund Site, Niagara Falls, Niagara County, New York

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with Section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given by the U.S. Environmental Protection Agency (''EPA''), Region II, of two separate proposed cost recovery settlement agreements pursuant to Section 122(h) of CERCLA, 42 U.S.C. 9622(h), with Honeywell International Inc. and RR Donnelley and Sons Company (the ''Settling Parties''), respectively, for the Power City Superfund Site (''Site''), located in Niagara Falls, Niagara County, New York. Honeywell International Inc. agrees to pay EPA $825,000 and RR Donnelley and Sons Company agrees to pay $103,200, plus interest, respectively, in reimbursement of their respective shares of EPA's past response costs paid at or in connection with the Site.

Each settlement includes a covenant by EPA not to sue or to take

administrative action against each respective Settling Party pursuant to Section 107(a) of CERCLA, 42 U.S.C. 9607(a), with regard to the response costs related to the work at the Site enumerated in each settlement agreement. For thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the settlement. EPA will consider all comments received and may modify or withdraw its consent to either or both settlements if comments received disclose facts or considerations that indicate that one or both of the proposed settlements is inappropriate, improper, or inadequate. EPA's response to any comments received will be available for public inspection at EPA Region II, 290 Broadway, New York, New York 10007–1866.

DATES: Comments must be submitted on or before December 14, 2015.

ADDRESSES: The proposed settlements are available for public inspection at EPA Region II offices at 290 Broadway, New York, New York 10007–1866. Comments should reference the Power City Superfund Site, Niagara Falls, Niagara County, New York, Index No. CERCLA–02–2015–2007 for the Honeywell International Inc. settlement agreement, and CERCLA–02–2015–2022 for the RR Donnelley and Sons Company settlement agreement. To request a copy of either or both proposed settlement agreements, please contact the EPA employee identified below.

FOR FURTHER INFORMATION CONTACT: Andrew Praschak, Assistant Regional Counsel, New York/Caribbean Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency, 290 Broadway—17th Floor, New York, New York 10007–1866. Email: *praschak.andrew@epa.gov* Telephone: 212–637–3172.

Dated: October 15, 2015.

Walter Mugdan,

Director, Emergency and Remedial Response Division, U.S. Environmental Protection Agency, Region 2.

[FR Doc. 2015–28837 Filed 11–12–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R08–OAR–2012–0479; FRL–9937–10-Region 8]

Proposed Information Collection Request; Comment Request; Federal Implementation Plan for Oil and Natural Gas Well Production Facilities; Fort Berthold Indian Reservation (Mandan, Hidatsa, and Arikara Nation), North Dakota

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), ''Federal Implementation Plan for Oil and Natural Gas Well Production Facilities; Fort Berthold Indian Reservation (Mandan, Hidatsa, and Arikara Nation), North Dakota'' (EPA ICR No. 2478.02 OMB Control No. 2008–0001) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA, 44 U.S.C. 3501 *et se.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through April 2016. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before January 12, 2016.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–R08–OAR–2012–0479 online using *www.regulations.gov* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Deirdre Rothery, U.S. Environmental Protection Agency, Region 8, Air Program, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, CO 80202–1129; telephone number: (303) 312–6431; fax number: (303) 312–6064; email address: *rothery.deirdre@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, CO 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding federal holidays. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) 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; (ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: This ICR covers information collection requirements in the final Federal Implementation Plan (FIP) for Oil and Natural Gas Well Production Facilities; Fort Berthold Indian Reservation (Mandan, Hidatsa, and Arikara Nation), North Dakota (40 CFR part 49, subpart K, §§ 49.4161 through 49.4168), herein referred to as the FBIR FIP. In general, owners or operators are required to: (1) Conduct certain monitoring; (2) keep specific records to be made available at the EPA's request; and (3) to prepare and submit an annual report (40 CFR part 49, subpart K, §§ 49.4166 through 49.4168). These records and reports are necessary for the EPA Administrator (or the tribal agency

if delegated), for example, to: (1) Confirm compliance status of stationary sources; (2) identify any stationary sources not subject to the requirements and identify stationary sources subject to the regulations; and (3) ensure that the stationary source control requirements are being achieved. All information submitted to us pursuant to the recordkeeping and reporting requirements for which a claim of confidentiality is made is safeguarded according to the agency policies set forth in 40 CFR part 2, subpart B.

Form Numbers: None.

Respondents/affected entities: Owners or operators of oil and natural gas facilities.

Respondent's obligation to respond: Mandatory (42 U.S.C. 7414).

Estimated number of respondents: 780 (total).

Frequency of response: On occasion, annually.

Total estimated burden: 29,655 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $6,503,000 (per year), includes $5,121,000 annualized capital or operation and maintenance costs.

Changes in Estimates: There is likely an increase in burden in this ICR compared with the ICR currently approved by OMB due to an anticipated adjustment in the estimated number of respondents to account for industry growth. In addition, there is likely an increase in cost in this ICR to take into account current labor rates.

Dated: November 3, 2015.

Darcy O'Connor,

Acting Assistant Regional Administrator, Office of Partnerships and Regulatory Assistance, Region 8.

[FR Doc. 2015–28836 Filed 11–12–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2015–0504; FRL–9936–40]

Certain New Chemicals; Receipt and Status Information for September 2015

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA) to publish in the **Federal Register** a notice of receipt of a premanufacture notice (PMN); an application for a test marketing exemption (TME), both pending and/or expired; and a periodic status report on any new chemicals under EPA review and the receipt of notices of commencement (NOC) to manufacture those chemicals. This document covers the period from September 1, 2015 to September 30, 2015.

DATES: Comments identified by the specific case number provided in this document, must be received on or before December 14, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2015–0504, and the specific PMN number or TME number for the chemical related to your comment, 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:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 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.html.*

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: *For technical information contact:* Jim Rahai, IMD 7407M, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8593; email address: *rahai.jim@epa.gov.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply. Although others may be affected, this action applies directly to the submitters of the actions addressed in this document.

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 preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. What action is the agency taking?

This document provides receipt and status reports, which cover the period from September 1, 2015 to September 30, 2015, and consists of the PMNs and TMEs both pending and/or expired, and the NOCs to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

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

Under TSCA, 15 U.S.C. 2601 *et seq.,* EPA classifies a chemical substance as either an ''existing'' chemical or a ''new'' chemical. Any chemical substance that is not on EPA's TSCA Inventory is classified as a ''new chemical,'' while those that are on the TSCA Inventory are classified as an ''existing chemical.'' For more information about the TSCA Inventory go to: *http://www.epa.gov/opptintr/newchems/pubs/inventory.htm.*

Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required by TSCA section 5 to provide EPA with a PMN, before initiating the activity. Section 5(h)(1) of TSCA authorizes EPA to allow persons, upon application, to manufacture (includes import) or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a), for ''test marketing'' purposes, which is referred to as a test marketing exemption, or TME. For more

information about the requirements applicable to a new chemical go to: *http://www.epa.gov/oppt/newchems.*

Under TSCA sections 5(d)(2) and 5(d)(3), EPA is required to publish in the **Federal Register** a notice of receipt of a PMN or an application for a TME and to publish in the **Federal Register** periodic reports on the status of new chemicals under review and the receipt of NOCs to manufacture those chemicals.

IV. Receipt and Status Reports

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that the information in the table is generic information because the specific information provided by the submitter was claimed as CBI.

For the 55 PMNs received by EPA during this period, Table 1 provides the following information (to the extent that such information is not claimed as CBI): The EPA case number assigned to the PMN; The date the PMN was received by EPA; the projected end date for EPA's review of the PMN; the submitting manufacturer/importer; the potential uses identified by the manufacturer/importer in the PMN; and the chemical identity.

TABLE 1—PMNS RECEIVED FROM SEPTEMBER 1, 2015 TO SEPTEMBER 30, 2015

Case No.	Date received	Projected end date for EPA review	Manufacturer/ importer	Use(s)	Chemical identity
P–15–0703	8/26/2015	11/24/2015	CBI	(G) Additive in toner	(G) Alkyl alkenoic acid, substituted alkyl ester, polymer with alkyl alkenoate and substituted alkyl alkenoate compd. with alkyl alkyl carbomonocyclic salt.
P–15–0713	9/1/2015	11/30/2015	CBI	(G) Contained use	(G) Cellulose, polymer with substituted oxirane, 2-(diethylamino) ethyl ether.
P–15–0714	9/1/2015	11/30/2015	Kemira	(G) Paper strength additive	(G) Modified polyacrylamide.
P–15–0715	9/3/2015	12/2/2015	CBI	(G) Additive for inks	(G) Oxirane, 2-ethyl-, homopolymer, 3-(5-carboxy-1,3-dihydro-,1,3-dioxo-2H-isoindol-2-yl) alkyl ethers.
P–15–0717	9/3/2015	12/2/2015	CBI	(G) Adhesive additive	(G) Triethoxysilylalkoxy polyalkylene glycol urethane.
P–15–0718	9/3/2015	12/2/2015	CBI	(G) Adhesive additive	(G) Triethoxysilylalkoxy polyalkylene glycol urethane.
P–15–0719	9/3/2015	12/2/2015	CBI	(G) Flame retardant synergist.	(S) Poly (1,4-diisopropyl benzene).
P–15–0720	9/4/2015	12/3/2015	CBI	(S) Polyurethane prepolymer.	(G) Aliphatic polyester polyol.
P–15–0721	9/4/2015	12/3/2015	CBI	(S) Polyurethane prepolymer.	(G) Aliphatic polyester polyol.
P–15–0722	9/4/2015	12/3/2015	CBI	(S) Polyurethane prepolymer.	(G) Aliphatic polyester polyol.
P–15–0723	9/4/2015	12/3/2015	CBI	(S) Polyurethane prepolymer.	(G) Aliphatic polyester polyol.
P–15–0724	9/4/2015	12/3/2015	CBI	(S) Polyurethane prepolymer.	(G) Aliphatic polyester polyol.
P–15–0725	9/4/2015	12/3/2015	CBI	(S) Polyurethane prepolymer.	(G) Aliphatic polyester polyol.
P–15–0726	9/4/2015	12/3/2015	CBI	(S) Co-polymer for use in adhesives and sealant formulations.	(G) Triethoxysilylalkoxy polyalkylene glycol.
P–15–0728	9/9/2015	12/8/2015	TAKASAGO	(S) Fragrance in household products.	(S) Benzenemethanol, 3-ethoxy-4-hydroxy-.
P–15–0728	9/9/2015	12/8/2015	TAKASAGO	(S) Fragrance in a fine fragrance.	(S) Benzenemethanol, 3-ethoxy-4-hydroxy-.
P–15–0728	9/9/2015	12/8/2015	TAKASAGO	(S) Fragrance in consumer products.	(S) Benzenemethanol, 3-ethoxy-4-hydroxy-.
P–15–0728	9/9/2015	12/8/2015	TAKASAGO	(S) Fragrance in other products.	(S) Benzenemethanol, 3-ethoxy-4-hydroxy-.
P–15–0730	9/10/2015	12/9/2015	CBI	(G) Additive for paper and paperboard.	(G) Amphoteric polyacrylamide.
P–15–0731	9/10/2015	12/9/2015	CBI	(G) Additive for paper and paperboard.	(G) Amphoteric polyacrylamide.
P–15–0733	9/10/2015	12/9/2015	Cadence Chemical Corporation.	(S) Coating for glass	(G) Alkane carboxylic acid, hydroxy, hydroxyalkyl-alkyl, polymer with .alpha.-hydro-.omega.-hydroxypoly(oxy-1,2-ethanediyl) ether with alkyl-(hydroxyalkyl)-alkanediol (X:1), .alpha.-hydro-.omega.-hydroxypoly[oxy(alkyl-alkyldiyl)] and alkylenebis [isocyanatoalkane],-blocked.
P–15–0734	9/11/2015	12/10/2015	CBI	(S) Wastewater Heavy Metals Removal.	(G) Polymeric Sulfide.

TABLE 1—PMNS RECEIVED FROM SEPTEMBER 1, 2015 TO SEPTEMBER 30, 2015—Continued

Case No.	Date received	Projected end date for EPA review	Manufacturer/ importer	Use(s)	Chemical identity
P–15–0735	9/15/2015	12/14/2015	Cray Valley USA, LLC.	(S) Adhesive Formulation	(S) Hydrocarbons, C5-rich, polymers with (6E)-7, 11-dimethyl-3-methylene-1,6,10-dodecatriene, 2-methylbutene and methylstyrene.
P–15–0735	9/15/2015	12/14/2015	Cray Valley USA, LLC.	(S) Rubber Formulation	(S) Hydrocarbons, C5-rich, polymers with (6E)-7, 11-dimethyl-3-methylene-1,6,10-dodecatriene, 2-methylbutene and methylstyrene.
P–15–0736	9/18/2015	12/17/2015	CBI	(S) Industrial coating resin for wood substances.	(G) Castor oil, polymer with substituted alkanoic acid, substituted carbomonocycle, dialkyl substituted alkanediol and TDI, substituted alkanone-blocked.
P–15–0737	9/16/2015	12/15/2015	CBI	(G) Intermediate	(G) Ammonium salts of phosphate methacrylate.
P–15–0738	9/17/2015	12/16/2015	CBI	(S) Injection molding additive to improve the physical properties of plastic parts.	(G) Polysiloxane-polycarbonate copolymer.
P–15–0739	9/17/2015	12/16/2015	CBI	(S) Component of Flexible Foam.	(G) Epoxy Terminated Polymer.
P–15–0740	9/17/2015	12/16/2015	Allnex USA, Inc	(S) Digital printing applications.	(G) Disubstituted alkanedioic acid, polymer with substituted carbomonocycle, dialkyl carbonate, alkanediol and (alkylimino) bis [alkanol], acetate (salt).
P–15–0741	9/17/2015	12/16/2015	CBI	(S) Mixture of modified urethane polymers used as a deflocculating and dispersing additive in industrial coatings.	(G) Mixture of Modified urethane polymers.
P–15–0742	9/17/2015	12/16/2015	CBI	(G) Component for tire	(G) Modified Copolymer of Buta-1,3-diene and Styrene.
P–15–0743	9/17/2015	12/16/2015	Eden Innovations	(G) The liquid solution is an admixture that is used by the concrete industry to enhance product performance. It is mainly used to increase the concrete's abrasion resistance, and increase the compressive and split tensile strengths; see internal comments.	(G) Nano particle liquid concrete admixture.
P–15–0744	9/18/2015	12/17/2015	3 M Company	(G) Construction material	(G) Naturally-occurring minerals, reaction products with boron sodium oxide (b4na2o7), hetero substituted alkyl acrylate polymer, kaolin and sodium silicate.
P–15–0745	9/18/2015	12/17/2015	3 M Company	(G) Construction material	(G) Naturally-occurring minerals, reaction products with boron sodium oxide (b4na2o7), hetero substituted alkyl acrylate polymer, kaolin and sodium silicate.
P–15–0746	9/18/2015	12/17/2015	3 M Company	(G) Construction material	(G) Naturally-occurring minerals, reaction products with boron sodium oxide (b4na2o7), hetero substituted alkyl acrylate polymer, kaolin and sodium silicate.
P–15–0747	9/18/2015	12/17/2015	3 M Company	(G) Construction material	(G) Naturally-occurring minerals, reaction products with boron sodium oxide (b4na2o7), hetero substituted alkyl acrylate polymer, kaolin and sodium silicate.
P–15–0748	9/18/2015	12/17/2015	3 M Company	(G) Construction material	(G) Naturally-occurring minerals, reaction products with hetero substituted alkyl acrylate polymer, kaolin and sodium silicate.

TABLE 1—PMNS RECEIVED FROM SEPTEMBER 1, 2015 TO SEPTEMBER 30, 2015—Continued

Case No.	Date received	Projected end date for EPA review	Manufacturer/ importer	Use(s)	Chemical identity
P–15–0749	9/18/2015	12/17/2015	3 M Company	(G) Construction material	(G) Naturally-occurring minerals, reaction products with hetero substituted alkyl acrylate polymer, kaolin and sodium silicate.
P–15–0750	9/18/2015	12/17/2015	3 M Company	(G) Construction material	(G) Naturally-occurring minerals, reaction products with hetero substituted alkyl acrylate polymer, kaolin and sodium silicate.
P–15–0751	9/18/2015	12/17/2015	3 M Company	(G) Construction material	(G) Naturally-occurring minerals, reaction products with hetero substituted alkyl acrylate polymer, kaolin and sodium silicate.
P–15–0752	9/22/2015	12/21/2015	CBI	(G) Additive, open, non-dispersive use.	(G) Polysiloxane, di-Me, epoxyfunctional.
P–15–0753	9/22/2015	12/21/2015	CBI	(G) Additive, open, non-dispersive use.	(G) Polyester amine adduct.
P–15–0754	9/22/2015	12/21/2015	CBI	(G) Additive, open, non-dispersive use.	(G) Polyester amine adduct.
P–15–0755	9/22/2015	12/21/2015	CBI	(G) Additive, open, non-dispersive use.	(G) Polyester amine adduct.
P–15–0759	9/24/2015	12/23/2015	CBI	(G) Polyurethane prepolymer for use in cast polyurethane elastomer parts: Open, non-dispersive use.	(G) Isocyanate-terminated urethane prepolymer.
P–15–0760	9/24/2015	12/23/2015	CBI	(G) Polyurethane prepolymer for use in cast polyurethane elastomer parts: Open, non-dispersive use.	(G) Isocyanate-terminated urethane prepolymer.
P–15–0761	9/24/2015	12/23/2015	CBI	(G) Polyurethane prepolymer for use in cast polyurethane elastomer parts: Open, non-dispersive use.	(G) Isocyanate-terminated polyester-based urethane prepolymer.
P–15–0762	9/24/2015	12/23/2015	CBI	(G) Polyurethane prepolymer for use in cast polyurethane elastomer parts: Open, non-dispersive use.	(G) Isocyanate-terminated polyester-based urethane prepolymer.
P–15–0763	9/24/2015	12/23/2015	CBI	(G) Polyurethane prepolymer for use in cast polyurethane elastomer parts: Open, non-dispersive use.	(G) Isocyanate-terminated polyester-based urethane prepolymer.
P–15–0764	9/24/2015	12/23/2015	CBI	(G) Polyurethane prepolymer for use in cast polyurethane elastomer parts: Open, non-dispersive use.	(G) Isocyanate-terminated polybutadiene-based urethane polymer.
P–15–0765	9/25/2015	12/24/2015	ANGUS Chemical Company.	(G) Chemical Absorbant	(G) Tertiary Amino Polyol.
P–15–0766	9/28/2015	12/27/2015	Reichhold	(S) Resin for flame retardant polyesters.	(G) Halogenated epoxy polymer with alkeneoic acid.
P–15–0767	9/29/2015	12/28/2015	Reichhold	(S) Resin used for flame retardant polyester applications.	(G) Halogenated bisphenol a, polymer with epoxy resin and phenolic epoxy, alkeneoic acids.
P–15–0768	9/29/2015	12/28/2015	Allnex USA, Inc	(S) Crosslinker in the construction of an in-site encapsulation product.	(G) Alkanedial, polymer with alkyleneurea and alkyl-alkanediol.
P–15–0769	9/30/2015	12/29/2015	LUNA, Inc	(S) Component of protective coating.	(G) Polyurethane Silane.

For the one TME received by EPA during this period, Table 2 provides the following information (to the extent that such information is not claimed as CBI): The EPA case number assigned to the TME, the date the TME was received by EPA, the projected end date for EPA's review of the TME, the submitting manufacturer/importer, the potential uses identified by the manufacturer/ importer in the TME, and the chemical identity.

TABLE 2—TME RECEIVED FROM SEPTEMBER 1, 2015 TO SEPTEMBER 30, 2015

Case No.	Date received	Projected end date for EPA review	Manufacturer/ importer	Use	Chemical identity
T–15–0017	9/21/2015	11/5/2015	NON–CBI	Resin for coating formulation.	(S) EHTM.

For the 25 NOCs received by EPA during this period, Table 3 provides the following information (to the extent that such information is not claimed as CBI): The EPA case number assigned to the NOC; the date the NOC was received by EPA; the projected date of commencement provided by the submitter in the NOC; and the chemical identity.

TABLE 3—NOCS RECEIVED FROM SEPTEMBER 1, 2015 TO SEPTEMBER 30, 2015

Case No.	Received date	Projected date of commencement	Chemical identity
J–15–0017	9/11/2015	8/14/2015	(G) Modified organism.
P–12–0078	9/15/2015	8/26/2015	(S) 1-Octanesulfonic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-, barium salt (2:1).
P–12–0437	9/3/2015	8/13/2015	(S) Quaternary ammonium compounds, bis (hydrogenated tallow alkyl) dimethyl, salts with tannins.
P–13–0246	9/9/2015	8/12/2015	(G) Cobalt based polymer with fatty acids, and polyol.
P–13–0309	9/24/2015	9/15/2015	(S) Alcohols, c9-11-branched, ethoxylated propoxylated.
P–14–0142	9/24/2015	9/22/2015	(G) Ethoxylated Resin.
P–14–0605	9/10/2015	9/10/2015	(G) Substituted cyclosiloxane.
P–14–0738	9/3/2015	8/31/2015	(G) Polyalkylene ether alkyl phosphate polyurethane prepolymer.
P–14–0809	9/29/2015	9/2/2015	(G) Depolymerized waste plastics.
P–15–0036	9/1/2015	8/28/2015	(S) 2-Pyridinecarboxylic acid, 4,5,6-trichloro-.
P–15–0152	9/24/2015	9/2/2015	(G) Urethane acrylate.
P–15–0308	9/14/2015	8/31/2015	(G) Dicarboxylic acid, cycloaliphatic anhydride polymer with alkyldiol, hydroxy-[(oxoalkyl)oxy]alkyl ester.
P–15–0311	9/18/2015	9/3/2015	(G) Triarylsulfonium salt with haloalkyl phosphate.
P–15–0364	9/23/2015	9/13/2015	(G) Reaction mixture of copper, [29h,31h-phthalocyaninato(2-)-.kappa.n29,.kappa.n30,.kappa.n31,.kappa.n32]-, (sp-4–1)- and metal, [substituted 29h,31h-phthalocyanine-.kappa.n29,.kappa.n30,.kappa.n31,lkappa.n32]-.
P–15–0365	9/2/2015	8/21/2015	(G) Alkyl alkenoic acid polymers with alkyl acrylate, alkyl methacrylate, polyether methacrylate alkyl ethers and substituted heteromonocycle, compds. with substituted alkyl alkanol.
P–15–0390	9/10/2015	9/3/2015	(G) Substituted carbopolycyclic dicarboxylic acid dialkyl ester, polymer with dialkyl carbopolycyclic ester, alkanediol and carbopolycyclic bis (substituted carbomonocycle).
P–15–0396	9/24/2015	9/4/2015	(G) Alkylmethacrylate, polymer with alkenylbenzene, branched alkylmethacrylate, hydroxyalkylmethacrylate and acrylic acid, t-butyl alkaneperoxoic acid ester-initiated.
P–15–0410	9/18/2015	8/18/2015	(S) 1,3-Butadiene, homopolymer, hydrogenated, 2-hydroxyethyl-terminated, bis[n-[4-[(4-isocyanatophenyl)methyl]phenyl]carbamates].
P–15–0411	9/7/2015	9/3/2015	(G) Fatty acid esters with polyols polyalkyl ethers.
P–15–0427	9/24/2015	8/9/2015	(G) Substituted alkylene carbomonocycle, homopolymer, substituted polyol and mono alkyl ether-blocked polyol.
P–15–0456	9/4/2015	8/21/2015	(G) Amine functional epoxy, organic acid salt.
P–15–0466	9/16/2015	9/11/2015	(G) Acrylic acid polymer.
P–15–0467	9/18/2015	9/14/2015	(S) 2-Oxepanone, polymer with 5-amino-1,3,3-trimethylcyclohexanemethanamine, 1,2-ethanediol and 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane.
P–15–0495	9/9/2015	8/30/2015	(G) Aromatic anhydride, polymer with alkane diol and alkane triol, 2-propenoate.
P–15–0497	9/9/2015	8/30/2015	(G) Bisphenol an epoxy polymer with aromatic anhydride, mixed caprolactone acrylate and hydroxyethyl acrylate esters.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: November 5, 2015.

Pamela Myrick,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2015–28842 Filed 11–12–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9023–9]

Environmental Impact Statements; Notice of Availability Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or http://www2.epa.gov/nepa

Weekly receipt of Environmental Impact Statements (EISs)
Filed 11/02/2015 Through 11/06/2015
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: *https://www.cdxnodengn.epa.gov/cdx-nepa-public/action/eis/search.*

EIS No. 20150312, Draft, FRA, 00, Northeast Corridor (NEC) FUTURE Program Tier 1, Comment Period Ends: 01/30/2016, Contact: Rebecca Reyes-Alicea 212–668–2282

EIS No. 20150313, Draft, NRC, MI, Generic—License Renewal of Nuclear Plants: Supplement 56 Regarding Fermi 2 Nuclear Power Plant, Comment Period Ends: 12/28/2015, Contact: Elaine M. Keegan 301–415–8517

EIS No. 20150314, Draft, NOAA, WA, Analyze Impacts of NOAA's National Marine Fisheries Service Proposed 4(d) Determination under Limit 6 for Five Early Winter Steelhead Hatchery Programs in Puget Sound, Comment Period Ends: 12/28/2015, Contact: Steve Leider 360–753–4650

EIS No. 20150315, Final, BLM, CA, Desert Renewable Energy Conservation Plan Proposed Land Use Plan Amendment, Review Period Ends: 12/14/2015, Contact: Vicki Campbell 916–978–4401

EIS No. 20150316, Final, DOE, OK, Plains and Eastern Clean Line Transmission Line Project, Review Period Ends: 12/14/2015, Contact: Dr. Jane Summerson 505–845–4091

EIS No. 20150317, Final, USACE, USFS, MN, NorthMet Mining Project and Land Exchange, Review Period Ends: 12/14/2015, Contact: Douglas Bruner 651–290–5378

The U.S. Department of Army's Corps of Engineers and the U.S. Department of Agriculture's Forest Service are joint lead agencies for the above project.

EIS No. 20150318, Final, USFS, ID, Salmon-Challis National Forest Invasive Plant Treatment, Review Period Ends: 01/04/2016, Contact: Jennifer Purvine 208–879–4162

Amended Notices:

EIS No. 20150278, Draft, USACE, GA, Update of the Water Control Manual for the Apalachicola-Chattahoochee-Flint River Basin in Alabama, Florida, and Georgia and Water Supply Storage Assessment, Comment Period Ends: 01/15/2016, Contact: Lewis C. Sumner 251–694–3857

Revision to FR Notice Published 10/09/2015; Extending Comment Period from 12/01/2015 to 01/15/2016

Dated: November 9, 2015.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2015–28890 Filed 11–12–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0634; FRL–9934–46]

Cancellation of Pesticides for Non-Payment of Year 2015 Registration Maintenance Fees; Summary of Orders Issued

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the payment of an annual maintenance fee is required to keep pesticide registrations in effect. The fee due last January 15, 2015, has gone unpaid for the 236 registrations identified in this document. If the fee is not paid, the EPA Administrator may cancel these registrations by order and without a hearing; orders to cancel these registrations have been issued.

FOR FURTHER INFORMATION CONTACT: Mick Yanchulis, Information Technology and Resources Management Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0237; email address: *yanchulis.michael@epa.gov.*

Product-specific status inquiries may be made by calling toll-free, 1–800–444–7255.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. Although this action may be of particular interest to persons who produce or use pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0634, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. 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 OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

Complete lists of registrations canceled for non-payment of the maintenance fee are also available for reference in the OPP Docket.

II. Background

Section 4(i)(5) of FIFRA (7 U.S.C. 136a–1(i)(5)) requires that all pesticide registrants pay an annual registration maintenance fee, due by January 15 of each year, to keep their registrations in effect. This requirement applies to all registrations granted under FIFRA section 3 (7 U.S.C. 136a) as well as those granted under FIFRA section 24(c) (7 U.S.C. 136v(c)) to meet special local needs. Registrations for which the fee is not paid are subject to cancellation by order and without a hearing.

Under FIFRA, the EPA Administrator may reduce or waive maintenance fees for minor agricultural use pesticides when it is determined that the fee would be likely to cause significant impact on the availability of the pesticide for the use.

In fiscal year 2015, maintenance fees were collected in one billing cycle. In late October of 2014, all holders of either FIFRA section 3 registrations or FIFRA section 24(c) registrations were sent lists of their active registrations, along with forms and instructions for responding. They were asked to identify which of their registrations they wished to maintain in effect, and to calculate

and remit the appropriate maintenance fees. Most responses were received by the statutory deadline of January 15. A notice of intent to cancel was sent in April of 2015 to companies who did not respond and to companies who responded, but paid for less than all of their registrations. Since mailing the notices of intent to cancel, EPA has maintained a toll-free inquiry number through which the questions of affected registrants have been answered.

In fiscal year 2015, the Agency has waived the fee for 286 minor agricultural use registrations at the request of the registrants. Maintenance fees have been paid for about 16,032 FIFRA section 3 registrations, or about 97% of the registrations on file in October 2014. Fees have been paid for about 1,912 FIFRA section 24(c) registrations, or about 86% of the total on file in October 2014. Cancellations for non-payment of the maintenance fee affect about 216 FIFRA section 3 registrations and about 20 FIFRA section 24(c) registrations.

The cancellation orders generally permit registrants to continue to sell and distribute existing stocks of the canceled products until January 15, 2016, 1 year after the date on which the fee was due. Existing stocks already in the hands of dealers or users, however, can generally be distributed, sold, or used legally until they are exhausted. Existing stocks are defined as those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation order.

The exceptions to these general rules are cases where more stringent restrictions on sale, distribution, or use of the products have already been imposed, through special reviews or other Agency actions. These general provisions for disposition of stocks should serve in most cases to cushion the impact of these cancellations while the market adjusts.

III. Listing of Registrations Canceled for Non-Payment

Table 1 of this unit lists all of the FIFRA section 24(c) registrations, and Table 2 of this unit lists all of the FIFRA section 3 registrations which were canceled for non-payment of the 2015 maintenance fee. These registrations have been canceled by order and without hearing. Cancellation orders were sent to affected registrants via certified mail in the past several days. The Agency is unlikely to rescind cancellation of any particular registration unless the cancellation resulted from Agency error.

TABLE 1—FIFRA SECTION 24(C) REGISTRATIONS CANCELLED FOR NON-PAYMENT OF 2015 MAINTENANCE FEE

SLN No.	Product name
AR–08–0012	Strada WG.
CA–76–0166	Ortho Malathion 25 Wettable.
CA–83–0007	Sevin Brand 80s Carbaryl Insecticide.
CA–98–0015	Affirm Fire Ant Insecticide.
ID–01–0015	Ro-Neet 6–E Selective Herbicide.
LA–08–0007	IR5878 WG.
MI–08–0004	Ro-Neet 6–E.
MO–08–0002	Strada WG.
NC–07–0004	8.5% Ethylene Oxide & Carbon Dioxide Sterilizing Gas.
NE–03–0004	Echo 720 Agricultural Fungicide.
NE–03–0005	Echo Zn Agricultural Fungicide.
NV–13–0002	Avitrol Double Strength Whole Corn.
OR–01–0022	Ro-Neet 6–E Selective Herbicide.
OR–01–0023	Ro-Neet 6–E Selective Herbicide.
TX–08–0007	Strada WG.
TX–08–0019	Paraquat SL Herbicide.
WA–01–0021	Ro-Neet 6–E Selective Herbicide.
WA–01–0023	Ro-Neet 6–E Selective Herbicide.
WA–02–0003	Ro-Neet 6–E Selective Herbicide.
WY–08–0006	Paraquat SL Herbicide.

TABLE 2—FIFRA SECTION 3 REGISTRATIONS CANCELLED FOR NON-PAYMENT OF 2015 MAINTENANCE FEE

Registration No.	Product name
000003–00013	Harris Deltamax Concentrate Insecticide.
000178–00017	Stera-Sheen Sanitizer.
000178–00018	Stera-Sheen Advantage.
000322–00001	Fort Dodge Gopher Bait.
000358–00165	Nott Mole-Nots.
000577–00571	Seaguard 1083 Ablative Antifouling Paint.
000814–00004	Force's Ro-Dex.
000875–00099	Diversey Wyandotte Liquid Bacteriostatic Softener F–501.
000875–00147	Fybrfluf G+.
000875–00189	HLC–18 Quaternary Germicidal Cleaner.
001020–00001	Oakite Sanitizer No. 1.
001022–00540	IPBC RTU.
001022–00551	Chapman DCD Copper Complex.
001022–00562	Chap-Fume.
001022–00564	Sta Brite C.
001022–00580	Tuffgard 404.
001022–00581	Tuffgard 5 RTU.
001130–00019	Weiman Disinfecting Wipes.
001672–00014	Austin's Pine Oil Cleaner.

TABLE 2—FIFRA SECTION 3 REGISTRATIONS CANCELLED FOR NON-PAYMENT OF 2015 MAINTENANCE FEE—Continued

Registration No.	Product name
003276–20002	Al-Clor 10.
003573–00046	Mild Abrasive Formula Comet Liquid Disinfectant Cleanser.
003573–00051	Comet Cleanser with Chlorinol.
003573–00062	Cleaning Magic II.
003573–00089	Snipe.
004313–00009	Pure Pine Oil Disinfectant.
005741–00006	PD–64 Phenolic Base Cleaner & Disinfectant.
006186–00051	Ster-O-Kem No. 15.
007152–00005	Algi-Sea.
007152–00021	Seaboard Granular Stabilized Chlorine.
007152–00032	Algi-Cide.
007152–00065	Super Algi-Sea.
007152–00087	Day Tabs.
007152–00089	Slo-Tab Technical Trichloro-S-Triazinetrone.
008177–00072	Natural Wood Preservative.
008177–00073	Enterprise Clear Wood Preservative.
008281–00005	Hormex Rooting Powder No. 45.
008383–00011	Sporicidin Pro AD.
008622–00012	98–2.
008622–00013	67–33 Preplant Soil Fumigant.
008622–00015	75–25 Preplant Soil Fumigant.
008622–00039	50–50 Preplant Soil Fumigant.
008730–00065	Hercon Disrupt Micro-Flake CM.
008730–00074	Hercon Disrupt Bio-Flake CM.
008730–00079	Hercon Disrupt Bio-Dispenser BB.
008730–00080	Hercon Disrupt Bio-Dispenser DFB.
008848–00086	Black Jack Roach & Ant Killer VI.
008996–00009	Sulfur Dioxide.
009009–00016	So White Brand Ultra Bleach and Disinfectant.
009198–00231	The Andersons GC Fertilizer Bait Granules Plus 0.058% Bifenthrin.
009468–00033	Kull 41 S.
009468–00034	Kull 62 MUP.
009468–00035	Kull Tgai Glyphosate.
009768–00007	T-Chlor.
010707–00051	X-Cide 508 Industrial Microbicide.
011631–00004	Antimicrobial Alphasan RC 7000.
011631–00005	Antimicrobial Alphasan CW 12.
011694–00034	Do-It All.
011930–00005	Omego Mist Wet.
011930–00011	Pyrifos Poultry House Mist.
013283–00009	Rainbow Weed Killer.
013283–00017	Rainbow Ko Fire Ant Killer.
015297–00007	Bio-Groom Flea & Tick-14 Long Lasting Residual Spray with Lanolin.

TABLE 2—FIFRA SECTION 3 REGISTRATIONS CANCELLED FOR NON-PAYMENT OF 2015 MAINTENANCE FEE—Continued

Registration No.	Product name
015297–00017	Bio-Groom Flea & Tick Pyrethrin Spray.
017545–00012	R.D. 20.
019369–00002	Algaecide 30 Concentrate-L.
033906–00016	Pyridaben Technical Product.
033906–00022	Pyridaben K.
033981–00012	Sodium Hypochlorite MP 12.5%.
035138–00090	Aero General Use Insecticide.
035253–00005	BCS-Copper Fungicide.
035512–00037	Turf Pride Fertilizer + 0.67% Preemergent Weed Control.
035512–00056	Turf Pride Lawn Food with Trimec Herbicide.
035512–00061	Turf Pride Fertilizer + 1.0% Preemergent Weed Control.
036638–00036	Nomate CM Fiber.
041209–00004	Chlorine Liquified Gas.
041209–20002	Sodium Hypochlorite Solution 10% EUP.
041428–20001	Scott Chlor.
041504–20002	Borchlor 10.
042519–00034	Prosoy PPT.
043813–00013	Wocosen Technical.
043813–00027	Econea Technical.
043813–00041	Wocosen 150 EC.
043813–00042	Wocosen 15 TK.
043813–00043	Wocosen 450.
043813–00044	Wocosen 45 TK.
044446–00073	Beat-It Insect Repellent Pump Spray.
046597–00002	Q-San.
051934–00014	Cidetrak CMDA 115/30.
051934–00015	Cidetrak CMDA 185/60.
052374–00016	Chlorine.
054614–00007	Spa-Chlor.
054614–00008	Lithchlor.
054614–00009	Mini Pucks.
056212–00001	DMX–7 Mold Inhibitor.
058007–00011	Ultrathon Insect Repellent Pump 8.
058616–00005	PCT 3023.
063823–00064	Game Stop.
063838–00011	Enviro-Brom 20l.
065615–00007	Scoot Deer & Rabbit Repellent.
066171–00010	Iodis.
069061–00001	Davis Pyrethrins.
069061–00002	Sivad Davis Dip and Spray.
069361–00035	Triclo 4 Specialty Herbicide.
069361–00036	Imida 2C Insecticide.
069361–00043	Permethrin Technical.
069361–00045	Permethrin AG.
069361–00046	Repar Permethrin H&G.
069361–00047	Deltamethrin Technical.
069836–00001	Ecosharp Weed & Grass Killer.
069836–00002	Ecosharp Weed & Grass Killer Ready To Use.
070627–00011	Johnson End-Bac Liquid Disinfectant.
070627–00012	Johnson End Bac Pressurized Disinfectant Spray.
070627–00013	Johnson Envy Instant Cleaner for Washrooms.
070627–00014	Johnson Crew Bathroom Power Cleanser.
070627–00016	Johnson J–80 Sanitizer.
070627–00019	Johnson J–81 Hospital Cleaner-Germicidal.
070627–00020	Johnson Wax Liquid Envy Instant Cleaner Germicidal.
070627–00022	Virex II Ready To Use (RTU).
070627–00025	Liquid Vanish Disinfectant Toilet Bowl Cleaner.
070627–00029	Surfacide/6.
070627–00031	Absolute.
070627–00032	Johnson Envy II Instant Cleaner.
070627–00036	Easy Paks 4-Shot Disinfectant Cleaner.
070627–00048	Crew 10.
070627–00049	Crew 11.
070627–00050	Crew 12.
070950–00003	Avachem Sorbitol Octanoate (90%).
071532–00004	LG Permethrin 3.2 HG.
072112–00011	Provair PGR.
072138–00004	Xtra-Pine Cleans Disinfects* Deodorizes.
072500–00021	Mouse Hook.
072679–00005	Copper Paint No.1 Red.
072693–00004	Acephate 90 WDG.
072693–00011	Chlorpyrifos 4E.
072992–00016	Flora Patch.
074320–00001	RB–90 Jumbo Tab.
074320–00003	RB–56 Chlor.
074779–00013	Xytect 2F.
075108–00001	Red Scale Down.
075499–00003	Plant Synergists, Inc. GA3 4% Liquid Plant Growth Regulator Solution.
080203–00002	Go-Away Fabric Treatment/ <Article>.
080286–00015	Splat CLM.
081117–00001	Ro-Pel Tree Squirrel, Vole, Dog, and Cat Repellent.
081390–00001	Provisiongard 23207 Rub Resistant Carton Top Coat.
082771–00001	King Pine Brand Disinfectant.
082932–00001	All-Clear.
083070–00002	Tee-1 Up WDG Fungicide.
083411–00002	Clean Field 88.8 WDG.
083451–00010	Aquate.
083518–00002	SDIC–G Dihydrate Granules.
083525–00003	Wegochlor 60.
083529–00020	Sharda Glyphosate 41 SL.
084009–00006	Malathion-5 Emulsifiable Concentrate.
084009–00007	Diamond Copper Sulphate (Bluestone).
084009–00008	Trifluralin 4EC Herbicide.
084009–00010	Atrazine 4L Herbicide.
084009–00011	Atrazine 90 Herbicide.
084009–00014	Mepiquat Chloride 4.2.
084009–00015	Bifenthrin 2EC.
084009–00016	Ethephon 6.0.
084009–00017	UCPA Simazine 4L.
084009–00018	UCPA Simazine 90DF.
084009–00019	Lambda CY 1EC.
084009–00020	Abamectin 0.15 EC.
084009–00021	Acetochlor ATZ.
084009–00022	Paraquat 3.0.
084009–00023	Tebucon 3.6F.
084009–00024	Fomesafen 2.0.
084009–00025	Propiconazole 41.8.
084214–00001	AG3+ Fiber 17%.
084214–00003	AG3+ Fiber 13%.
084542–00004	Anti-Dustmite Fibers and Fabrics.
084622–00001	Microlite.
084993–00001	Capsicum Oleoresin 300,000 SHU.
085678–00030	Iprodione 41.6SC.
085724–00004	Rimon 100EC Insecticide.
085738–00001	pH 12.6.
086004–00002	Glyphosate 2% Ready-To-Use.
086153–00003	Enclosure 4 Flowable Fungicide and Nematicide.
086313–00001	Grotek Elimaweed Weed and Grass Killer.
086374–00001	Ecopel All-Family Protection Insect Repellent Spray.
086461–00003	2,4-D Amine Manufacturing Concentrate.
086461–00004	2,4-D Ester Manufacturing Concentrate.
086461–00005	Bifenthrin 2EC.
086461–00007	2,4-D Acid Technical.
086461–00013	Bifenthrin Technical.
086834–00001	Gly-Force 1.
087203–00001	AMS Biguanide 20.
087273–00001	Pro Chlor Granules.
087290–00009	Pronamide 50W WSB Herbicide.
087290–00027	Willowood Bromacil 80DF.
087290–00028	Willowood Diuron 80DF.
087290–00029	Willowood Diuron 4SC.
087290–00031	Willowood Diuron/Bromacil 80DF.
087373–00003	Thiophanate Methyl 70W.
087373–00008	Iprodione/Thiophanate Methyl Combo.
087373–00009	Thiophanate Methyl 85EG.
087886–00001	Primeclo2.
088452–00001	Juicy Roots.
088498–00001	Willowood Bromacil Technical.
088529–00001	Willowood Diuron Technical.
088602–00001	Prodigy Fipronil Technical.
088633–00001	Copper Sulfate Pentahydrate Technical.
088633–00002	Delcup L.
088710–00001	Abluere Disinfectant Spray.
088779–00001	CU Fusion Csp.
088801–00001	Ceresus IM.
088911–00001	Liquid Copper Sulfate.
088966–00002	Vetguard for Dogs.
089530–00001	Sani-Du.
089550–00001	Tip-Top Cl02.
089711–00001	Zap'em All Purpose Insect Spray.

TABLE 2—FIFRA SECTION 3 REGISTRATIONS CANCELLED FOR NON-PAYMENT OF 2015 MAINTENANCE FEE—Continued

Registration No.	Product name
089816–00004	Mebrom 67–33.
089816–00005	Mebrom 75–25.
089816–00006	Mebrom 50–50.
089816–00007	Mebrom 80–20.

IV. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks until January 15, 2016, 1 year after the date on which the fee was due.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation order. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold, or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product. Exception to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in a special review action, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 27, 2015.

Jack E. Housenger,

Director, Office of Pesticide Programs.

[FR Doc. 2015–28855 Filed 11–12–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL 9936–93–OA]

Meetings of the Small Community Advisory Subcommittee and the Local Government Advisory Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Announcement of meetings.

SUMMARY: The Small Community Advisory Subcommittee (SCAS) will meet via teleconference on Wednesday, December 9, 2015, 11 a.m. to 12 p.m. (EDT). The Subcommittee will discuss small community issues related to environmental issues which effect small communities. These issues include: Municipal Separate Storm Sewer Systems (MS4s) remand issue, decentralized wastewater treatment, capacity building and other environmental issues effecting small, rural and disadvantaged communities. This is an open meeting. Individuals or organizations wishing to address the Subcommittee meeting will be allowed a maximum of five minutes to present their point of view on issues pertaining to small communities.

The Local Government Advisory Committee (LGAC) will meet via teleconference on Wednesday, December 9, 2015, 12:30 p.m. to 1:45 p.m. (EDT). The Committee meeting will focus on reviewing recommendations of the LGAC's subcommittee and workgroups. These issues include: MS4 remand issue, toxic algal blooms and other water issues, including decentralized wastewater treatment, pharmaceutical proposed rule, waste generator proposed rule, brownfields, capacity building and sustainability, Animas River toxic spill issues, and Plan EJ 2020.

These are open meetings, and all interested persons are invited to participate. The Subcommittee will hear comments from the public between 11:15 a.m. and 11:25 a.m. on Wednesday, December 9, 2015, and the Committee will hear comments from the public between 1:00 p.m. and 1:15 p.m. on Wednesday, December 9, 2015. Individuals or organizations wishing to address the Subcommittee or the Committee will be allowed a maximum of five minutes to present their point of view. Also, written comments should be submitted electronically to *eargle.frances@epa.gov.* Please contact the Designated Federal Officer (DFO) at the number listed below to schedule a time on the agenda. Time will be allotted on a first-come first-serve basis, and the total period for comments may be extended if the number of requests for appearances requires it.

ADDRESSES: The Small Communities Advisory Subcommittee and Local Government Advisory Committee meetings will meet via teleconference. Meeting summaries will be available after the meeting online at *www.epa.gov/ocir/scas_lgac/lgac_index.htm* and can be obtained by written request to the DFO.

FOR FURTHER INFORMATION CONTACT: Local Government Advisory Committee (LGAC) and Small Communities Advisory Subcommittee (SCAS), contact Frances Eargle, Designated Federal Officer, at (202) 564–3115 or email at *eargle.frances@epa.gov.*

Information on Services for those with Disabilities: For information on access or services for individuals with disabilities, please contact Frances Eargle at (202) 564–3115 or email at *eargle.frances@epa.gov.* To request accommodation of a disability, please request it 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: October 27, 2015.

Frances Eargle,

Designated Federal Officer, Local Government Advisory Committee.

[FR Doc. 2015–28765 Filed 11–12–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–xxxx]

Information Collection Being Reviewed by the Federal Communications Commission

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 Communications 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 PRA comments should be submitted on or before January 12, 2016. 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 contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: *OMB Control No.:* 3060–xxxx.

Title: Media Bureau Incentive Auction Implementation, Sections 73.3700(b)(4)(i)–(ii), (c), (d), (h)(5)–(6) and (g)(4).

Form No.: N/A.

Type of Review: New information collection.

Respondents: Business or other for-profit entities; Not for profit institutions.

Number of Respondents and Responses: 1,950 respondents and 174,219 responses.

Estimated Time per Response: .004–15 hours.

Frequency of Response: One-time reporting requirement; on occasion reporting requirement; recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for these collections are contained in 47 U.S.C. 151, 154, 301, 303, 307, 308, 309, 310, 316, 319, 325(b), 332, 336(f), 338, 339, 340, 399b, 403, 534, 535, 1404, 1452, and 1454.

Total Annual Burden: 24,932 hours.

Annual Cost Burden: $1,214,400.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection.

Needs and Uses: The collection is being made to the Office of Management (OMB) for the approval of information collection requirements contained in the Commission's Incentive Auction Order, FCC 14–50, which adopted rules for holding an Incentive Auction, as required by the Middle Class Tax Relief and Job Creation Act of 2012 (Spectrum Act). The information gathered in this collection will be used to require broadcasters transitioning to a new station following the Incentive Auction, or going off the air as a result of a winning bid in the Incentive Auction, to notify their viewers of the date the station will terminate operations on its pre-Auction channel by running public service announcements, and allow these broadcasters to inform MVPDs of their relinquishment or change in channel. It requires channel sharing agreements enter into by television broadcast licensees to contain certain provisions regarding access to facilities, financial obligations and to define each party's rights and responsibilities; the Commission will review each channel sharing agreement to ensure it comports with general rules and policies regarding license agreements. The provisions contained in this collection also require wireless licensees to notify low-power television and TV translator stations commence wireless operations and the likelihood of receiving harmful interference from the low power TV or TV translator station to such operations within the wireless licensee's licensed geographic service area. Finally, it requires license relinquishment stations and channel sharing stations to comply with notification and cancellation procedures as they terminate operations on their pre-Auction channel.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2015–28776 Filed 11–12–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0844]

Information Collection Being Reviewed by the Federal Communications Commission

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 Communications 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 PRA comments should be submitted on or before January 12, 2016. 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 contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0844.

Title: Carriage of the Transmissions of Television Broadcast Stations: Section 76.56(a), Carriage of qualified noncommercial educational stations; Section 76.57, Channel positioning; Section 76.61(a)(1)–(2), Disputes concerning carriage; Section 76.64, Retransmission consent.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 835 respondents and 14,040 responses.

Estimated Time per Response: 1 to 5 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in Sections 1, 4(i) and (j), 325, 336, 614 and 615 of the Communications Act of 1934, as amended.

Total Annual Burden: 14,840 hours.

Total Annual Cost: No cost.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: Under Section 614 of the Communications Act and the implementing rules adopted by the Commission, commercial TV broadcast stations are entitled to assert mandatory carriage rights on cable systems located within the station's television market. Under Section 325(b) of the Communications Act, commercial TV broadcast stations are entitled to negotiate with local cable systems for carriage of their signal pursuant to retransmission consent agreements in lieu of asserting must carry rights. This system is therefore referred to as ''Must-Carry and Retransmission Consent.'' Under Section 615 of the Communications Act, noncommercial educational (NCE) stations are also entitled to assert mandatory carriage rights on cable systems located within the station's market; however, noncommercial TV broadcast stations are not entitled to retransmission consent. The information collection requirements for this collection are contained in 47 CFR Sections 76.56(a), 76.57, 76.61(a)(1)–(2) and 76.64.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2015–28777 Filed 11–12–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE AND TIME: Tuesday, November 17, 2015 at 10:00 a.m. and Thursday, November 19, 2015 at 1:30 p.m.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This Meeting Will Be Closed to the Public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 52 U.S.C. 30109.

Internal personnel rules and internal rules and practices.

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

Matters concerning participation in civil actions or proceeding, or arbitration.

* * * * *

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shelley E. Garr,

Deputy Secretary.

[FR Doc. 2015–29173 Filed 11–10–15; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: November 17, 2015; 10:00 a.m.

PLACE: 800 N. Capitol Street NW., First Floor Hearing Room, Washington, DC.

STATUS: The first portion of the meeting will be held in Open Session; the second in Closed Session.

MATTERS TO BE CONSIDERED:

Open Session

1. Briefing on the Danish Maritime Forum.

Closed Session

1. Briefing on FMC-Transpacific Stabilization Agreement Semi-Annual Meeting.
2. Ocean Common Carrier and Marine Terminal Operator Agreements Subject to the 1984 Shipping Act—Regulatory Review.

CONTACT PERSON FOR MORE INFORMATION: Karen V. Gregory, Secretary, (202) 523–5725.

Karen V. Gregory,

Secretary.

[FR Doc. 2015–29161 Filed 11–10–15; 4:15 pm]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

[Docket No. OP–1521]

Supervisory Rating System for Financial Market Infrastructures

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice and request for comment.

SUMMARY: Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act'') granted the Board of Governors of the Federal Reserve System (''Board'') enhanced authority to supervise ''financial market utilities'' that are designated as systemically important by the Financial Stability Oversight Council (financial market utilities are defined to comprise a subset of the entities that, outside the United States, are generally called ''financial market infrastructures'' or ''FMIs''). In addition, the Board may have direct supervisory authority over other FMIs subject to its jurisdiction. The Board and, under delegated authority, the Federal Reserve Banks (collectively, the ''Federal Reserve'') propose to use the ORSOM (*O*rganization; *R*isk Management; *S*ettlement; *O*perational Risk and Information Technology (IT); and *M*arket Support, Access, and Transparency) rating system in reviews of FMIs. The Board is seeking comment on this system for rating FMIs. The Federal Reserve anticipates implementing the ORSOM rating system in 2016.

DATES: Comments must be received by January 22, 2016.

ADDRESSES: When submitting comments, please consider submitting your comments by email or fax because paper mail in the Washington, DC area and at the Board may be subject to delay. You may submit comments, identified by Docket No. OP–1521, by any of the following methods:

- *Agency Web site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include docket number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Robert deV. Frierson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 3515, 1801 K Street NW. (between 18th and 19th Street NW.), Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays

FOR FURTHER INFORMATION CONTACT: Stuart Sperry, Deputy Associate Director (202) 452–2832 or Kristopher Natoli, Sr. Financial Services Analyst (202) 452–3227, Division of Reserve Bank Operations and Payment Systems; Evan H. Winerman, Counsel (202) 872–7578, Legal Division; for users of

Telecommunications Device for the Deaf (TDD) only, contact (202) 263–4869.

SUPPLEMENTARY INFORMATION:

Background

FMIs are multilateral systems that transfer, clear, settle, or record payments, securities, derivatives, or other financial transactions among participants or between participants and the FMI operator. FMIs include payment systems, central securities depositories (''CSDs''), securities settlement systems (''SSSs''), central counterparties (''CCPs''), and trade repositories (''TRs''). FMIs can strengthen the markets that they serve and play a critical role in fostering financial stability. If not properly managed, however, they can pose significant risks to the financial system and be a potential source of contagion, particularly in periods of market stress. For example, improperly managed FMIs can be sources of financial shocks or channels through which shocks are transmitted across domestic and international financial markets.

The Federal Reserve supervises certain FMIs that provide payment, clearing, and settlement services for critical U.S. financial markets. Specifically, under Title VIII of the Dodd-Frank Act, the Federal Reserve is the ''Supervisory Agency'' for certain ''designated financial market utilities'' (''DFMUs'').[1] These DFMUs are subject to risk-management standards set out in Regulation HH.[2] In addition, the Federal Reserve may have supervisory authority over FMIs that are operated by state member banks, Edge or agreement corporations, or bank holding companies. Furthermore, the Board supervises FMIs that are operated by the Federal Reserve Banks, such as the Fedwire Funds Service.[3] These latter two categories of FMIs are expected to meet the risk-management standards set out in the Board's Payment System Risk (''PSR'') policy.[4] The risk management standards set out in both Regulation HH and the PSR policy are based on the Principles for Financial Market Infrastructures (''PFMI'').[5]

The ORSOM (*O*rganization; *R*isk Management; *S*ettlement; *O*perational Risk and IT; and *M*arket Support, Access, and Transparency) rating system is a supervisory tool that the Federal Reserve will use to provide a consistent internal framework for discussing FMI assessments across the Federal Reserve's FMI portfolio. The ORSOM rating system will be applied to DFMUs for which the Board is the Supervisory Agency pursuant to Title VIII, other DFMUs over which the Board has supervisory authority because they are members of the Federal Reserve System, and FMIs that are operated by a Federal Reserve Bank.[6] The Federal Reserve will convey the annual rating to a DFMU's management and board of directors. The rating system is designed to link supervisory assessments and messages to the regulations and guidance that form the foundation of the supervisory program, such as Regulation HH and the PSR policy.

The Federal Reserve is requesting public comment on all aspects of the FMI rating system.

Proposed Text of the Supervisory Rating System for FMIs

Introduction

Under the ORSOM rating system for FMIs, the Federal Reserve develops a rating for each of the ORSOM categories and rolls those category ratings into an overall composite rating. The rating system is designed to (1) be clearly tied to relevant Federal Reserve regulations and guidance, (2) facilitate a clear and logical discussion of the FMI's condition with the FMI's management and board of directors, (3) be easily understood and used by both supervisors and FMIs, (4) be flexible, (5) facilitate comprehensive and consistent assessments across the Federal Reserve's FMI portfolio, and (6) promote financial stability by ensuring that systemically important FMIs understand and are held to the Federal Reserve's rigorous risk-management standards. Importantly, the rating system is designed to allow for supervisory judgment and discretion, and should not be viewed as establishing a formula for determining an FMI's rating. Each of the assigned ratings, including the composite rating, should reflect supervisory judgment about the importance of the individual categories and issues as they pertain to the FMI. Relevant provisions of Regulation HH and the PSR policy, which are reflected in each rating category, help to organize and structure ratings for each category. The criticality of categories and issues, however, may differ among FMIs because of factors such as their differing services, risk profiles, and operational and organizational structures. An FMI's rating should also take into account the FMI's responsiveness to supervisory concerns and the sustainability of any measures that the FMI has implemented to address those concerns, both in terms of long-term viability and demonstrated effectiveness.

Categories

The ORSOM rating system consists of the following five categories, which were selected to highlight broadly the risk management issues that FMIs face, to guide supervisory examinations, and to provide a structure for organizing assessment letters:

- Organization
- Risk Management
- Settlement
- Operational Risk and IT
- Market Support, Access, and Transparency

Analysis of the issues considered under each category should be consistent with Regulation HH, the PSR policy, and relevant guidance, such as supervision and regulation (SR) letters and guidance of the Federal Financial Institutions Examination Council (FFIEC). The categories' order is not a reflection of their relative importance. The weight prescribed to either a category or a category's components is a matter of supervisory judgment and expertise, and may differ among FMIs. In addition, supervisory staff's assessment of an FMI should take into account the categories' interrelationships and the FMI's entire

[1] The term ''financial market utility'' (''FMU'') is defined in Title VIII as ''any person that manages or operates a multilateral system for the purpose of transferring, clearing, or settling payments, securities, or other financial transactions among financial institutions or between financial institutions and the person'' (12 U.S.C. 5462(6)). FMUs are a subset of FMIs; for example, trade repositories are excluded from the definition of a FMU. Pursuant to section 804 of the Dodd-Frank Act, the Financial Stability Oversight Council (''Council'') is required to designate those FMUs that the Council determines are, or are likely to become, systemically important. Such a designation by the Council makes an FMU subject to the supervisory framework set out in Title VIII of the Dodd-Frank Act.

The term ''Supervisory Agency'' is defined in Title VIII as the ''Federal agency that has primary jurisdiction over a designated financial market utility under Federal banking, securities, or commodity futures laws'' (12 U.S.C. 5462(8)). Currently, the Board is the Supervisory Agency for two DFMUs: (i) The Clearing House Payments Company, L.L.C., on the basis of its role as operator of the Clearing House Interbank Payments System (CHIPS), and (ii) CLS Bank International (CLS).

[2] 12 CFR 234.3 (2014).

[3] *See* Sections 11(a)(1) and 11(j) of the Federal Reserve Act, 12 U.S.C. 248(a)(1) and 248(j).

[4] The Board's PSR policy is available at *http://www.federalreserve.gov/paymentsystems/files/psr_policy.pdf.*

[5] The PFMI, published by the Committee on Payment and Settlement Systems (now the Committee on Payments and Market Infrastructures) and the Technical Committee of the International Organization of Securities Commissions in April 2012, is widely recognized as the most relevant set of international risk-management standards for payment, clearing, and settlement systems.

[6] At present, the first group includes CLS and CHIPS, the second group includes the Depository Trust Company, and the third group includes Fedwire Funds Service and Fedwire Securities Service.

risk management framework, and should integrate knowledge derived from all available sources, including examination work, continuous monitoring efforts, and other relevant sources (for example, the Regulation HH advance notice process for designated financial market utilities (''DFMUs'') and lessons learned from market events). Finally, an FMI's category rating should reflect consideration of the sustainability of any remediation measures that the FMI has implemented to address supervisory concerns, both in terms of the measures' demonstrated effectiveness and long-term viability.

Organization

The foundations of an FMI's risk management framework are its management and governance structures, which include the board of directors' and management's authority, responsibilities, and reporting. The Organization category evaluates the FMI's overarching objectives, and the ability of the FMI's board and management to implement them. This category also considers the relationships among the FMI's stakeholders and their influence on the FMI's business strategy. Further, analysis under this category considers the independence and effectiveness of the FMI's internal audit function and its ability to inform the board and management about the robustness of the FMI's risk management and control processes. As a result, the Organization category contains two subcomponents, Board and Management Oversight, and Internal Audit. The FMI's assessment under these subcomponents is reflected in a single category rating.[7]

Board and Management Oversight

The Board and Management Oversight subcomponent addresses the organization and conduct of the FMI's board of directors and senior management. It assesses the structure and effectiveness of the FMI's legal and compliance risk monitoring and management framework. This rating evaluates how effectively the board of directors and senior management guide and manage the FMI, and ensure that the FMI operates in a safe and sound manner; specific considerations in this regard include management's responsiveness to supervisory concerns. This rating component also evaluates the board's effectiveness at establishing the FMI's objectives, strategy, and risk tolerances, and management's effectiveness at ensuring that the FMI's activities are consistent with them. Specific considerations in this regard include the board's effectiveness in setting strategic objectives, developing a risk-management framework, creating clear and responsive corporate governance structures, and establishing corporate risk tolerances. This rating also evaluates the effectiveness of the FMI's governance program for risk models and its use of independent validation mechanisms to validate the FMI's model methodologies and output.

Relevant statutes, regulations and guidance include—

- Regulation HH § 234.3(a)(1)–(3) (excluding (a)(2)(iv)(I))
- Regulations implementing the Bank Secrecy Act (BSA)[8]
- PSR policy: Legal Basis (PFMI 1), Governance (PFMI 2, excluding references to internal audit), Framework for Comprehensive Management of Risks (PFMI 3, excluding references to internal audit)

Internal Audit

The Internal Audit subcomponent reflects the ability and independence of the FMI's internal audit function to assess risk and to inform the board and management. An FMI should have an effective internal audit function with sufficient resources and independence from management to provide a rigorous and unbiased assessment of the FMI's risk appetite and risk exposure, including financial and operational risk, as well as the effectiveness of risk management and controls. The Internal Audit subcomponent assesses the internal audit function's day-to-day management, including its annual risk assessment, audit program, quality of work papers, quality assurance, planning and reporting, and training.[9]

Relevant regulations and guidance include—

- Regulation HH § 234.3(a)(2)(iv)(I)
- Audit guidance (for example, Institute of Internal Auditors, FFIEC, SR Letters, Bank for International Settlements, and ISACA)
- PSR policy: Governance (PFMI 2, as it pertains to internal audit), Framework for Comprehensive Management of Risks (PFMI 3, as it pertains to internal audit), Operational Risk (PFMI 17, as it pertains to internal audit)

Risk Management

The Risk Management category evaluates the effectiveness of the FMI's risk management, including the availability to the FMI of acceptable financial resources to contain and manage losses and liquidity pressures, and the FMI's ability to meet its obligations in the event of a participant's default. Further, the rating assesses the FMI's ability to implement a recovery or orderly wind-down of its operations and the viability of its capital plan. The rating also considers the FMI's ability and practices in safeguarding its own assets and those of its participants, and the FMI's ability to ensure those assets are accessible at all times with minimum losses. In addition, the Risk Management rating assesses the FMI's awareness of, and control over, the risk that its participants' customers and other FMIs indirectly introduce.

Relevant regulations and guidance include—

- Regulation HH § 234.3(a)(4)–(7), (14)–(16), (19)–(20)
- PSR policy: Credit risk (PFMI 4), Collateral (PFMI 5), Margin (PFMI 6), Liquidity risk (PFMI 7), Segregation and Portability (PFMI 14), General Business Risk (PFMI 15), Custody and Investment Risks (PFMI 16), Tiered Participation Arrangements (PFMI 19), and FMI Links (PFMI 20)

Settlement

Final settlement is the irrevocable and unconditional transfer of an asset or financial instrument, or the discharge of an obligation by an FMI or its participants in accordance with the underlying contract's terms. Settlement risk, which is the risk that settlement will not take place as expected, is a key risk that FMIs and their participants face. Failure to settle a transaction on time and in full can create liquidity and credit problems for an FMI or its participants, with potential systemic implications. This is especially true during a participant default event. Well-designed, clearly articulated, and effectively disclosed default management rules are imperative to maintaining market confidence in the event of a participant default.

[7] The *Board and Management Oversight* and the *Internal Audit* subcomponents are not individually rated; they represent matters examiners should consider when assigning the *Organization* category rating. Depending on the issues at the FMI, examiners should use their judgment in weighting each of these subcomponents in their assessment of the *Organization* category overall.

[8] The BSA is codified at 31 U.S.C. 5311 *et seq.*, 12 U.S.C. 1829b, and 12 U.S.C. 1951–1959. Federal Reserve supervised institutions that are subject to the BSA include state member banks (Regulation H, 12 CFR part 208), bank holding companies (Regulation Y, 12 CFR part 225), Edge and agreement corporations, and foreign banking organizations operating in the United States (Regulation K, 12 CFR part 211). The U.S. Department of the Treasury's Financial Crimes Enforcement Network has published regulations implementing the BSA at 31 CFR chapter X.

[9] The Internal Audit subcomponent does not assess the board's effectiveness at establishing and overseeing an internal audit function at the FMI; that is assessed in the *Board and Management Oversight* subcomponent.

The Settlement category focuses on the risk-management tools that an FMI uses to ensure settlement takes place as expected, and the default management procedures the FMI follows in the event of a participant default. The rating assesses the FMI's ability to ensure settlement finality, and its ability to manage the risks related to money settlements and the delivery of physical assets. The rating also includes CSDs' abilities to safeguard the rights of securities issuers and holders, and to ensure the integrity of the securities issues that they hold in custody. Finally, this category includes assessing the adequacy of the FMI's participant default rules and procedures, and the steps that the FMI takes to ensure that it is prepared to execute them.

Relevant regulations and guidance include—

- Regulation HH § 234.3(a)(8)–(13)
- PSR Policy: Settlement Finality (PFMI 8), Money Settlements (PFMI 9), Physical Deliveries (PFMI 10), Central Securities Depositories (PFMI 11), Exchange-of-Value Settlement Systems (PFMI 12), and Participant Default Rules and Procedures (PFMI 13)

Operational Risk and IT

FMIs face significant operational and IT risks in their provision of post-trade services. Operational risk entails deficiencies in information systems, internal processes, and personnel, or disruptions from external events that may result in the reduction, deterioration, or breakdown of services provided by an FMI. FMIs are expected to ensure that, through the development of appropriate systems, controls, and procedures, their operations and IT infrastructure are reliable, secure, and have adequately scalable capacity. FMIs' information security practices and controls are expected to be strong and effective. FMIs should protect and secure the systems, media, and facilities that process and maintain information vital to their operations in the context of a continually changing threat landscape. Further, FMIs are expected to have robust business continuity plans that allow for the rapid recovery and timely resumption of critical operations. FMIs are expected to test and update these plans regularly.

The Operational Risk and IT category focuses on the FMI's operational reliability and its ability to support the safe and continuous functioning of the markets that it serves. This category considers the FMI's operational risk management framework and IT infrastructure, including the adequacy of the FMI's operational risk management governance, internal controls, physical and information security, data management, capacity management, interdependency monitoring programs, and business continuity plan.

Relevant regulations and guidance include—

- Regulation HH § 234.3(a)(17)
- PSR Policy: Operational Risk (PFMI 17, excluding references to internal audit)
- Interagency Paper on Sound Practices to Strengthen Resilience of the U.S. Financial System
- FFIEC and relevant industry guidance

Market Support, Access, and Transparency

FMIs should be designed and operated to meet the needs of their participants and the markets that they serve. Access to FMIs' services is often necessary for meaningful participation in the markets that they serve, and FMIs' efficiency and effectiveness can influence financial activity and market structure. Also, access to, and understanding of, relevant information about an FMI fosters confidence among participants and the public.

The Market Support, Access, and Transparency category focuses on the FMI's efforts to support the markets they serve, to ensure fair and open access to, and use of, its services, and to provide participants with the information necessary to understand the risks and responsibilities attendant with their participation in the FMI. Analysis under this category should consider, among other things, an FMI's participation requirements; its member monitoring framework; the efficiency with which it consumes resources in providing its services; and the adequacy of its disclosure of its rules, procedures, and relevant information about its operations.

Relevant regulations and guidance include—

- Regulation HH § 234.3(a)(18), (21)–(23)
- PSR policy: Access and Participation Requirements (PFMI 18), Efficiency and Effectiveness (PFMI 21), Communication Procedures and Standards (PFMI 22), Disclosure of Rules, Key Procedures, and Market Data (PFMI 23), Disclosure of Market Data by Trade Repositories (PFMI 24)

Category Ratings

FMIs receive a rating for each ORSOM category based on an evaluation of the FMI against that category's key attributes as described herein. Regulation HH prescribes risk-management standards for DFMUs for which the Board or another federal banking agency is the Supervisory Agency under Title VIII of the Dodd-Frank Act. Other FMIs subject to Federal Reserve supervision—for example, FMIs that are members of the Federal Reserve System—are subject to the Federal Reserve Act and the expectations set out in the Federal Reserve's PSR policy. An FMI's rating should be consistent with the expectations set forth in Regulation HH, the PSR policy, and supervisory guidance, such as SR letters and FFIEC guidance.[10] The rating scale ranges from 1 to 5, with a rating of 1 indicating the strongest performance and, therefore, the level of least supervisory concern. A rating of 5 indicates the most critically deficient level of performance and, therefore, the greatest level of supervisory concern. Importantly, an FMI's category rating should reflect supervisory judgment and expertise as to the materiality of any issues identified based on the resulting effect those issues have on the safety and soundness of the FMI, the growth of systemic risks, or the stability of the broader financial system.[11]

A common set of definitions for each rating level is applied across all of the ORSOM categories. These general definitions focus on broad supervisory interests, which are—

- The extent to which any issues identified, either individually or cumulatively, are issues of concern for the safety and soundness of the FMI, the growth of systemic risks, or the stability of the broader financial system.
- the immediacy with which the FMI is expected to remedy the issues, and the extent to which close supervisory monitoring of the FMI's remediation efforts, or supervisory action,[12] is needed.

Supervisors may identify multiple issues with differing degrees of concern. In such cases, supervisors typically

[10] In any event where Regulation HH's provisions establish standards different from those articulated in supervisory guidance, designated FMUs subject to the jurisdiction of the Federal Reserve under Title VIII of the Dodd-Frank Act should adhere to, and will be assessed against, Regulation HH's provisions.

[11] *See* Dodd-Frank Act Section 805, 12 U.S.C. 5464(b).

[12] FMIs are responsible for remedying supervisory concerns. ''Supervisory action'' in this context refers to the range of supervisory measures that relevant laws authorize the Federal Reserve to take. These include issuing a Matter Requiring Attention (MRA) or Matter Requiring Immediate Attention (MRIA); entering into a Memorandum of Understanding (MOU) with the FMI; or more severe enforcement action measures as authorized under Title VIII of the Dodd-Frank Act or other relevant laws.

should assign the category a rating that reflects their judgment of the severity of the most serious concerns identified. For example, if a payment system meets the majority of supervisory standards for the Settlement category, but only partly observes the risk management standard pertaining to settlement finality, then, because of that issue's criticality to a payment system, the payment system's rating for the Settlement category should reflect its weaknesses with regard to that key risk management standard.

1: Strong

- Any issues identified, either individually or cumulatively, are not issues of concern with respect to the category's supervisory guidance. For example, the FMI observes all of the key risk management standards in Regulation HH or the PSR policy, as applicable.[13]
- The FMI can correct any issues identified in the normal course of business and dedicated supervisory monitoring of the FMI's remediation efforts is not needed.

2: Satisfactory

- Any issues identified, either individually or cumulatively, are not presently issues of concern with respect to the category's supervisory guidance, but may become so if left uncorrected. For example, the FMI either observes or broadly observes the key risk management standards in Regulation HH or the PSR policy, as applicable.
- The FMI can correct any issues identified in the normal course of business, but limited, dedicated supervisory monitoring of the FMI's remediation efforts may be needed.

3: Fair

- One or more issues identified, either individually or cumulatively, are issues of concern with respect to the category's supervisory guidance. For example, the FMI, at a minimum, broadly observes most of the key risk management standards in Regulation HH or the PSR policy, as applicable, but may partly observe some of them.
- The FMI should correct one or more of the issues identified within a defined period, dedicated supervisory monitoring of the FMI's remediation efforts is likely needed, and supervisory action may be needed.

4: Marginal

- One or more issues identified, either individually or cumulatively, are substantial issues of concern with respect to the category's supervisory guidance. For example, the FMI only partly observes many key risk management standards in Regulation HH or the PSR policy, as applicable, and may not observe some of them.
- The FMI should correct one or more of the issues identified immediately, dedicated supervisory monitoring of the FMI's remediation efforts is needed, and supervisory action is likely.

5: Unsatisfactory

- One or more issues identified, either individually or cumulatively, are critical and immediate issues of concern with respect to the category's supervisory guidance. For example, the FMI does not observe key risk management standards in Regulation HH or the PSR policy, as applicable.
- The FMI must correct one or more of the issues identified immediately, and immediate supervisory action and monitoring of the FMI's remediation efforts are needed.

Composite Ratings

An FMI's composite rating indicates whether and to what extent the issues identified, in the aggregate, give cause for supervisory concern. Like the category ratings, an FMI's composite rating ranges from 1 to 5. A rating of 1 indicates the strongest performance and, therefore, the level of least supervisory concern, and a rating of 5 indicates a critically deficient level of performance and, therefore, the greatest level of supervisory concern. Importantly, an FMI's composite rating should not represent a formulaic combination of its category ratings, such as an arithmetic average. Rather, the ratings definitions provide factors that supervisory staff should consider when viewing an FMI's performance against the totality of supervisory guidance.

1: Strong

- As reflected in its category ratings, an FMI with a composite rating of 1 is substantially sound in every respect and does not give cause for supervisory concern.
- Any issues identified do not reflect a pattern of risk management or governance failures and, either individually or cumulatively, are not issues of concern for the safety and efficiency of either the FMI or the markets that it supports.
- The FMI can correct any issues identified in the normal course of business and dedicated supervisory monitoring of the FMI's remediation efforts is not needed.

2: Satisfactory

- As reflected in its category ratings, an FMI with a composite rating of 2 is sound in most respects and does not presently give cause for supervisory concern.
- Any issues identified do not reflect a pattern of risk management or governance failures and, either individually or cumulatively, are not presently issues of concern for the safety and efficiency of either the FMI or the markets that it supports, but may become so if left uncorrected.
- The FMI can correct any issues identified in the normal course of business, but limited, dedicated supervisory monitoring of the FMI's remediation efforts may be needed.

3: Fair

- As reflected in its category ratings, an FMI with a composite rating of 3 is sound in many respects, but gives cause for some supervisory concern, and supervisory action may be necessary.
- Any issues identified, either individually or cumulatively, are issues of concern for the safety and efficiency of either the FMI or the markets that it supports.
- The FMI should correct one or more of the issues of concern identified within a defined period and dedicated monitoring of the FMI's remediation efforts is likely needed.

4: Marginal

- As reflected in its category ratings, an FMI with a composite rating of 4 may be unsound in one or more respects and gives cause for substantial supervisory concern, which will likely lead to supervisory action.
- Any issues identified, either individually or cumulatively, are substantial issues of concern for the safety and efficiency of either the FMI or the markets that it supports.
- The FMI should correct one or more of the issues of concern identified immediately and dedicated supervisory monitoring of the FMI's remediation efforts is needed.

5: Unsatisfactory

- As reflected in its category ratings, an FMI with a composite rating of 5 is considered critically unsound and gives

[13] The applicable standards are based on the Federal Reserve's source of authority. DFMUs for which the Federal Reserve acts as the Supervisory Agency under Title VIII of the Dodd-Frank Act are subject to Regulation HH. Other FMIs subject to Federal Reserve supervision, for example, by virtue of being members of the Federal Reserve System, are subject to the Federal Reserve Act and the expectations set out in the Federal Reserve's PSR policy. The applicable standards in both Regulation HH and the PSR policy are based on the PFMI. The Board has stated that it does not intend for differences in language in the two documents to lead to inconsistent policy results.

cause for substantial and immediate supervisory concern and action.

- Any issues identified, either individually or cumulatively, are critical and immediate issues of concern for the safety and efficiency of either the FMI or the markets that it supports.
- The FMI must correct one or more of the issues of concern identified immediately, and immediate supervisory action and monitoring of the FMI's remediation efforts are needed.

Administrative Law Matters

Regulatory Flexibility Act Analysis

Congress enacted the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) to address concerns related to the effects of agency rules on small entities, and the Board is sensitive to the impact its rules may impose on small entities. The RFA requires agencies either to provide an initial regulatory flexibility analysis with a proposed rule or to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. The Board has reviewed the proposed text of the ORSOM rating system. In this case, the rating system would apply to FMUs that are designated by the Council under Title VIII of the Dodd-Frank Act as systemically important, for which the Board is the Supervisory Agency, and which are subject to Regulation HH. In addition, the supervisory rating system for FMIs will apply to other FMIs over which the Board has supervisory authority, including FMIs operated by the Federal Reserve Banks, pursuant to the PSR policy. Based on current information, none of the designated FMIs are ''small entities'' for purposes of the RFA, and so, the proposed rating system likely would not have a significant economic impact on a substantial number of small entities (5 U.S.C. 605(b)). The following Initial Regulatory Flexibility Analysis, however, has been prepared in accordance with 5 U.S.C. 603, based on current information. The Board will, if necessary, conduct a final regulatory flexibility analysis after consideration of comments received during the public comment period. The Board requests public comments on all aspects of this analysis.

1. *Statement of the need for, objectives of, and legal basis for, the proposed rule. The* Board is proposing the ORSOM rating system in order to carry out its supervisory responsibilities regarding FMIs under Title VIII of the Dodd-Frank Act and other applicable law, as discussed above. As noted above, the ORSOM rating system is a supervisory tool that the Federal Reserve will use to provide a consistent internal framework for discussing FMI assessments across the Federal Reserve's FMI portfolio, including DFMUs for which the Board is the Supervisory Agency pursuant to Title VIII, other DFMUs that are members of the Federal Reserve System, and FMIs that are operated by a Federal Reserve Bank. The Federal Reserve will convey the annual ORSOM rating to a DFMU's management and board of directors. The rating system is designed to link supervisory assessments and messages to the regulations and guidance that form the foundation of the supervisory program, such as Regulation HH and the PSR policy.

2. *Small entities affected by the proposed rule.* Pursuant to regulations issued by the Small Business Administration (SBA) (13 CFR 121.201), a ''small entity'' includes an establishment engaged in (i) financial transaction processing, reserve and liquidity services, and/or clearinghouse services with an average annual revenue of $35.5 million or less (NAICS code 522320); (ii) securities and/or commodity exchange activities with an average annual revenue of $35.5 million or less (NAICS code 523210); and (iii) trust, fiduciary, and/or custody activities with an average annual revenue of $35.5 million or less (NAICS code 523991). Based on current information, the Board does not believe that any of the FMIs that would be subject to the ORSOM rating system would be ''small entities'' pursuant to the SBA regulation.

3. *Projected reporting, recordkeeping, and other compliance requirements.* The proposed ORSOM rating system does not impose any reporting or recordkeeping requirements on the relevant FMIs. Although the rating system reflects risk management standards set out in Regulation HH, the PSR policy, and other applicable rules and guidance, the ORSOM rating system itself does not impose any compliance requirements.

4. *Identification of duplicative, overlapping, or conflicting Federal rules.* The Board does not believe that any Federal rules duplicate, overlap with, or conflict with the proposed rating system.

5. *Significant alternatives.* The Board is not aware of any significant alternatives to the proposed rating system that accomplish the objectives of reflecting the relevant risk management standards in the supervisory rating system and that minimize any significant economic impact on small entities.

Competitive Impact Analysis

As a matter of policy, the Board subjects all operational and legal changes that could have a substantial effect on payment system participants to a competitive impact analysis, even if competitive effects are not apparent on the face of the proposal. Pursuant to this policy, the Board assesses whether the proposed changes ''would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services'' and whether any such adverse effect ''was due to legal differences or due to a dominant market position deriving from such legal differences.'' If, as a result of this analysis, the Board identifies an adverse effect on the ability to compete, the Board then assesses whether the associated benefits—such as improvements to payment system efficiency or integrity—can be achieved while minimizing the adverse effect on competition.

Designated FMUs are subject to the supervisory framework established under Title VIII of the Dodd-Frank Act. At least one currently designated FMU that is subject to Regulation HH competes with a similar service provided by the Reserve Banks. Under the Federal Reserve Act, the Board has general supervisory authority over the Reserve Banks, including the Reserve Banks' provision of payment and settlement services (''Federal Reserve priced services''). This general supervisory authority is much more extensive in scope than the authority provided under Title VIII over designated FMUs. In practice, Board oversight of the Reserve Banks goes well beyond the typical supervisory framework for private-sector entities, including the framework provided by Title VIII.

The Board is committed to applying risk-management standards to the Reserve Banks' Fedwire Funds Service and Fedwire Securities Service that are at least as stringent as the applicable Regulation HH standards applied to DFMUs that provide similar services. The risk management and transparency expectations in part I of the PSR policy, which applies to the Federal Reserve priced services, are consistent with those in Regulation HH. The proposed ORSOM rating system will be applied equally to both designated FMUs subject to Regulation HH and to the other FMIs subject to the Board's authority, including the Federal Reserve priced services, subject to the PSR policy. Therefore, the Board does not believe the proposed rating system will have

any direct and material adverse effect on the ability of other service providers to compete with the Reserve Banks.

Paperwork Reduction Act Analysis

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR part 1320, appendix A.1), the Board may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a valid Office of Management and Budget (OMB) control number. The Board has reviewed this rating system proposal and determined that it contains no collections of information. As the Board considers the public comments received and finalizes the proposal, the Board will reevaluate this PRA determination.

By order of the Board of Governors of the Federal Reserve System, November 9, 2015.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2015–28821 Filed 11–12–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0073; Docket 2015–0055; Sequence 29]

Information Collection; Advance Payments

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

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning advance payments.

DATES: Submit comments on or before January 12, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000–0073 Advance Payments by any of the following methods:

- Regulations.gov: *http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0073, Advance Payments''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0073, Advance Payments'' on your attached document.

- Mail: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0073, Advance Payments.

Instructions: Please submit comments only and cite Information Collection 9000–0073, Advance Payments, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Kathy Hopkins, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA 202–969–7226 or email *kathlyn.hopkins@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Advance payments may be authorized under Federal contracts and subcontracts. Advance payments are the least preferred method of contract financing and require special determinations by the agency head or designee. Specific financial information about the contractor is required before determinations by the agency head or designee can be made, and before such payments can be authorized (see FAR 32.4 and 52.232–12). The information is used to determine if advance payments should be provided to the contractor.

B. Annual Reporting Burden

Respondents: 500.
Responses per Respondent: 1.
Annual Responses: 500.
Hours per Response: 6.
Total Burden Hours: 3,000.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies Of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0073, Advance Payments, in all correspondence.

Edward Loeb,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2015–28803 Filed 11–12–15; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0053; Docket 2015–0055; Sequence 25]

Information Collection; Permits, Authorities, or Franchises

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

ACTION: Notice of request for public comments regarding an extension of a previously existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning permits, authorities, or franchises for regulated transportation.

DATES: Submit comments on or before January 12, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000–0053, Permits, Authorities, or Franchises, by any of the following methods:

• *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0053, Permits, Authorities, or Franchises''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0053, Permits, Authorities, or Franchises'' on your attached document.

• Mail: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0053, Permits, Authorities, or Franchises.

Instructions: Please submit comments only and cite ''Information Collection 9000–0053, Permits, Authorities, or Franchises,'' in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA 202–208–4949 or email *michaelo.jackson@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The FAR requires insertion of clause 52.247–2, Permits, Authorities, or Franchises, when regulated transportation is involved. The clause requires the contractor to indicate whether it has the proper authorization from the Federal Highway Administration (or other cognizant regulatory body) to move material. The contractor may be required to provide copies of the authorization before moving material under the contract. The clause also requires the contractor, at its expense, to obtain and maintain any permits, franchises, licenses, and other authorities issued by State and local governments. The Government may request to review the documents to ensure that the contractor has complied with all regulatory requirements.

B. Annual Reporting Burden

Respondents: 255.
Responses per Respondent: 1.
Annual Responses: 255.
Hours per Response: 0.5.
Total Burden Hours: 128.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405 telephone 202–501–4755.

Please cite OMB Control No. 9000–0053, Permits, Authorities, or Franchises, in all correspondence.

Edward Loeb,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2015–28802 Filed 11–12–15; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9093–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July through September 2015

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

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July through September 2015, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the **Federal Register**	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410)786-7548
IV Medicare National Coverage Determinations	Wanda Belle	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	Mitch Bryman	(410) 786-5258
VII Medicare –Approved Carotid Stent Facilities	Lori Ashby	(410) 786-6322
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Marie Casey, BSN, MPH	(410) 786-7861
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Marie Casey, BSN, MPH	(410) 786-7861
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Marie Casey, BSN, MPH	(410) 786-7861
XIV Medicare-Approved Bariatric Surgery Facilities	Jamie Hermansen	(410) 786-2064
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
All Other Information	Annette Brewer	(410) 786-6580

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS Web site or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the Web site list provides more timely access for beneficiaries, providers, and suppliers. We also believe the Web site offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and ''real time'' accessibility. In addition, many of the Web sites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the Web site. These listservs avoid the need to check the Web site, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a Web site proves to be difficult, the contact person listed can provide information.

III. How to Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at *http://www.cms.gov/manuals.*

Dated: November 6, 2015.

Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120–01–P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: November 14, 2014 (79 FR 68253), February 2, 2015 (80 FR 5537), April 24, 2015 (80 FR 23013) and August 3, 2015 (80 FR 45980). For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (July through September 2015)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: http://cms.gov/manuals.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - October 2015 Update, use Medicare Claims Processing (CMS-Pub. 100-04)Transmittal No. 3304.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
	Medicare General Information (CMS-Pub. 100-01)
93	Internet Only Manual (IOM) Publication 100-01 - General Information, Eligibility, and Entitlement, Chapter 7 - Contract Administrative Requirements, Section 40 – Shared System Maintainer Responsibilities for Systems Releases Shared System Maintainer and Part A/Part B (A/B)/Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) and the Shared System Maintainer and Part A/Part B (A/B)/Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) and the Single Testing Contractor (STC) Responsibilities for Systems Releases Standardized Terminology for Claims Processing Systems Standard Terminology Chart Release Software Implementing Validated Workarounds for Shared System Claims Processing by All Medicare DME MACs Next Generation Desktop (NGD) Requirements

	Shared System Testing Requirements for Shared System Maintainers Single Testing Contractor (STC), and DME MACs Minimum Testing Standards for Shared System Maintainers and the Single Testing Contractor (STC)/Beta Testers Testing Standards Applicable to all Beta Testers Part A/Part B (A/B) Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) (User) Testing Requirements Testing Requirements Applicable to all CWF Data Centers (Hosts) Timeframe Requirements for all Testing Entities Testing Documentation Requirements Definitions Test Case Specification Standard Shared System Testing Requirements for Shared System Maintainers, Single Testing Contractor (STC)/Beta Testers, and Part A/Part B (A/B) Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs)
Medicare Benefit Policy (CMS-Pub. 100-02)	
210	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
Medicare National Coverage Determination (CMS-Pub. 100-03)	
183	National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test
184	Update to Pub. 100-03, National Coverage Determination Manual, Chapter 1, Part 1, Section 50.1 Speech Generating Device
185	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
Medicare Claims Processing (CMS-Pub. 100-04)	
3288	Medicare Internet Only Manual Publication 100-04 Chapter 22 Remittance Advice Background Remittance Balancing Electronic Remittance Advice - ERA or ASC X12 835 ASC X12 835 Medicare Standard Electronic PC-Print Software for Institutional Providers Medicare Remit Easy Print Software for Professional Providers and Suppliers Standard Paper Remittance Advice Claim Adjustment Reason Codes Remittance Advice Remark Codes Requests for Additional Codes The Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) Mandated Operating Rules Health Care Claim Payment/Advice (835) Infrastructure Rule Uniform Use of CARCs and RARCs Rule EFT Enrollment Data Rule ERA Enrollment Form
3289	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2016

3290	October 2015 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
3291	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2015
3292	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2015 Update Average Sales Price (ASP) Payment Methodology
3293	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3294	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3295	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3296	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3297	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3298	Remittance Advice Remark and Claims Adjustment Reason Code and Medicare Remit Easy Print and PC Print Update
3299	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3300	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3301	Claims Processing Instructions for Diagnostic Digital Breast Tomosynthesis Digital Breast Tomosynthesis Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages
3302	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3303	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3304	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - October 2015 Update
3305	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3306	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3307	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3308	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) – October 2015
3309	Applying Therapy Caps to Maryland Hospitals Determining Payment Amounts – Institutional Claims Application of Financial Limitations Exceptions to Therapy Caps – General Exceptions Process Use of the KX Modifier for Therapy Cap Exceptions Therapy Cap Manual Review Threshold

	Identifying the Certifying Physician MSN Messages Regarding the Therapy Cap Part B Outpatient Rehabilitation and Comprehensive Outpatient Rehabilitation Facility (CORF) Services – General
3310	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3311	End Stage Renal Disease (ESRD) Home Dialysis Policy Guidelines for Physician or Practitioner Billing -- (Per Diem)
3312	None
3313	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3314	Procedure for Medicare Contractors to Perform and Record Outlier Reconciliation Adjustments
3315	New and Revised Place of Service Codes (POS) for Outpatient Hospital Part B Medicare Administrative Contractor (MAC) Instructions for Place of Service (POS) Codes Selection of Level of Evaluation and Management Service Payment for Office or Other Outpatient Evaluation and Management (E/M) Visits (Codes 99201 - 99215) Place of Service (POS) Instructions for the Professional Component (PC or Interpretation) and the Technical Component (TC) of Diagnostic Tests Professional Billing Requirements Items 14-33 - Provider of Service or Supplier Information Place of Service Codes (POS) and Definitions Site of Service Payment Differential
3316	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3317	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October CY 2015 Update
3318	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3319	National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test
3320	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3321	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3322	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3323	October Quarterly Update for 2015 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule
3324	Clarification of the Policy for Competitively-Bid Wheelchair Accessories Furnished with Non-Competitively Bid Wheelchair Base Equipment Exception for Wheelchair Accessories Furnished with Non-Competitively Bid Wheelchair Base Equipment
3325	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3326	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3327	New Waived Tests
3328	October 2015 Integrated Outpatient Code Editor (I/OCE) Specifications Version 16.3
3329	Update to Pub. 100-04, Chapter 18 to Provide Language-Only Changes for Updating ICD-10, the 02/12 version of the Form CMS-1500, and ASC X12 Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes Roster Claims Submitted to A/B MACs (B) for Mass Immunization Centralized Billing for Influenza Virus and Pneumococcal Vaccines to Medicare A/B MACs (B) Claims Submitted to A/B MACs (A) for Mass Immunizations of Influenza Virus and Pneumococcal Vaccinations HCPCS and Diagnosis Codes for Mammography Services Billing Requirements – A/B MAC (B) Claims Remittance Advice Messages Pap Smears On and After July 1, 2001 HCPCS Codes for Billing Diagnoses Codes Remittance Advice Codes Screening Pelvic Examinations on and After July 1, 2001 Diagnoses Codes Revenue Code and HCPCS Codes for Billing Remittance Advice Codes Diagnosis Coding Remittance Advice Notices Payment Determining High Risk for Developing Colorectal Cancer Billing Requirements for Claims Submitted to A/B MACs Remittance Advice Notices Claims Submission Requirements and Applicable HCPCS Codes HCPCS and Diagnosis Coding Remittance Advice Notices A/B Medicare Administrative Contractor (MAC) (B) and Contractor Billing Requirements A/B MAC (B) Billing Requirements Modifier Requirements for Pre-diabetes A/B MAC (A) Billing Requirements Modifier Requirements for Pre-diabetes Diagnosis Code Reporting Medicare Summary Notices A/B MAC (B) Billing Requirements A/B MAC (A) Billing Requirements Diagnosis Code Reporting Medicare Summary Notice Billing Requirements Diagnosis Code Reporting Medicare Summary Notice (MSN) and Claim Adjustment Reason Codes (CARCs) Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claims Adjustment Reason Codes (CARCs), and Advance Beneficiary Notices (ABNs) Healthcare Common Procedure Coding System (HCPCS) and Diagnosis

	Coding Common Working File (CWF) Edits Diagnosis Code Reporting Billing Requirements Policy Professional Billing Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claims Adjustment Reason Codes (CARCs), and Group Codes
3330	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3331	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2016
3332	Update-Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Fiscal Year (FY) 2016 Annual Update
3333	October 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3334	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3335	Implement Operating Rules - Phase III ERA EFT: CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC) and Remittance Advice Remark Codes (RARC) Rule - Update from CAQH CORE
3336	Healthcare Provider Taxonomy Codes (HPTCs) October 2015 Code Set Update
3337	Instructions for Downloading the Medicare ZIP Code File for January 2016
3338	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3339	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3340	Annual Clotting Factor Furnishing Fee Update 2016
3341	Influenza Vaccine Payment Allowances - Annual Update for 2015-2016 Season
3342	Common Edits and Enhancements Modules (CEM) Code Set Update
3343	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3344	Claim Status Category and Claim Status Codes Update
3345	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and Hospice Pricer for FY 2016
3346	Removing References to Network Service Vendors from Chapter 24 of the Medicare Claims Processing Manual, Pub. 100-04
3347	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3348	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3349	2016 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Update
3350	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3351	Additional Fields Added to the Outlier Reconciliation Lump Sum Utility
3352	October 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3353	Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 22.0, Effective January 1, 2016
3354	January 2016 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
3355	Annual Medicare Physician Fee Schedule (MPFS) Files Delivery and Implementation Maintenance and Update of the Temporary Hook Created to Hold OPPS Claims that Include Certain Drug HCPCS Codes
3356	Maintenance and Update of the Temporary Hook Created to Hold OPPS Claims that Include Certain Drug HCPCS Codes
3357	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3358	Claims Processing Medicare Secondary Payer (MSP) Policy and Procedures Regarding Ongoing Responsibility for Medicals (ORM)
3359	October 2015 Integrated Outpatient Code Editor (I/OCE) Specifications Version 16.3
3360	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3361	October 2015 Update of the Ambulatory Surgical Center (ASC) Payment System
3362	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3363	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3364	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October CY 2015 Update
3365	2016 Healthcare Common Procedure Coding System (HCPCS) Annual Update Reminder
3366	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2016
Medicare Secondary Payer (CMS-Pub. 100-05)	
113	Instructions for the Shared Systems and Medicare Administrative Contractors (MACs) to follow when a Medicare Residual Payment must be Paid on Workers' Compensation Medicare Set-aside Arrangement (WCMSA) or for Ongoing Responsibility of Medicals (ORM) Non-Group Health Plan (NGHP) Medicare TOC Secondary Payer (MSP) Claims. MSP "W' Record and Accompanying Processes Medicare Residual Payments Due When On-going Responsibility for Medicals (ORM) Benefits Terminate, or Deplete, During a Beneficiary's Provider Facility Stay or Upon a Physician, or Supplier, Visit. Workers' Compensation (WC)
114	Claims Processing Medicare Secondary Payer (MSP) Policy and Procedures Regarding Ongoing Responsibility for Medicals (ORM)

	MSP Utilization Edits and Resolutions for Claims Submitted to CWF Identification of Liability and No-Fault Situations Identify Claims with Possible WC Coverage Identification of On-Going Responsibility for Medicals (ORM) in Liability, No-Fault, and Workers' Compensation Situations Background Regarding ORM for Contractors Policy Regarding ORM Operationalizing ORM for Liability, No-Fault, and Workers' Compensation Situations MSP Auxiliary File Errors Sources That May Identify Other Insurance Coverage
Medicare Financial Management (CMS-Pub. 100-06)	
251	Notice of New Interest Rate for Medicare Overpayments and Underpayments –4th Qtr. Notification for FY 2015
252	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
253	Update the Contractor Reporting of Operational and Workload Data (CROWD) CMS-2592 Report to Indicate Requests Received in Claims and Requests Received That Are Recovery Audit Related
Medicare State Operations Manual (CMS-Pub. 100-07)	
141	Revisions to the State Operations Manual (SOM), Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals
142	Revisions to State Operations Manual (SOM) Chapter 9 Exhibits
143	Revisions to State Operations Manual (SOM) Chapter 2, The Certification Process and Appendix W, Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs
144	Revisions to State Operations Manual (SOM) Appendix J, Part II – Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities
145	Revisions to Medicare State Operations Manual (SOM), Chapter 9 - Exhibits
146	State Operations Manual (SOM), Section 2185- Home Health Agencies (HHAs), Change of Address to a Medical Administrative Contractor (MAC) within 90 Days Home Health Agencies (HHAs)/2185-HHA Change of Address
Medicare Program Integrity (CMS-Pub. 100-08)	
600	Workload Reporting Prepay Complex Service Specific Review Prepay Complex Provider Specific Review
601	Review of Home Health Claims Home Health
602	Medical Review of Home Health Services Table of Contents Medical Review of Home Health Services Physician Certification of Patient Eligibility for the Medicare Home Health Benefit Certification Requirements Physician Recertification Recertification Elements The Use of the Patient's Medical Record Documentation to Support the Home Health Certification Coding Medical Necessity of Services Provided Examples of Sufficient Documentation Incorporated Into a Physician's Medical Record Medical Review of Home Health Demand Bills
603	Medical Review of Home Health Services Table of Contents Medical Review of Home Health Services Physician Certification of Patient Eligibility for the Medicare Home Health Benefit Certification Requirements Physician Recertification Recertification Elements The Use of the Patient's Medical Record Documentation to Support the Home Health Certification Coding Medical Necessity of Services Provided Examples of Sufficient Documentation Incorporated Into a Physician's Medical Record Medical Review of Home Health Demand Bills
604	Signature Requirements
605	Clarification Regarding the Processing of Certain Provider Enrollment-Related Transactions
606	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
607	Workload Reporting Prepay Complex Provider Specific Review
608	Update to Pub. 100-08 to Provide Language-Only Changes for Updating ICD-10 and ASC X12
609	Clarification Regarding the Processing of Certain Provider Enrollment-Related Transactions Denials Licenses and Certifications Final Adverse Action Supporting Documents Special Processing Guidelines for Form CMS-855A, Form CMS-855B, Form CMS-855I and Form CMS-855R Applications Sole Proprietorships CMHC 40 Percent Rule
610	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
611	Changes to Supplier Documentation and Evidence of Medical Necessity for 3 Oxygen Claims Supplier Documentation Evidence of Medical Necessity for the Oxygen Claims
612	Changes to Supplier Documentation and Evidence of Medical Necessity for Oxygen Claims Evidence of Medical Necessity for the Oxygen Claims
613	Postpayment Review Requirements Complex Medical Review

614	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
	None
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Demonstrations (CMS-Pub. 100-19)	
121	Medicare Care Choices Model (MCCM) - Per Beneficiary per Month Payment (PBPM) - Implementation
One Time Notification (CMS-Pub. 100-20)	
1514	Award of Medicare Administrative Contractor (MAC) Contract for Jurisdiction J
1515	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1516	Analysis and Design for Part B Detail Line Expansion
1517	Tester Resolution Reports for International Classification of Diseases, Tenth Revision (ICD-10) Limited End to End Testing with Submitters
1518	Contractor Reporting of Operational and Workload Data (CROWD) Form 5 Remittance Advice Reporting
1519	Medicare Appeals System (MAS) Upgrade
1520	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1521	CMS Information Security Acceptable Risk Safeguards Update - Multifactor Authentication
1522	Data Act Treasury Referral Timeframe and Reporting - DME MAC Changes
1523	Procedures for Processing Under Tolerance Part A 935, Part A-Other, Part A and B Healthcare Professional Shortage Area (HPSA), and Part A-Provider Recovery Audit Contractor (RAC) Identified debts in the Healthcare Integrated General Ledger Accounting System (HIGLAS)
1524	Medicare Remit Easy Print (MREP) Upgrade
1525	Add Original Common Working Files (CWF) Occurrence Number to the CWF Feed to MBD
1526	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1527	Update for Paper Claims Processing Under the Administrative Simplification Compliance Act (ASCA)
1528	Reporting of Anti-Cancer and Anti-Emetic Drugs
1529	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1530	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1531	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1532	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1533	Update Hard Coded Audit 205A MSP Return Code 3925 and Edit 152D
1534	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for January 2016
1535	International Classification of Diseases, 10th Revision (ICD-10) Additional Acknowledgement Testing Reporting
1536	Increasing Tax Withholding to 100 Percent for Internal Revenue Service (IRS) Federal Payment Levy Program (FPLP)
1537	ICD-10 Conversion/Coding Infrastructure Revisions to National Coverage Determinations (NCDs)--3rd Maintenance CR
1538	Medicare Prior Authorization of Power Mobility Devices (PMDs) Demonstration: Advance Determination of Medicare Coverage (ADMC) Reviews for Beneficiaries Who Have Representative Payees
1539	Implementing the Insertion of a Sheet of Paper Promoting the Electronic Medicare Summary Notices (eMSNs) into Mailed Medicare Summary Notices (MSNs)
1540	Modification to the Telehealth Originating Site Facility Fee Billing Requirements for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
1541	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for October 2015
1542	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1543	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1544	Implementation of Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) Based on Specific Clinical Criteria
1545	Procedures for Processing Under Tolerance Part A 935, Part A-Other, Part A and B Healthcare Professional Shortage Area (HPSA), and Part A-Provider Recovery Audit Contractor (RAC) Identified debts in the Healthcare Integrated General
1546	Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
46	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
47	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (July through September 2015)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register,** contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-3Q15QPU.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (July through September 2015)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we list only the specific updates that have occurred in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Medicare Coverage of Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)	NCD 210.14	R185	08/21/2015	02/05/2015
National Coverage Determination (NCD) for Screening for Colorectal Cancer Using Cologuard™ - A Multitarget Stool DNA Test	NCD 210.3	R183	08/06/2015	10/09/2014

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2015)

Addendum V includes listings of the FDA-approved investigational device exemption (IDE) numbers that the FDA assigns. The listings are organized according to the categories to which the devices are assigned (that is, Category A or Category B), and identified by the IDE number. For the purposes of this quarterly notice, we list only the specific updates to the Category B IDEs as of the ending date of the period covered by this notice and a contact person for questions or additional information. For questions or additional information, contact John Manlove (410-786-6877).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved

investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

IDE	Device	Start Date
G130235	ACTIGAIT IMPLANTABLE DROP FOOT STIMULATOR SYSTEM	09/18/15
G140192	Organ Care System (OCS) - Liver, Organ Care System (OCS) - Liver Console, OCS Liver Perfusion Set	07/09/15
G140202	AEQUALIS PYROCARBON HUMERALHEAD	08/26/15
G140221	Intergraft System	07/31/15
G140243	Organox Metra System	08/21/15
G150029	Tack Endovascular System	08/14/15
G150119	MagVenture MagProX100 with MagOption stimulator, C-B60 butterfly coil and MagPro Cool Coil B65 A/P	07/02/15
G150120	Pilot Study of Novottf - 100A System in Conjunction with Temozolomide Chemoradiation For Newly Diagnosed Glioblastoma	07/15/15
G150123	Argus II Retinal Prosthesis System	07/08/15
G150125	BreathID MCS System C-Methacetin Breath Test	07/31/15
G150127	SaluSTIM, a transcutaneous electrical nerve stimulation (TENS) device	07/10/15
G150131	Monovisc	07/16/15
G150132	University of Minnesota Medical School	08/11/15
G150134	HiResolution Bionic Ear System	07/16/15
G150136	Percutaneous Osseointegrated Prosthesis Implant	07/22/15
G150138	FLT3 Mutation Assay	07/23/15
G150140	CP810 Sound Processor	07/23/15
G150143	Juvederm Voluma XC For Chin Augmentation	07/31/15
G150145	Modulight Laser, Isotropic Probe, Cylindrical Light Diffuser, and Diffusing Balloon Catheter	07/31/15
G150147	SENTUS OTW QP L-75/ SENTUS OTW QP L-85/ SENTUS OTW QP L-95; SENTUS OTW QP S-75/ SENTUS OTW QP S-85/ SENTUS OTW QP S-95 MODEL 389 835/ 386 836/ 386 837/ 400 719/ 400 720/ 400 721	08/05/15
G150150	REPLICATE System	08/07/15
G150155	Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA)	08/14/15
G150161	Boston Scientific Vessix system	08/19/15
G150167	Medtronic Restore ULTRA 37712 spinal cord stimulator, Medtronic Specify 5-6-5, 16-electrode surgical lead	08/28/15
G150169	Visualase Thermal Therapy System	08/28/15
G150170	Mitralign Percutaneous Tricuspid Valve Annuloplasty System (PTVAS)	08/28/15
G150171	ELUVIA Drug-Eluting Vascular Stent System	09/02/15
G150173	MemoryGel Breast Implant UHP-L Smooth Round UHP-L Silicone Gel-Filled Breast Implant, MemoryGel Breast Implant UHP-L Siltex Round UHP-L Silicone Gel-Filled Breast Implant	09/03/15
G150174	Cutera Excel V	09/02/15
G150175	QUARTET MODEL 1457Q IDE STUDY	09/03/15
G150177	Cardiac Resynchronization Therapy Pacemakers	09/11/15
G150178	StimGuard Protect Chronic Tibial Nerve Stimulator (CTNS) System	09/18/15
G150179	SCD (Selective Cytopheretic Device)	09/17/15
G150180	Cook Antimicrobial Hernia Repair Device	09/17/15
G150182	VENTANA PD-L1 (SP142) CDx Assay	09/17/15
G150183	Cochlear Nucleus CI532 Cochlear Implant	09/18/15

Addendum VI: Approval Numbers for Collections of Information (July through September 2015)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact Mitch Bryman (410-786-5258).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (July through September 2015)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Lori Ashby (410-786-6322).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
Pikeville Medical Center 911 Bypass Road Pikeville, KY 41501	180044	09/22/2015	KY
Truman Medical Center 2301 Holmes Street Kansas City, MO 64108	1467595793	09/22/2015	MO
Editorial changes (in bold) for this quarter.			
FROM: University Medical Center **TO: Banner University Medical Center Tucson** 1501 N. Campbell Avenue Tucson, AZ 85724	030064	06/01/2005	AZ
FROM: University Physicians Hospital **TO: Banner University Medical Center South** 2800 East Ajo Way Tucson, AZ 85713	030111	06/21/2012	AZ
FROM: Orlando Regional Healthcare System, Inc. **TO: Orlando Health** 52 West Underwood Street Orlando, FL 32806	100006	04/05/2006	FL
FROM: Medcenter One **TO: Sanford Health Bismarck** 300 North 7th Street Bismarck, ND 58506	350015	05/26/2005	ND

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2015)

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC-NCDR ICD Registry by April 2006.

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS website at http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC-NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC-NCDR ICD registry. The entire list of facilities that participate in the ACC-NCDR ICD registry can be found at www.ncdr.com/webncdr/common

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available by accessing our website and clicking on the link for the American College of Cardiology's National Cardiovascular Data Registry at: www.ncdr.com/webncdr/common. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Facility	City	State
The following facilities are new listings for this quarter.		
Mountain Point Medical Center	Lehi	UT
University Health Conway	Monroe	LA
Sentara Albemarle Medical Center	Elizabeth City	NC
Fort Hamilton Hospital	Hamilton	OH
Piedmont Newnan Hospital	Newnan	GA
The following facilities are terminated as of this quarter.		
Baton Rouge General Medical Center (Mid City)	Baton Rouge	LA
Unity Medical and Surgical Hospital	Mishawaka	IN

Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2015)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month

period. For questions or additional information, contact JoAnna Baldwin (410-786-7205).

Addendum X:
List of Special One-Time Notices Regarding National Coverage Provisions (July through September 2015)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact JoAnna Baldwin (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (July through September 2015)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (July through September 2015)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred to the list of Medicare-approved facilities that meet our standards in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Facility	Provider Number	Date Approved	State
The following facilities are new listings for this quarter.			
Riverside Methodist Hospital 3535 Olentangy River Road Columbus, OH 43214	360006	8/11/2015	OH
Delray Medical Center, Inc 5352 Linton Boulevard Delray Beach, FL	100258	8/12/2015	FL
Editorial changes (in bold) for this quarter.			
TO: Keck Hospital of USC **FROM: USC University Hospital** 1500 San Pablo Street Los Angeles, CA 90033	050696	01/09/2004	CA

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 2015)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commision on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (July through September 2015)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Jamie Hermansen (410-786-2064).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2015)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

[FR Doc. 2015–28870 Filed 11–12–15; 8:45 am]
BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Family and Child Experiences Survey (FACES).

OMB No.: 0970–0151.

Description: The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new round of the Head Start Family and Child Experiences Survey (FACES). Featuring a new ''Core Plus'' study design, FACES will provide data on a set of key indicators, including information for performance measures. The design allows for more rapid and frequent data reporting (Core studies) and serves as a vehicle for studying more complex issues and topics in greater detail and with increased efficiency (Plus studies).

The FACES Core study will assess the school readiness skills of Head Start children, survey their parents, and ask their Head Start teachers to rate children's social and emotional skills. In addition, FACES will include observations in Head Start classrooms, and program director, center director, and teacher surveys. FACES Plus studies include additional survey content of policy or programmatic interest, and may include additional programs or respondents beyond those participating in the Core FACES study.

Previous notices provided the opportunity for public comment on the proposed Head Start program recruitment and center selection process (FR V.78, pg. 75569 12/12/2013; FR V.79, pg. 8461 02/12/2014), the child-level data collection in fall 2014 and spring 2015(FR V. 79, pg. 11445 02/28/2014; FR V. 79; pg. 27620 5/14/2014), the program- and classroom-level spring 2015 data collection activities (FR v.79; pg. 73077 12/09/2014), and the American Indian and Alaska Native Head Start Family and Child Experiences Survey (AI/AN FACES) child-level data collection activities in fall 2015 and spring 2016 (FR V. 80, pg. 30250 08/07/2015). This 30-day notice describes the planned additional data collection activities for AI/AN FACES in spring 2016, including surveys with parents, teachers, program directors, and center directors.

AI/AN FACES spring 2016 data collection includes site visits to 37 centers in 22 Head Start programs. As in fall 2015, parents of sampled children will complete surveys on the Web or by telephone (or in person if needed) about their children, activities family members engage in with their children, and family and household background characteristics. Head Start teachers, program directors, and center directors will complete surveys about the Head Start classroom or program and their own background using the Web or paper-and-pencil forms.

The purpose of the Core data collection is to support the 2007 reauthorization of the Head Start program (Pub. L. 110–134), which calls for periodic assessments of Head Start's quality and effectiveness. As additional information collection activities are fully developed, in a manner consistent with the description provided in the 60-day notice (79 FR 11445) and prior to use, we will submit these materials for a 30-day public comment period under the Paperwork Reduction Act.

Respondents: Parents of Head Start children, Head Start teachers and Head Start staff.

ANNUAL BURDEN ESTIMATES—CURRENT INFORMATION COLLECTION REQUEST

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Estimated annual burden hours
Head Start core parent survey for plus study (AI/AN FACES Spring 2016)	800	267	1	0.50	134
Head Start core teacher survey for plus study (AI/AN FACES)	80	27	1	0.58	16
Head Start program director core survey for plus study (AI/AN FACES)	22	7	1	0.33	2
Head Start center director core survey for plus study (AI/AN FACES)	37	12	1	0.33	4
Total					156

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

ACF Reports Clearance Officer.

[FR Doc. 2015–28815 Filed 11–12–15; 8:45 am]
BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Self-Assessment Review and Report.

OMB No.: 0970–0223.

Description: Section 454(15)(A) of the Social Security Act, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, requires each State to annually assess

the performance of its child support enforcement program in accordance with standards specified by the Secretary of the Department of Health and Human Services, and to provide a report of the findings to the Secretary. This information is required to determine if States are complying with Federal child support mandates and providing the best services possible. The report is also intended to be used as a management tool to help States evaluate their programs and assess performance.

Respondents: State Child Support Enforcement Agencies or the Department/Agency/Bureau responsible for Child Support Enforcement in each State.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Self-assessment report	54	1	4	216
Estimated Total Annual Burden Hours:				216

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–28820 Filed 11–12–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0920]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: On September 17, 2015, the Agency submitted a proposed collection of information entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0751. The approval expires on October 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: November 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28790 Filed 11–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0049]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with the reporting of harmful and potentially harmful constituents in tobacco products and tobacco smoke under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by January 12, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–D–0049 for the information collection request entitled ''Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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: 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: 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. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act (OMB Control Number 0910–0732)—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) into law. This law amended the FD&C Act and granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Section 904(a)(3) of the FD&C Act (21 U.S.C. 387d(a)(3)) required each tobacco product manufacturer or importer, or an agent, to begin reporting to FDA no later than June 22, 2012, ''all constituents, including smoke constituents, identified by [FDA] as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product.'' Reports must be by the brand and by quantity in each brand and subbrand. Section 904(c)(1) of the FD&C Act states that manufacturers of tobacco products not on the market as of June 22, 2009, must also provide information reportable under section 904(a)(3) at least 90 days prior to introducing the product into interstate commerce.

FDA has taken several steps to identify harmful and potentially harmful constituents (HPHCs) to be reported under sections 904(a)(3) and (c)(1) of the FD&C Act, including issuing a guidance discussing FDA's current thinking on the meaning of the term ''harmful and potentially harmful constituent'' in the context of implementing the HPHC list requirement under section 904(e) of the FD&C Act (76 FR 5387, January 31, 2011). The guidance is available on the Internet at *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm241339.htm.*

In addition, in the **Federal Register** of April 3, 2012 (77 FR 20034), FDA published a notice (the HPHC list notice) announcing the established list of HPHCs as required by section 904(e) of the FD&C Act and describing the criteria we used in identifying the HPHCs for the established list. Previously, FDA sought comment on both the criteria that would be used to identify HPHCs for the established list and a list of chemicals and chemical compounds that met the proposed criteria.

The purpose of the information collection is to collect statutorily mandated information regarding HPHCs in tobacco products and tobacco smoke, by quantity in each brand and subbrand.

To facilitate the submission of HPHC information, FDA has developed Forms 3787a, 3787b, and 3787c in both paper and electronic formats. Manufacturers or importers, or their agents, may submit information either electronically or in paper format. The FDA eSubmitter tool provides electronic forms to streamline the data entry and submission process for reporting HPHCs. Users of eSubmitter may populate an FDA-created Excel file and import data into eSubmitter. Whether respondents decide to submit reports electronically or on paper, each form provides instructions for completing and submitting HPHC information to FDA. The forms contain fields for company information, product information, and HPHC information. Respondents finished reporting initial HPHC information under section 904(a)(3) in 2012, and this collection of information is in connection with the reporting requirements under section 904(c)(1) of the FD&C Act for tobacco products introduced into interstate commerce after June 22, 2009.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collected	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting for Section 904(c)(1) Products					
1. Reporting of Manufacturer Company and Product Information by Completing Submission Forms					
Cigarette	78	0.79	62	1.82	113
Roll-Your-Own	39	0.21	8	0.43	3
Smokeless	52	0.21	11	0.63	7
Total					123
2. Testing of HPHC Quantities in Products					
Cigarette Filler	78	0.79	62	9.42	584
Roll-Your-Own	39	0.21	8	9.42	75
Smokeless	52	0.21	11	12.06	133
Total					792
3. Testing of HPHC Quantities in Mainstream Smoke					
Cigarette: International Organization for Standardization (ISO) Regimen	78	0.79	62	23.64	1,466
Cigarette: Health Canada Regimen	78	0.79	62	23.64	1,466
Total					2,932
Total Section 904(c)(1) Reporting Burden Hours					3,847

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

Table 1 contains estimates for new product information received annually under section 904(c)(1) of the FD&C Act. Manufacturers must report HPHC information under section 904(c)(1) of the FD&C Act at least 90 days prior to delivery for introduction into interstate commerce. The total annual burden for this collection of information is estimated to be 3,847 hours. The burden estimate for this collection of information includes the time it will take to test the products and prepare the HPHC report.

Table 1 indicates that 169 respondents will submit HPHC reports when new products enter the market. Section 1 of the table addresses the time required for manufacturers to report their company information. We estimate that the time to report HPHC information is no more than 1.82 hours for cigarettes, 0.42 hours for roll-your-own, and 0.63 hours for smokeless tobacco products for each response regardless of whether the paper or electronic form (Form FDA 3787) is used. (The estimated times to report smokeless tobacco products (0.63 hour) and roll-your-own tobacco products (0.43 hour) are lower than the estimated reporting time for cigarette products because fewer HPHCs are normally reported for these two types of products. The total annual burden for reporting company and product information is 123 hours.

Section 2 of the table addresses the time required for manufacturers to test quantities of HPHCs in their products. The burden hour estimates include the time needed to test the tobacco products, draft testing reports, and draft the report for FDA. For cigarette filler, smokeless, and roll-your-own products, we estimate the burden to be 792 annual burden hours. The burden for each product type reflects our estimate of the time to test the tobacco products (*i.e.,* carry out laboratory work).

In addition to addressing the time required to report information and test quantities of HPHCs in tobacco products, section 3 of table 1 addresses the time required for manufacturers to test quantities of HPHCs in cigarette smoke. The burden estimates include testing the tobacco products, drafting testing reports, and drafting the report for FDA. We estimate the annualized

burden for this section to be 2,932 hours. The annual burden reflects our estimate to test the tobacco products (*i.e.,* carry out laboratory work). The burden estimate assumes that manufacturers report HPHC quantities in cigarette mainstream smoke according to the two smoking regimens described in the table.

The estimated total annual burden for the reporting of HPHC under section 904(c)(1) of the FD&C Act is 3,847 hours. We do not believe there are any capital costs associated with this collection.

Dated: November 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28787 Filed 11–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1630]

Guidance on Qualification of Biomarker—Galactomannan in Studies of Treatments of Invasive Aspergillosis; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Guidance on Qualification of Biomarker—Galactomannan in Studies of Treatments of Invasive Aspergillosis.'' This guidance provides a qualified context of use (COU) for Galactomannan detection in serum and/or bronchoalveolar lavage (BAL) fluid as the sole microbiological criterion to classify patients as having probable invasive Aspergillosis (IA) for enrollment in clinical trials. This guidance also describes the experimental conditions and constraints for which this biomarker is qualified through the CDER Biomarker Qualification Program. This biomarker can be used by drug developers for the qualified COU in submissions of investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the guidance by January 12, 2016

ADDRESSES: You may submit comment as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–1630 for ''Guidance on Qualification of Biomarker—Galactomannan in Studies of Treatments of Invasive Aspergillosis.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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: Marianne Noone, Center for Drug Evaluation and Research (Office of Translational Sciences, Immediate Office), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4528, Silver Spring, MD 20993–0002, 301–796–2600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Guidance on Qualification of Biomarker—Galactomannan in Studies of Treatments of Invasive Aspergillosis.'' In the **Federal Register** of October 27, 2014 (79 FR 63921), FDA

announced the availability of a draft guidance entitled ''Draft Guidance on Qualification of Biomarker—Galactomannan in studies of Treatments of Invasive Aspergillosis.'' The Agency received one comment during the public comment period which was supportive of the qualification of this biomarker. This guidance finalizes the draft guidance issued in October 2014.

This guidance provides qualification recommendations for the use of Galactomannan detection in serum and/or BAL fluid as the sole microbiological criterion to classify patients with hematologic malignancies and recipients of allogeneic hematopoietic stem cell transplants and who also have radiologic evidence suggestive of invasive fungal infection (Ref. 1) as having probable IA for enrollment in clinical trials.

Specifically, this guidance provides the COU for which this biomarker is qualified through the CDER Biomarker Qualification Program. Qualification of this biomarker for this specific COU represents the conclusion that analytically valid measurements of the biomarker can be relied on to have a specific use and interpretable meaning. This biomarker can be used by drug developers for the qualified COU in submission of INDs, NDAs, and BLAs without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker. ''Qualification'' means that the use of this biomarker in the specific COU is not limited to a single, specific drug development program. Making the qualification recommendations widely known and available for use by drug developers will contribute to drug innovation, thus supporting public health.

Innovative and improved Drug Development Tools (DDTs) can help streamline the drug development process, improve the chances for clinical trial success, and yield more information about a treatment and/or disease. DDTs include, but are not limited to, biomarkers, clinical outcome assessments, and animal models. Refer to DDTs Qualification Programs at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/default.htm* for additional information.

In the **Federal Register** of January 7, 2014 (79 FR 831), FDA announced the availability of a final guidance for industry entitled ''Qualification Process for Drug Development Tools'' that described the process that would be used to qualify DDTs and to make new DDT qualification recommendations available on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* The current guidance is an attachment to that final guidance.

CDER has initiated this formal qualification process to work with developers of these biomarker DDTs to guide them as they refine and evaluate DDTs for use in the regulatory context. Once qualified, biomarker DDTs will be publicly available for use in any drug development program for the qualified COU. As described in the January 2014 guidance, biomarker DDTs should be developed and reviewed using this process. For more information on FDA's DDTs Qualification Programs, refer to the following Web page: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/default.htm.*

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking for the use of Galactomannan detection in serum and/or BAL fluid as the sole microbiological criterion to classify patients as having probable IA for enrollment in clinical trials. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it 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 312.30, 21 CFR 314.50(d)(5), and 21 CFR 314.126(b)(6) have been approved under OMB control numbers 0910–0001 and 0910–0014.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

IV. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *http://www.regulations.gov.*

1. De Pauw, B., T. J. Walsh, J. P. Donnelly, et al., ''Revised Definitions of Invasive Fungal Disease from European Organization for Research and Treatment of Cancer/Invasive Fungal Infections Cooperative Group and the National Institute of Allergy and Infectious Diseases Mycoses Study Group (EORTC/MSG) Consensus Group,'' *Clinical Infectious Diseases*, 46:12, pp. 1813–1821, 2008.

Dated: November 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28804 Filed 11–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0922]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: On September 17, 2015, the Agency submitted a proposed collection of information entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0789. The approval expires on October 31, 2018. A copy of the supporting statement for this

information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: November 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28789 Filed 11–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0564]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dietary Supplement Labeling Requirements and Recommendations Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act

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 December 14, 2015.

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 0910–0642. 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.

Dietary Supplement Labeling Requirements and Recommendations Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act—(OMB Control Number 0910–0642)–Extension

In 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application. The DSNDCPA also amended the FD&C Act to add section 403(y) (21 U.S.C. 343(y)), which requires the label of a dietary supplement marketed in the United States to include a domestic address or domestic telephone number through which the product's manufacturer, packer or distributor may receive a report of a serious adverse event associated with the dietary supplement.

In the **Federal Register** of September 1, 2009 (74 FR 45221), we announced the availability of a guidance document entitled, ''Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' The guidance document contains questions and answers related to the labeling requirements in section 403(y) of the FD&C Act and provides guidance to industry on the use of an explanatory statement before the domestic address or telephone number. The guidance document provides our interpretation of the labeling requirements for section 403(y) of the FD&C Act and our views on the information that should be included on the label. We believe that the guidance will enable persons to meet the criteria for labeling that are established in section 403(y) of the FD&C Act.

In the **Federal Register** of August 24, 2015 (80 FR 51278), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Domestic address or phone number labeling requirement (21 U.S.C. 343(y))	1,700	3.27	5,560	0.2	1,112
FDA recommendation for label statement explaining purpose of domestic address or phone number	1,700	3.27	5,560	0.2	1,112
Total					2,224

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

The labeling requirements of section 403(y) of the FD&C Act became effective on December 22, 2007, although we exercised enforcement discretion until September 30, 2010, to enable all firms to meet the labeling requirements for dietary supplements. At this time, therefore, we expect that all labels required to include the domestic address or telephone number issued in section 403(y) have been revised accordingly. Thus our current burden estimate for this information collection applies only to new product labels.

In row 1 of Table 1 we estimate the total annual hourly burden necessary to comply with the requirement under section 403(y) of the FD&C Act (21 U.S.C. 343(y)) to be 1,112 hours. Using historical A.C. Nielson Sales Scanner Data, we estimate the number of dietary supplement SKUs for which product sales are greater than zero to be 55,600. Assuming that the flow of new products is 10 percent per year, then each year approximately 5,560 new dietary supplement products are projected to enter the market. Estimating that there are 1,700 dietary supplement manufacturers, re-packagers, re-labelers, and holders of dietary supplements subject to the information collection requirement (using the figure 1,460 as

provided in our final rule of June 25, 2007 (72 FR 34752) on the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, and factoring for a two percent annual growth rate), we calculate an annual disclosure burden of 3.27 disclosures (labels) per firm. Last, we expect that firms prepare the required labeling for their products in a manner that takes into account at one time all information required to be disclosed and therefore believe that less than 0.2 hours (12 minutes) per product label would be expended to fulfill this requirement.

In row 2 of Table 1 we estimate the total burden associated with the recommendation to include an explanatory statement on dietary supplement product labels letting consumers know the purpose of the domestic address or telephone number to be 1,112 hours. Based upon our knowledge of food and dietary supplement labeling, we estimate it would require less than 0.2 hours (12 minutes) per product label to include such a statement.

Dated: November 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28788 Filed 11–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the Battelle King Avenue Site in Columbus, Ohio, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: NIOSH gives notice of a decision to evaluate a petition to designate a class of employees from the Battelle King Avenue site in Columbus, Ohio, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

SUPPLEMENTARY INFORMATION:

Authority: 42 CFR 83.9–83.12.

Pursuant to 42 CFR 83.12, the initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Battelle King Avenue.

Location: Columbus, Ohio.

Job Titles and/or Job Duties: All Atomic Weapons Employees who worked at the facility owned by the Battelle Laboratories at the King Avenue site in Columbus, Ohio, during the period from July 1, 1956 through December 31, 1970, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the Special Exposure Cohort.

Period of Employment: July 1, 1956 through December 31, 1970.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2015–28905 Filed 11–12–15; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: December 10–11, 2015.

Time: December 10, 2015, 9:00 a.m. to 5:00 p.m.

Agenda: NIH Director's report and ACD Working Group reports.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6C6, 31 Center Drive, Bethesda, MD 20892.

Time: December 11, 2015, 9:00 a.m. to Adjournment

Agenda: IC Director reports and any other committee business.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6C6, 31 Center Drive, Bethesda, MD 20892

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–4272, *woodgs@od.nih.gov*.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://acd.od.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: November 6, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–28797 Filed 11–12–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute On Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; U54 Review.

Date: December 3, 2015.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jeannette L. Johnson, Ph.D., National Institutes on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7705, *JOHNSONJ9@NIA.NIH.GOV.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: November 5, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–28798 Filed 11–12–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2015–0961]

Recreational Boating Safety—2016 Nonprofit Organization Grants

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability and request for comments.

SUMMARY: The Coast Guard requests public comments on whether it should modify or move forward with its tentative list of topics on which it would invite applications for Fiscal Year 2016 grants to nonprofit organizations. These grants are intended to promote recreational boating safety.

DATES: Comments must be submitted to the online docket via *http://www.regulations.gov,* or reach the Docket Management Facility, on or before 30 days after date of publication in the **Federal Register**.

ADDRESSES: You may submit comments identified by docket number USCG–2014–0911 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Carlin Hertz, Nonprofit Grants Coordinator; 202–372–1060, *carlin.r.hertz@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Public Participation and Comments

We encourage you to submit comments or related material on this notice, and we may modify our tentative list of topics for Fiscal Year 2016 accordingly. The Coast Guard does not anticipate another FR Notice to discuss any of the comments received but your input will be considered in the development of the 2016 Nonprofit Organization Grants. If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Discussion

Chapter 131 of Title 46, U.S. Code, requires the Secretary of Homeland Security to maintain a national recreational boating safety program, and gives the Secretary certain regulatory authority to implement that program. The Secretary has delegated that authority to the Coast Guard.[1] Chapter 131 mandates annual allocations of funds to State boating safety programs, and allows the Coast Guard to allocate up to 5% of the total amount of those funds to the national boating safety programs undertaken by national nonprofit public service organizations.[2] These allocations are made pursuant to statutory guidelines that prescribe the purposes for which allocated funds may be used.[3] The Coast Guard annually evaluates the statutory guidelines to determine how they can best be met in the coming fiscal year.

For Fiscal Year 2016, the Coast Guard has tentatively determined that it will invite national nonprofit public service organizations to apply for grant allocations in the following ''areas of interest'' we have identified as well as other topics.

1. Conduct Elements of a Year-Round Safe Boating Campaign. This area of interest would conduct national campaigns throughout the year that are coordinated with other safety initiatives and media events, and would—

- Align with the National Recreational Boating Safety Strategic Plan, particularly Objective 2: Boating Safety Outreach;
- Target specific boating safety topics and specific boater market segments;
- Reach boaters at the local level;
- Educate boaters about the consequences of drinking alcohol, taking drugs, or other irresponsible behavior on the water;
- Educate boaters about reporting boating accidents;
- Stress the importance of wearing life jackets;
- Educate boaters on the ''New Life Jacket Standards,'' as published by the Coast Guard;
- Educate boaters on propeller strike dangers and avoidance, particularly emphasizing the use of engine cut-off switch (lanyards and electronic devices);
- Stress the importance of boater safety training; and
- Emphasize that boat operators are responsible for their own safety and that of their passengers.

2. Outreach and Awareness Conference. This area of interest would use a single national conference to focus on the topics discussed under the first area of interest, in support of the National Recreational Boating Safety Strategic Plan's Objective 2—Boating Safety Outreach. Conference organizers must focus on professional development opportunities for conference participants while making every effort to ensure affordability to gain maximum attendance. The conference must provide opportunities for grant recipients, as appropriate, to present results of completed grant projects and on plans for using new Coast Guard

[1] DHS Delegation No. 0170.1(II)(92.i).

[2] 46 U.S.C. 13104(c).

[3] 46 U.S.C. 13107(b).

grants. Three to six months after the conference, the organizers must survey participants on the long term impacts of the conference and include survey results in their final report.

3. Standardize Statutes and Regulations. This area of interest would foster measurable standardization and reciprocity among State boating safety statutes and regulations and how they are administered and enforced, especially with respect to accident reporting, boater education, and life jacket wear requirements. Hands-on coordination of state efforts and the establishment of cooperative environments where state officials can discuss issues regarding this topic are encouraged. This standardization should be compatible with other State boating safety efforts and promote RBS program effectiveness, the use of Coast Guard-recognized boater education programs, and improved administration of Coast Guard-approved vessel numbering and accident reporting systems. A further desired outcome of this area of interest is an updated comprehensive guide to State recreational boating safety laws and regulations.

4. Accident Investigations Seminars. This area of interest would develop Coast Guard-approved curriculum and materials for seminars for Federal and State recreational boating accident investigators in support of the National Recreational Boating Safety Strategic Plan's Objective 9—Boating Accident Reporting. The curriculum must cover the requirements of 46 U.S.C. 6102 and 33 CFR parts 173 subpart C, part 174 subparts C & D (in particular the accident-reporting system administration requirements of 33 CFR 174.103), and part 179. Between four and eight 60 student regional seminars are desired, as well as between two and four advanced courses at an appropriate location designed to garner maximum participation at the lowest cost. Three 20-student regional train-the-trainer seminars would also be required with seminar locations agreed to with the Coast Guard. Each seminar would reserve at least four places for Coast Guard marine investigators to be assigned by the Coast Guard. Each regional seminar must cover an overview of recreational boat accident investigations, witness interviews, collision dynamics, evidence collection and preservation, diagramming, and report writing with an emphasis on adherence to definitions and detail in the accident narrative, with particular focus on human factor causal elements. The advanced seminars must include instruction in the investigation of video-simulated accidents with actual recreational boats used as training aids.

5. Life Jacket Wear Rate Study. This area of interest would provide alternatives to achieving reliable estimates of nationwide recreational boater life jacket wear rates. This estimate will directly address the National Recreational Boating Safety Strategic Plan's Strategy 4.1—Track and Evaluate Life Jacket Wear Rates. Plans presented should lay out the advantages and disadvantages and projected costs of an annual, biannual, and every three years study. Plans can include the use of paid or volunteer observers, and must be based on actual observation of a representative sample of boaters on high-use lakes, rivers, and bays, ideally conducted in different locations at different times of the year to accurately capture the impact of the seasonal nature of boating. Methods for developing estimates must be replicable and must be able to collect data by number, type, length, operation, and activity of boats and by boater age and gender.

6. Voluntary Manufacturing Standards Development. This area of interest would develop and carry out a program to promote the formulation of technically sound voluntary standards for building recreational boats and associated equipment such as electronics. Development of these standards will address the National Recreational Boating Safety Strategic Plan's Strategy 7.3—Manufacturer Outreach. The standards must help reduce accidents in which stability, speed, operator inattention, and navigation lights are factors. For example, standards could be developed for labeling flying-bridge capacity or horsepower rating, or for minimizing operator distraction, or for determining the effects of underwater or decorative lighting.

7. Targeted Boating Safety Knowledge and Skills Awareness Training. This area of interest would build a sustainable network of training providers to target traditionally underrepresented groups in boating. The program should have structured, engaging, in-depth opportunities for learning basic boating safety and for practicing on-the-water boating safety skill. The curriculum used must be based on appropriate elements of the national skills standards being promulgated through the ANSI (or other comparable) process and available currently in draft form, and must compliment the national knowledge standards. This effort must support Objectives 2 and 3 of the National Recreational Boating Safety Program Strategic Plan—Boating Safety Outreach and Advanced and/or On the Water, Skills Based Boating Education.

8. ''*Boating Under the Influence*'' *(BUI) Detection and Enforcement Courses.* This area of interest would develop and conduct train-the-trainer and BUI detection and enforcement training courses for State and local marine patrol officers, Coast Guard boarding officers, and others. The goal of the training would be to give students the knowledge and skills they need to deter recreational boater alcohol use and alcohol-related accidents.

Additionally, the area of interest would support the execution of a focused national outreach effort to highlight the dangers of BUI through education and enforcement. This outreach effort would be targeted to run during a specified time frame during a time of high boating participation to achieve maximum exposure. These courses and outreach actions will directly address National Recreational Boating Safety Strategic Plan Strategy 6.2, Train marine law enforcement officers in Boating Under the Influence and Strategy 6.3, Expand nationwide use of the validated Standardized Field Sobriety Tests (SFST).

9. Media ''*toolbox*''. This area of interest would develop a ''toolbox'' of methods and strategies to assist entities in carrying out media and other awareness campaigns related to pertinent boating safety messaging including, but not limited to, Boating Under the Influence (BUI), life jacket wear, accident reporting, and boating safety education. Any ''toolbox'' developed should include the use of social media and other innovative techniques to be used in a prevention campaign and should build on currently available boating safety messaging. This initiative directly supports Objective 2: Boating Safety Outreach.

This notice is issued under authority of 5 U.S.C. 552(a).

Dated: November 4, 2015.

Verne B. Gifford,

Captain, Coast Guard, Director of Inspections and Compliance.

[FR Doc. 2015–29139 Filed 11–10–15; 4:15 pm]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Test To Collect Biometric Information at the Otay Mesa Port-of-Entry

AGENCY: U.S. Customs and Border Protection; Department of Homeland Security.

ACTION: General notice.

SUMMARY: This notice announces that U.S. Customs and Border Protection (CBP) intends to conduct a test to collect biometric information at the Otay Mesa, California land border port-of-entry from certain aliens entering and departing the United States. During this test, CBP will also collect biographic data from all travelers departing the United States at the Otay Mesa port-of-entry. This notice describes the scope of the test, its purpose, how it will be implemented, the persons covered, the duration of the test, and privacy considerations.

DATES: This test will begin no earlier than December 7, 2015 and will end on or before June 30, 2016.

FOR FURTHER INFORMATION CONTACT: Edward Fluhr, Assistant Director, Entry/Exit Transformation Office, U.S. Customs and Border Protection, by phone at (202) 344–2377 or via email at *edward.fluhr@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Department of Homeland Security (DHS) established the United States Visitor and Immigrant Status Indicator Technology (US–VISIT) Program in accordance with several federal statutory mandates requiring DHS to create an integrated, automated biometric entry and exit system that records the arrival and departure of aliens; compares the biometric data of aliens to verify their identity; and authenticates travel documents presented by such aliens through the comparison of biometric identifiers. Under US–VISIT, certain aliens, as described below, may be required to provide certain biometric information (digital fingerprint scans, photographs, facial and iris images, or other biometric identifiers[1]) when attempting to enter or depart the United States.

The federal statutes requiring DHS to create a biometric entry and exit system to record the arrival and departure of aliens include, but are not limited to:

- Section 2(a) of the Immigration and Naturalization Service Data Management Improvement Act of 2000 (DMIA), Public Law 106–215, 114 Stat. 337 (2000);
- Section 205 of the Visa Waiver Permanent Program Act of 2000, Public Law 106–396, 114 Stat. 1637, 1641 (2000);
- Section 414 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), Public Law 107–56, 115 Stat. 272, 353 (2001);
- Section 302 of the Enhanced Border Security and Visa Entry Reform Act of 2002 (Border Security Act), Public Law 107–173, 116 Stat. 543, 552 (2002);
- Section 7208 of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA), Public Law 108–458, 118 Stat. 3638, 3817 (2004); and
- Section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007, Public Law 110–52, 121 Stat. 266 (2007).

Section 7208 of IRTPA, as codified in 8 U.S.C. 1365b, requires specifically that DHS' entry and exit data system collects biometric exit data for all categories of individuals who are required to provide biometric entry data.

On January 5, 2004, DHS published an interim final rule in the **Federal Register** (69 FR 468) implementing the first phase of US–VISIT at certain U.S. air and sea ports-of-entry. The interim final rule amended 8 CFR 235.1 to authorize DHS to require certain aliens who arrive at designated U.S. air and sea ports-of-entry to provide biometric data to CBP during the inspection process. The air and sea ports-of-entry where such collection of biometric information occurs were designated by notice in the **Federal Register**. See 69 FR 482 (January 5, 2004). Since that time, aliens who are required by law to submit biometric information have been submitting fingerprints and photographs upon entry to the United States at designated air and sea ports-of-entry. This DHS biometric entry program is currently operational at 115 airports and 15 seaports across the United States.

The second phase of US–VISIT was implemented on August 31, 2004 when DHS published an interim final rule in the **Federal Register** (69 FR 53318) expanding the program to the 50 most highly trafficked land border ports-of-entry in the United States as required in 8 U.S.C. 1365a(d)(2).[2] This interim final rule amended 8 CFR 215.8, which provides that the Secretary, or his designee, may establish pilot programs to collect biometric information from certain aliens departing the United States at land border ports-of-entry, and up to fifteen air or sea ports of entry, designated through notice in the **Federal Register**. See 8 CFR 215.8(a)(1). The interim final rule also authorized DHS to identify the specific land border ports-of-entry in a separate notice published in the **Federal Register**.[3]

On November 9, 2004, DHS published a notice in the **Federal Register** (69 FR 64964) identifying the fifty most trafficked land border ports-of-entry where biometric data would be collected from certain aliens upon arrival. Today, DHS collects fingerprint biometric data to verify the identity of certain aliens seeking admission at all land border ports-of-entry. This notice also specified that DHS would announce, through a future **Federal Register** notice, the piloting of a future biometric collection program at a limited number of sites as part of DHS' efforts to process aliens upon departure from the United States.

On March 16, 2013, US–VISIT's entry and exit operations, including deployment of a biometric exit system, were transferred to U.S. Customs and Border Protection (CBP). See Consolidated and Further Continuing Appropriations Act, 2013, Public Law 113–6 (2013). The Act also transferred US–VISIT's overstay analysis function to U.S. Immigration and Customs Enforcement (ICE) and its biometric identity management services to the Office of Biometric Identity Management (OBIM), a newly-created office within the National Protection and Programs Directorate. CBP assumed the biometric entry and exit operations on April 1, 2013.

The purpose of this notice is to inform the public that CBP will be conducting a test on the collection of biometric exit information at the Otay Mesa, California land border port-of-entry. This notice describes the scope of the test, its purpose, how it will be implemented, the persons covered, the duration of the test, and privacy considerations.

[1] As used in this notice, a ''biometric identifier'' is a physical characteristic or other physical attribute unique to a person that can be collected, stored, and used to verify the identity of a person who presents himself or herself to a CBP officer at the border. To verify a person's identity, a similar physical characteristic or attribute is collected and compared against the previously collected identifier.

[2] Section 1365a(d)(2) provides in pertinent part: ''Not later than December 31, 2004, the Attorney General [now Secretary of Homeland Security] shall implement the integrated entry and exit data system . . . at the 50 land border ports of entry determined by the Attorney General to serve the highest numbers of arriving and departing aliens.''

[3] On December 19, 2008, DHS published a final rule in the **Federal Register** (73 FR 77473) finalizing this interim final rule without change.

Otay Mesa Land Border Port-of Entry Pedestrian Exit Test

The Otay Mesa Land Border Port-of Entry Pedestrian Exit Test is a short-term biometric data collection that will help CBP determine the viability of capturing biometric data from certain departing aliens in various environmental conditions. This test is one of CBP's key steps in developing the capability to fulfill DHS' mandate to collect biometric information from arriving and departing aliens.

Scope, Purpose and Implementation

Currently, aliens who seek admission at the Otay Mesa, California land border port-of-entry may be required to provide fingerprint biometric data for CBP to verify their identity. (Certain aliens, including individuals traveling on A or G visas and others as specified in 8 CFR 215.8(a)(2), are exempt from this requirement). During this test, facial and iris images of these non-exempt aliens will be captured, either via a biometric kiosk or freestanding facial and iris cameras, upon arrival and departure of the alien if they cross the border at the Otay Mesa land border port-of-entry. The captured biometric exit data will be stored in a secure, standalone database and analyzed for off-line matching against facial and iris images previously captured upon arrival and associated with biometric data already on file. No biometric data will be distributed from the standalone database, except for analysis and reporting purposes on the results of the test. Biometric information will not be collected from U.S. citizens under this test.

CBP will also collect biographic data from all travelers exiting the United States at the Otay Mesa port-of-entry, including U.S. citizens. Biographic data consists of the traveler's identifying information provided on his or her travel documents, such as full name, date of birth, gender, and country of citizenship, and does not involve biometric identifiers such as fingerprints and facial or iris images. The traveler's travel documents will be read upon exit via a Radio-Frequency Identification (RFID) technology reader, a kiosk, or a hand-held device.

Pursuant to various authorities under Titles 8 and 19 of the U.S. Code, and other authorities CBP enforces on behalf of third party agencies at the border, CBP routinely collects biographic data from travelers entering and departing the United States. See, *e.g.,* 8 U.S.C. 1181, 1185, 1221; and 19 U.S.C. 1433. During the test at the Otay Mesa port-of-entry, this same data will be collected from all departing travelers. This will enable CBP to evaluate the viability of using biographic or biometric data or a combination of the two to provide a high level of confidence in validating the traveler's identity upon exit.

CBP will use the results of the test to assess the operational feasibility of biometric information collection for potential deployment across the U.S. southwest border. Once the biometric data is captured, CBP will analyze and evaluate the test based on a number of criteria, including the speed and quality of the data capture, the ability to match biometric data captured upon arrival and departure, the concurrent and independent capability of facial and iris biometrics, and the feasibility and accuracy of capturing biometrics from a distance. With regard to biographic data, CBP will use such data to identify travelers who are known or suspected of being terrorists, have affiliations to terrorist organizations, have active warrants for criminal activity, are inadmissible, have overstayed their visas, or have been otherwise identified as potential security risks or are the subject of law enforcement concerns. A successful test will enhance DHS security efforts at our Nation's border while expediting the movement of legitimate travelers.

Persons Covered

For the duration of the test, all aliens shall provide the biometric information described above at the time of arrival to and departure from the United States to the extent they cross through the Otay Mesa land port-of-entry, except for aliens who, at the time of such arrival or departure, are exempt pursuant to 8 CFR 235.1(f)(1)(iv) and 8 CFR 215.8(a)(2). Exempted aliens include:

(1) Canadian citizens who under section 101(a)(15)(B) of the INA who are not otherwise required to present a visa or have been issued Form I–94 (see § 1.4) or Form I–95 upon arrival at the United States;

(2) Aliens admitted on A–1, A–2, C–3 (except for attendants, servants, or personal employees of accredited officials), G–1, G–2, G–3, G–4, NATO–1, NATO–2, NATO–3, NATO–4, NATO–5, or NATO–6 visas, and certain Taiwan officials who hold E–1 visas and members of their immediate families who hold E–1 visas who are maintaining such status at time of departure, unless the Secretary of State and the Secretary of Homeland Security jointly determine that a class of such aliens should be subject to this notice;

(3) Children under the age of 14;

(4) Persons over the age of 79;

(5) Classes of aliens the Secretary of Homeland Security and the Secretary of State jointly determine shall be exempt; or

(6) An individual alien whom the Secretary of Homeland Security, the Secretary of State, or the Director of Central Intelligence determines shall be exempt.

As a part of this test, CBP will also collect biographic information from all persons exiting the Otay Mesa port-of-entry.

Duration of Test

Beginning no earlier than December 7, 2015, CBP will collect facial and iris biometric data from non-exempt aliens subject to this notice upon arrival at the Otay Mesa land border port-of-entry.

Beginning no earlier than February 1, 2016, CBP will collect facial and iris biometric data from these non-exempt aliens when they exit the United States through the Otay Mesa land border port-of-entry.

Beginning no earlier than February 1, 2016, CBP will collect biographic information from all persons exiting the Otay Mesa port-of-entry.

This test will end on or before June 30, 2016.

For purposes of analysis, CBP will retain data collected from this test for approximately one year from the date of collection.

Privacy

CBP will ensure that all Privacy Act requirements and applicable policies are adhered to during the implementation of this test. Additionally, CBP will be issuing a Privacy Impact Assessment (PIA), which will outline how CBP will ensure compliance with Privacy Act protections. The PIA will examine the privacy impact of the Otay Mesa Land Border Port-of Entry Pedestrian Exit Test as it relates to DHS' Fair Information Practice Principles (FIPPs). The FIPPs account for the nature and purpose of the information being collected in relation to DHS' mission to preserve, protect and secure the United States. The PIA will address issues such as the security, integrity, and sharing of data, use limitation and transparency. Once issued, the PIA will be made publicly available at: *http://www.dhs.gov/privacy-documents-us-customs-and-border-protection.* CBP has also issued an update to the DHS/CBP–007 Border Crossing Information (BCI) System of Records, which fully encompasses all the data that is being collected at the Otay Mesa land border port-of-entry for purposes of this test. The system of records notice (SORN) was published in the **Federal Register** on May 11, 2015 (80 FR 26937).

Paperwork Reduction Act

CBP requires aliens subject to this notice to provide biometric and biographic data at the Otay Mesa port-of-entry in the circumstances described above. This requirement is considered an information collection requirement under the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*). The Office of Management and Budget (OMB), in accordance with the Paperwork Reduction Act, has previously approved this information collection for use. The OMB control number for this collection is 1651–0138.

Dated: November 9, 2015.

R. Gil Kerlikowske,

Commissioner.

[FR Doc. 2015–28843 Filed 11–12–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0108]

Agency Information Collection Activities: Canadian Border Boat Landing Permit

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Canadian Border Boat Landing Permit (CBP Form I–68). This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before December 14, 2015 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** (80 FR 25313) on May 4, 2015, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10. CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden, including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Canadian Border Boat Landing Permit.

OMB Number: 1651–0108.

Form Number: CBP Form I–68.

Abstract: The Canadian Border Boat Landing Permit (CBP Form I–68) allows participants entering the United States along the northern border by small pleasure boats weighing less than 5 tons to telephonically report their arrival without having to appear in person for an inspection by a CBP officer. United States citizens, Lawful Permanent Residents of the United States, Canadian citizens, and Landed Residents of Canada who are nationals of the Visa Waiver Program countries listed in 8 CFR 217.2(a) are eligible to participate.

The information collected on CBP Form I–68 allows people who enter the United States from Canada by small pleasure boats to be inspected only once during the boating season, rather than each time they make an entry. This information collection is provided for by 8 CFR 235.1(g) and Section 235 of Immigration and Nationality Act. CBP Form I–68 is accessible at *http://www.cbp.gov/newsroom/publications/forms?title=68&=Apply.*

Current Actions: This submission is being made to extend the expiration date with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Affected Public: Individuals or Households.

Estimated Number of Respondents: 68,000.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 11,288.

Estimated Annual Cost: $1,088,000.

Dated: November 9, 2015.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2015–28831 Filed 11–12–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Acyclovir Tablets

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (''CBP'') has issued a final determination concerning the country of origin of certain Acyclovir tablets. Based upon the facts presented, CBP has concluded that the country of origin of the Acyclovir Tablets is China and India for purposes of U.S. Government procurement.

DATES: The final determination was issued on November 5, 2015. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination no later than December 14, 2015.

FOR FURTHER INFORMATION CONTACT: Robert Dinerstein, Valuation and Special Programs Branch, Regulations

and Rulings, Office of International Trade (202) 325–0132.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on November 5, 2015, pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of certain Acyclovir Tablets, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ267177, was issued under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP concluded that the processing in the United States does not result in a substantial transformation. Therefore, the country of origin of the Acyclovir tablets is China and India for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: November 5, 2015.

Myles B. Harmon,

Acting Executive Director, Regulations and Rulings, Office of International Trade.

HQ H267177

November 5, 2015

MAR–2 OT:RR:CTF:VS H267177 RSD

CATEGORY: ORIGIN

Ms. Karen Yu, Regulatory Affairs, Carlsbad Technology Inc., 5923 Balfour Court, Carlsbad, California 92008

RE: U.S. Government procurement; Trade Agreements Act; Country of Origin of Acyclovir Tablets; Substantial Transformation

Dear Ms. Yu: This is in response to your ruling request dated July 7, 2015, requesting a final determination on behalf of Carlsbad Technology Inc., (Carlsbad) pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (CBP) Regulations (19 CFR part 177). Under these regulations, which implement Title III of the Trade Agreements Act of 1979 (''TAA''), as amended (19 U.S.C. 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain ''Buy American'' restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

This final determination concerns the country of origin of Acyclovir Tablets. As a U.S. manufacturer of a like product, Carlsbad Inc. is a party-at-interest within the meaning of 19 CFR 177.22(d)(1), and is entitled to request this final determination.

FACTS:

Acyclovir is a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The active pharmaceutical ingredient (''API''), Acyclovir is manufactured in China and India. The API is shipped to the U.S., where it undergoes five manufacturing steps. Inactive ingredient (excipients) used in the production of the product in the U.S. are corn starch, microcrystalline cellulose, magnesium stearate, and sodium starch glycolate.

The first stage of U.S. manufacturing is the sizing of the active and inactive ingredients including the corn starch glycolate, by passing them through a sieve to remove any larger granules.

The second stage of U.S. manufacturing is the preparation of Acyclovir granules. The Acyclovir API, corn starch, and sodium starch glycolate are de-lumped and granulated with a binding suspension of corn starch. The wet granules are then sieved through a comil and discharged into stainless steel drums. These granules are then moved to a tray dryer for a drying process for 10 to 18 hours or until it meets its dryness specification. The dried granules will then be sieved through a comil again and discharged into stainless steel drums. The third stage of U.S. manufacturing is the preparation of the tablet blend. The inactive ingredients, microcrystalline cellulose and sodium starch glycolated are de-lumped by passing them through a sieve and added to the de-lumped acyclovir granules for preblend. Then the magnesium stearate is sieved and added to the final blend. All the blended product is discharged into stainless steel drums. The fourth stage of U.S. manufacturing is tablet compression. The blended granules are then fed to a tablet press machine where the tablets are formed. The bulk tablets are collected into plastic bags, which are sealed and packaged in containers. The fifth stage of U.S. manufacturing is packaging in high density polyethylene plastic bottles. These bottles are then put into cartons for distribution in the U.S.

ISSUE:

What is the country of origin of the Acyclovir tablets processed as described above for purposes U.S. Government procurement?

LAW AND ANALYSIS:

Pursuant to Subpart B of Part 177, 19 CFR 177.21 *et seq.,* which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers if certain ''Buy American'' restrictions in U.S. law or practice for products offered for sale to the U.S. government.

Under the rule of origin set forth under 19 U.S.C. 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 CFR 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. government procurement, CBP applies the provisions of subpart B of part 177 consistent with the Federal Acquisition Regulations. *See* 19 CFR 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 CFR 25.403(c)(1). The Federal Acquisition Regulations define ''U.S.-made end product'' as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 CFR 25.003

A substantial transformation occurs when an article emerges from a process with a new name, character and use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States* v.

Gibson-Thomsen Co., 27 C.C.P.A. 267 (1940); and, *National Juice Products Association* v. *United States,* 628 F. Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. *See e.g.,* Headquarters Ruling Letter (''HQ'') 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; and, HQ 735146, dated November 15, 1993.

For instance, in HQ 561975, the anesthetic drug sevoflurane imported into the U.S. in bulk form and processed into dosage form by extensive testing operations, followed by filtering and packaging into bottles, was found not to have undergone a substantial transformation in the U.S. There was no change in name (the product was identified as sevoflurane in both its bulk and processed form). The sevoflurane retained its chemical and physical properties after the U.S. processing. Lastly, because the imported bulk sevoflurane had a predetermined medicinal use as an inhalable anesthetic drug, the processing in the United States resulted in no change in the product's use.

Likewise, in HQ 561544, the testing, filtering and sterile packaging of Geneticin Sulfate bulk powder, to create Geneticin Selective Antibiotic, was not found to have substantially transformed the antibiotic substance because the processing only involved the removal of impurities from the bulk chemical and the placement of the chemical into smaller packaging.

In HQ 735146, 100 percent pure acetaminophen imported from China was blended with excipients in the United States, granulated and sold to pharmaceutical companies to process into tablets for retail sale under private labels. It was found that the process in the United States did not substantially transform the imported product because the product was referred to as acetaminophen before importation and after U.S. processing, its use was for medicinal purposes and continued to be so used after U.S. processing, and the granulating process minimally affected the chemical and physical properties of the acetaminophen.

In HQ H233356 dated December 26, 2012, mefenamic acid imported from India was blended with excipients and packaged into dosage form in the United States. Based on prior rulings, we found that the specific processing consisting of blending the active ingredients with inactive ingredients in a tumbler and then encapsulating and packaging the product did not substantially transform the mefenamic acid because its chemical character remained the same. As such, we found that the country of origin of the Ponstel (mefenamic acid) capsules was India, where the mefanamic acid was manufactured.

In this case, the processing performed in the U.S. does not result in a change in the medicinal use of the finished product and the active ingredient. The Acyclovir retains its chemical and physical properties and is merely put into a dosage form and is packaged for sale. The active ingredient does not undergo a change in name, character or use. Therefore, in accordance with our prior rulings, we find that no substantial transformation occurs in U.S., and for purposes of government procurement, the Acyclovir tablets would be considered a product where the active ingredient was produced, which would be China and India.

HOLDING:

Based upon the facts in this case, we find that the imported Acyclovir is not substantially transformed in U.S. Accordingly, the country of origin for government procurement purposes of the Acyclovir tablets is China and India, where the active ingredient is produced.

Notice of this final determination will be given in the **Federal Register**, as required by 19 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31 that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of publication of the **Federal Register** notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Myles B. Harmon *Acting Executive Director*
Office of Regulations and Rulings
Office of International Trade

[FR Doc. 2015–28827 Filed 11–12–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0124]

Agency Information Collection Activities: Cargo Container and Road Vehicle Certification for Transport Under Customs Seal

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Cargo Container and Road Vehicle for Transport under Customs Seal. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before December 14, 2015 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** (80 FR 48117) on August 11, 2015, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10. CBP invites the general public and other Federal

agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden, including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Cargo Container and Road Vehicle for Transport under Customs Seal.

OMB Number: 1651–0124.

Abstract: The United States is a signatory to several international Customs conventions and is responsible for specifying the technical requirements that containers and road vehicles must meet to be acceptable for transport under Customs seal. Customs and Border Protection (CBP) has the responsibility of collecting information for the purpose of certifying containers and vehicles for international transport under Customs seal. A certification of compliance facilitates the movement of containers and road vehicles across international territories. The procedures for obtaining a certification of a container or vehicle are set forth in 19 CFR part 115.

Action: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 25.

Estimated Number of Annual Responses per Respondent: 120.

Estimated Time per Response: 3.5 hours.

Estimated Total Annual Burden Hours: 10,500.

Dated: November 4, 2015.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2015–28828 Filed 11–12–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Agency Information Collection Activities: National Initiative for Cybersecurity Careers and Studies (NICCS) Cybersecurity Training and Education Catalog (Training/Workforce Development Catalog) Collection

AGENCY: Cybersecurity Education & Awareness Office (CE&A), DHS.

ACTION: 30-Day notice and request for comments; reinstatement with change, 1601–0016.

SUMMARY: The Department of Homeland Security, Cybersecurity Education & Awareness Office (CE&A), will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). DHS previously published this information collection request (ICR) in the **Federal Register** on Wednesday, September 2, 2015 at 80 FR 53180 for a 60-day public comment period. No comments were received by DHS. The purpose of this notice is to allow additional 30-days for public comments.

DATES: Comments are encouraged and will be accepted until January 12, 2016. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to OMB Desk Officer, Department of Homeland Security and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

SUPPLEMENTARY INFORMATION: Title II, Homeland Security Act, 6 U.S.C. 121(d)(1) To access, receive, and analyze laws enforcement information, intelligence information and other information from agencies of the Federal Government, State and local government agencies . . . and Private sector entities and to integrate such information in support of the mission responsibilities of the Department. The following authorities also permit DHS to collect information of the type contemplated: Federal Information Security Management Act of 2002 (FISMA), 44 U.S.C. 3546; Homeland Security Presidential Directive (HSPD) 7, ''Critical Infrastructure Identification, Prioritization, and Protection'' (2003); and NSPD–54/HSPD–23, ''Cybersecurity Policy'' (2009).

In May 2009, the President ordered a Cyberspace Policy Review to develop a comprehensive approach to secure and defend America's infrastructure. The review built upon the Comprehensive National Cybersecurity Initiative (CNCI).

In response to increased cyber threats across the Nation, the National Initiative for Cybersecurity Education (NICE) expanded from a previous effort, the CNCI #8. NICE formed in March 2011, and is a nationally coordinated effort comprised of over 20 federal departments and agencies, and numerous partners in academia and industry. NICE focuses on cybersecurity awareness, education, training and professional development. NICE seeks to encourage and build cybersecurity awareness and competency across the Nation and to develop an agile, highly skilled cybersecurity workforce.

The NICCS Portal is a national online resource for cybersecurity awareness, education, talent management, and professional development and training. NICCS Portal is an implementation tool for NICE. Its mission is to provide comprehensive cybersecurity resources to the public.

To promote cybersecurity education, and to provide a comprehensive resource for the Nation, NICE developed the Cybersecurity Training and Education Catalog. The Cybersecurity Training and Education Catalog will be hosted on the NICCS Portal. Training Course and certification information will be included in the Training/Workforce Development Catalog. Note: Any information received from the public in support of the NICCS Portal and Cybersecurity Training and Education Catalog is completely voluntary. Organizations and individuals who do not provide information can still utilize the NICCS Portal and Cybersecurity Training and Education Catalog without restriction or penalty. An organization or individual who wants their information removed from the NICCS Portal and/or Cybersecurity Training and Education Catalog can email the NICCS Supervisory Office. There are no requirements for a provider to fill out a specific form for their information to be removed; standard email requests will be honored. Department of Homeland Security (DHS) Cybersecurity Education & Awareness Office (CE&A) intends for the collected information from the

NICCS Cybersecurity Training Course Form and the NICCS Cybersecurity Certification Form to be displayed on a publicly accessible Web site called the National Initiative for Cybersecurity Careers and Studies (NICCS) Portal (*http://niccs.us-cert.gov/*). Collected information from these two forms will be included in the Cybersecurity Training and Education Catalog that is hosted on the NICCS Portal.

The DHS CE&A NICCS Supervisory Office will use information collected from the NICCS Vetting Criteria Form to primarily manage communications with the training/workforce development providers; this collected information will not be shared with the public and is intended for internal use only. Additionally, this information will be used to validate training providers before uploading their training and certification information to the Training Catalog.

The information will be collected via fully electronic or partially electronic means. Collection will be coordinated between the public and DHS CE&A via email (*niccs@hq.dhs.gov*). The following form is fully electronic: NICCS Vetting Criteria Web Form. The following forms are partially electronic: NICCS Cybersecurity Training Course Form and NICCS Certification Course Form. All partially electronic forms are created in excel. The NICCS SO is looking to develop and transition partially electronic forms to fully electronic web forms. This transition is dependent on contract requirements and available department funding. All information collected from the NICCS Cybersecurity Training Course Form, the NICCS Cybersecurity Training Course Web Form, and the NICCS Certification Course Form will be stored in the public accessible NICCS Cybersecurity Training and Education Catalog (*http://niccs.us-cert.gov/training/training-home*). The NICCS Supervisory Office will electronically store information collected via the NICCS Vetting Criteria Form. This information will not be publicly accessible.

There is no assurance of confidentiality provided to the respondents. This collection is covered by the existing Privacy Impact Assessment, DHS General Contact List (DHS/ALL/PIA–006) and the existing Systems of Records Notice, Department of Homeland Security (DHS) Mailing and other Lists Systems (DHS/ALL/SORN–002). DHS CE&A has revised the collection to reflect three changes. These changes include the addition of: Training/WFD Provider Logo, Organization URL and National Cybersecurity Workforce Framework Role collection. These changes were added based on input received from the public. Including provider logos and an organization URL allows users to more easily find organization information. The addition of Cybersecurity Workforce Framework Role information will allow users to better align their courses with specific cybersecurity roles found in the newest Workforce Framework. The adjustments reported in the estimates of burden were based on historical data and current training provider outreach. The estimate of annualized cost was updated based off of actual wage.

The prior information collection request for OMB No. 1601–0016 was approved through April 30, 2015 by OMB. This collection will be submitted to OMB for review to request reinstatement of the collection. DHS CE&A has revised the collection to reflect three changes. These changes include the addition of: Training/WFD Provider Logo, Organization URL, National Cybersecurity Workforce Framework Role collection. These changes were added based on input received from the public. Including provider logos and an organization URL allows users to more easily find organization information. The addition of Cybersecurity Workforce Framework Role information will allow users to better align their courses with specific cybersecurity roles found in the newest Workforce Framework. The adjustments reported in the estimates of burden were based on historical data and current training provider outreach. The estimate of annualized cost was updated based off of actual wage.

The Office of Management and Budget is particularly interested in comments which:

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

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: Cybersecurity Education & Awareness Office, DHS.

Title: Agency Information Collection Activities: National Initiative for Cybersecurity Careers and Studies (NICCS) Cybersecurity Training and Education Catalog (Training/Workforce Development Catalog) Collection.

OMB Number: 1601–0016.

Frequency: On occasion.

Affected Public: Private Sector.

Number of Respondents: 1,000.

Estimated Time per Respondent: 2.5 hours.

Total Burden Hours: 2,125 hours.

Dated: November 5, 2015.

Carlene C. Ileto,

Executive Director, Enterprise Business Management Office.

[FR Doc. 2015–28884 Filed 11–12–15; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5828–N–46]

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: 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: 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; (This is not a toll-free number).

Dated: November 5, 2015.

Brian P. Fitzmaurice,

Director, Division of Community Assistance, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 11/13/2015

Suitable/Available Properties

Building

New York

Michael J. Dillon
U.S. Memorial Courthouse
68 Court Street
Buffalo NY 14202
Landholding Agency: GSA
Property Number: 54201540010
Status: Excess
GSA Number: NY–0993–AA
Comments: 180,950 gross sq. ft.; sits on 0.75 acres; 48+ months vacant; asbestos/LBP maybe present; eligible for Nat'l Register; subject to Historic Preserv. covenants; contact GSA for more info.

[FR Doc. 2015–28678 Filed 11–12–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2015–0162; FXIA 16710900000–156–FF09A30000]

Endangered Species; Marine Mammals; Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have issued the following permits to conduct certain activities with endangered species, marine mammals, or both. We issue these permits under the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA).

ADDRESSES: Brenda Tapia, U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358–2281.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (fax).

SUPPLEMENTARY INFORMATION: On the dates below, as authorized by the provisions of the ESA (16 U.S.C. 1531 *et seq.*), as amended, and/or the MMPA, as amended (16 U.S.C. 1361 *et seq.*), we issued requested permits subject to certain conditions set forth therein. For each permit for an endangered species, we found that (1) The application was filed in good faith, (2) The granted permit would not operate to the disadvantage of the endangered species, and (3) The granted permit would be consistent with the purposes and policy set forth in section 2 of the ESA.

ENDANGERED SPECIES

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
54794B ..	Tanganyika Wildlife Park	80 FR 33541; June 12, 2015	October 19, 2015.
68842B ..	Monty David	80 FR 39795; July 10, 2015	August, 12, 2015.
06588B ..	Frank Buck Zoo	80 FR 39795; July 10, 2015	October 30, 2015.
70086B ..	Timothy Twietmeyer	80 FR 43790; July 23, 2015	September 1, 2015.
59836B ..	The Wild Animal Sanctuary	80 FR 47947; August 10, 2015	October 13, 2015.
59837B ..	The Wild Animal Sanctuary	80 FR 47947; August 10, 2015	October 13, 2015.
669467 ..	Utica Zoo	80 FR 51299; August 24, 2015	October 15, 2015.

ENDANGERED SPECIES—Continued

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
73254B ..	William Mathers	80 FR 51299; August 24, 2015	October 5, 2015.
68861B ..	San Diego Zoo	80 FR 51299; August 24, 2015	October 30, 2015.

MARINE MAMMALS

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
225854 ..	Tom Smith	80 FR 16694; March 30, 2015	08/24/2015.
61681B ..	Florian Schulz	80 FR 46042; August 3, 2015	09/11/2015.

Availability of Documents

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to: U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, MS: IA, 5275 Leesburg Pike, Falls Church, VA 22041; fax (703) 358–2281.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2015–28781 Filed 11–12–15; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2015–0163: FXIA16710900000–156–FF09A30000]

Endangered Species; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibits activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before December 14, 2015.

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

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–IA–2015–0163.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2015–0163; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information). *Viewing Comments:* Comments and materials we receive will be available for public inspection on *http://www.regulations.gov,* or by appointment, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays, at the U.S. Fish and Wildlife Service, Division of Management Authority, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone 703–358–2095.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as

amended (16 U.S.C. 1531 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken.

III. Permit Applications

Endangered Species

Applicant: City of Idaho Falls Zoo, Idaho Falls, ID; PRT–73296B

The applicant requests a permit to export one captive-bred female snow leopard (*Uncia uncia*) for the purpose of enhancement of the survival of the species through captive breeding. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: San Francisco Zoological Society, San Francisco, CA; PRT–69861B

The applicant requests a permit to export one captive-bred male Francois langur (*Trachypithecus francoisi*) for the purpose of enhancement of the survival of the species captive-breeding. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Angelica Rodriquez/American Museum of Natural History, New York, NY; PRT–66999B

The applicant requests a permit to import biological samples from the lesser long-nosed bat (*Leptonycteris curasoae yerbabuenae*) collected from the wild in Mexico, for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Point Defiance Zoo and Aquarium, Tacoma, WA; PRT–71096B

The applicant requests a permit to import one captive-bred female Malayan tapir (*Tapirus indicus*) for the purpose of enhancement of the survival of the species through zoological display and captive propagation.

Applicant: University of Illinois, Veterinary Diagnostic Laboratory, Maywood, IL; PRT–73315B

The applicant requests a permit to re-export 49 glass slides and paraffin tissue blocks derived from captive-bred Cheetah (*Acinonyx jubatus*) for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Jerry Fife dba Fife Reptiles, Laveen, AZ; PRT–66860B

The applicant requests a permit to ten captive-bred Galapagos tortoise (*Chelonoidis nigra*) for the purpose of enhancement of the survival of the species through captive propagation.

Applicant: Fox Brown Outfitters, Indiantown, FL; PRT–71724B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: Barasingha (*Rucervus duvaucelii*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: The Sacramento Zoological Society, dba Sacramento Zoo, Sacramento, CA; PRT–677611

The applicant requests an amendment to their captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: Yellow-footed rock wallaby (*Petrogale xanthopus*). This notification covers activities to be conducted by the applicant over a 5-year period.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: David Hessler, Westlake OH; PRT–78797B

Applicant: Margaret Williams, Midland TX; PRT–79073B

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2015–28780 Filed 11–12–15; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[156A2100DD/AAKC001030/A0A501010.999900 253G]

Proclaiming Certain Lands as Reservation for the Cowlitz Indian Tribe

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of reservation proclamation.

SUMMARY: This notice informs the public that through the issuance of the Record of Decision on April 22, 2013 announcing the decision to acquire the subject property in trust, the Assistant Secretary—Indian Affairs proclaimed such subject property as the initial reservation of the Cowlitz Indian Tribe of Washington on November 6, 2015. The subject property was accepted by the United States in trust for the Tribe on March 9, 2015. Now that the subject property is held in trust by the United States for the Tribe, the Department is implementing its 2013 decision to proclaim the subject property as the initial reservation of the Tribe.

FOR FURTHER INFORMATION CONTACT: Sharlene Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1849 C Street NW., MS–4642–MIB, Washington, DC 20240, telephone (202) 208–3615.

SUPPLEMENTARY INFORMATION: This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by part 209 of the Departmental Manual.

A proclamation was issued according to the Act of June 18, 1934 (48 Stat. 984; 25 U.S.C. 467) for the land described below. The land was proclaimed to be the Cowlitz Indian Reservation of the Cowlitz Indian Tribe, County of Clark and State of Washington.

Cowlitz Indian Reservation

Legal description containing 156.401 acres, more or less [1]

PARCEL I—BEGINNING at the intersection of the West line of Primary State Highway No. 1 and the East line

[1] Prior to the transfer of the subject property into trust, the Department reviewed title evidence and the legal descriptions for the parcels comprising the subject property. At the time of the April 22, 2013 Record of Decision, these parcels were separately described in County records. Since that time, some of these parcels were consolidated in County records due to the parcels' common ownership. Accordingly, the legal description and estimated acreage total have been updated to reflect this consolidation in the title record and the final survey.

of the Southeast quarter of Section 5, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington; thence Northerly along said West line of Primary State Highway No. 1 a distance of 1307.5 feet to the Point of Beginning of this description; thence West 108.5 feet to an angle point thereon; thence Northerly along the fence 880.5 feet to the center line of a creek; thence Northerly along said creek 443 feet to the West line of Primary State Highway No. 1; thence Southerly along said West line of Highway to the Point of Beginning.

EXCEPT that portion conveyed to the State of Washington by Auditor's File Nos. G 450664 and G 147358.

PARCEL II—That portion of the Northeast quarter of the Northeast quarter of Section 8, and the West half of the Northwest quarter of Section 9, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington, described as follows:

COMMENCING at a railroad spike marking the North quarter corner of Section 8, as shown in Book 27 of Surveys, page 134, records of the Clark County Auditor; thence South 88°10′18″ East along the North line of the Northeast quarter of Section 8 for a distance of 1843.02 feet to the Point of Beginning; thence East to Highway Engineer's Station DB 9+50 on the DB line of SR–5 as shown on the Washington State Department of Highways Right of Way Plan ''Ridgefield Junction to Woodland'' Sheet 5 of 12 sheets dated August 10, 1965; thence South 01°49′42″ West 20.00 feet; thence South 78°34′39″ East 90.00 feet to a point 35 feet right of HES DB 10+38.74 (R/W Plan); thence South 34°20′13″ East 451.85 feet to a point 65 feet left of HES Co. Rd. No. 25 44+81.63 PT (R/W Plan); thence South 16°33′29″ East, 386.57 feet to a point 50 feet left of HES Co. Rd. No. 25 40+50 (R/W Plan); thence South 88°22′31″ East 50.00 feet to HES Co. Rd. No. 25 40+50 said point being on the section line between Sections 8 and 9; thence South 88°22′31″ East 50.00 feet; thence North 01°37′29″ East parallel with the West line of the Northwest quarter of Section 9 for a distance of 100.00 feet; thence South 80°57′04″ East, 42.57 feet to a point 160 feet left of the SR–5 ''L'' Line (R/W Plan); thence South 16°24′49″ East parallel with and 160 feet from, when measured perpendicular to the SR–5 ''L'' Line (R/W Plan), 586.32 feet to HES L 535+50 (R/W Plan); thence South 27°43′24″ East 101.98 feet to a point 140 feet left of HES L 534+50 (R/W Plan); thence South 16°24′49″ East parallel with and 140 feet from, when measured perpendicular to the SR–5 ''L'' Line (R/W Plan), 450.00 feet to a point 140.00 feet left of HES L 530+00 (R/W Plan); thence South 15°35′42″ East, 253.51 feet to the South line of the North half of the Southwest quarter of the Northwest quarter of Section 9; thence North 88°31′16″ West along said South line 537.76 feet to the West line of said Northwest quarter; thence North 01°37′29″ East along said West line 858.79 feet; thence North 88°07′39″ West 435.00 feet; thence South 01°37′29″ West 200.00 feet to the South line of the North half of the Northeast quarter of Section 8; thence North 88°07′39″ West along said South line 365.31 feet; thence North 01°29′02″ East parallel with the West line of said Northeast quarter 1316.97 feet to the Point of Beginning.

EXCEPT the right of way of NW 31st Avenue and NW 319th Street. Also known as Parcels II, III, VII and VIII of the Olson Survey recorded in Book 56, Page 193.

PARCEL IV—All that part of the Southeast quarter of Section 5, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington, lying West of Primary State Road No. 1 (Pacific Highway).

EXCEPT the Henry Ungemach tract recorded in Volume 76 of Deeds, page 33, records of Clark County, Washington, described as follows:

BEGINNING at a point 19.91 chains North of the Southwest corner of said Southeast quarter; thence East 13.48 chains to creek; thence Northerly along creek to North line of said Southeast quarter at a point 6.66 chains West of the Northeast corner thereof; thence West to Northwest corner of said Southeast quarter; thence South 19.91 chains to the Point of Beginning.

ALSO EXCEPT the John F. Anderson tract as conveyed by deed recorded under Auditor's File No. F 38759, records of Clark County, Washington, described as follows:

BEGINNING at the Northwest corner of the Southwest quarter of the Southeast quarter of Section 5, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington; and running thence East 514 feet; thence Southerly 340 feet; thence Northwesterly 487 feet to a point 196 feet due South of the Point of Beginning; thence North to the Point of Beginning.

ALSO EXCEPT that tract described as follows:

BEGINNING at a point 26 rods and 9 feet West of the Southeast corner of Section 5, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington; and running thence West 20 rods to County Road; thence North 182 feet; thence East 20 rods; thence South 182 feet to the Point of Beginning.

ALSO EXCEPT a certain reserved tract described as follows:

BEGINNING at the intersection of the West line of Primary State Highway No. 1 (Pacific Highway) and the East line of the Southeast quarter of said Section 5, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington; thence Northerly along said West line of Primary State Highway No. 1, a distance of 1307.5 feet to the True Point of Beginning of this description; thence West 108.5 feet to an angle point therein; thence Northerly along fence 880.5 feet to center line of creek; thence Northeasterly along said creek 443 feet, more or less, to the West line of Primary State Highway No. 1; thence Southerly along said West line of highway to the True Point of Beginning.

ALSO EXCEPT that portion thereof lying within Primary State Highway No. 1 (SR–5) as conveyed to the State of Washington by deed recorded under Auditor's File Nos. G 458085, G 143553 and D 94522.

ALSO EXCEPT the right of way of NW 319th Street and Primary State Highway No. 1.

PARCEL V—That portion of the Northwest quarter of the Northeast quarter of Section 8, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington, described as follows:

BEGINNING at a railroad spike marking the North quarter corner of Section 8 as shown in Book 27 of Surveys, page 134, records of the Clark County Auditor; thence South 88°10′18″ East along the North line of the Northwest quarter of the Northeast quarter of Section 8 for a distance of 921.75 feet; thence South 01°29′02″ West parallel with the West line of said Northwest quarter, 1316.26 feet to the South line thereof; thence North 88°07′39″ West along said South line, 921.76 feet to the Southwest corner of said Northwest quarter; thence North 01°29′02″ East along the West line of said Northwest quarter, 1315.55 feet to the Point of Beginning.

EXCEPT the right of way of NW 319th Street and NW 41st Avenue.

PARCEL VI—That portion of the North half of the Northeast quarter of Section 8, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington, described as follows:

BEGINNING at a railroad spike marking the North quarter corner of Section 8 as shown in Book 27 of Surveys, page 134, records of the Clark County Auditor; thence South 88°10′18″ East along the North line of the

Northeast quarter of Section 8 for a distance of 921.75 feet to the Point of Beginning; thence continuing along said North line, South 88°10′18″ East 921.26 feet; thence South 01°29′02″ West parallel with the West line of said Northeast quarter, 1316.97 feet to the South line of the North half of said Northeast quarter; thence North 88°07′39″ West along said South line, 921.26 feet; thence North 01°29′02″ East, 1316.26 feet to the Point of Beginning.

EXCEPT the right of way of NW 319th Street.

The above-described lands contain a total of 156.401 acres, more or less, which are subject to all valid rights, reservations, rights-of-way, and easements of record.

This proclamation does not affect title to the lands described above, nor does it affect any valid existing easements for public roads, highways, public utilities, railroads, and pipelines, or any other valid easements of rights-of-way or reservations of record.

Dated: November 6, 2015.

Kevin Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2015–28805 Filed 11–12–15; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO210000.16X.L11100000.PH0000 LXSISGST0000]

Extension of Public Comment Period and Schedule of Public Scoping Meetings and Public Meetings for the Proposed Withdrawal of Sagebrush Focal Areas in Idaho, Montana, Nevada, Oregon, Utah, and Wyoming, and an Associated Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: On September 24, 2015, the Bureau of Land Management (BLM) published a Notice of Proposed Withdrawal; Sagebrush Focal Areas; Idaho, Montana, Nevada, Oregon, Utah, and Wyoming and Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Withdrawal in the **Federal Register**. This notice extends the comment period for both the proposed withdrawal and initial scoping for the environmental impact statement (EIS) being prepared to consider the merits of the proposed withdrawal and announces the times, dates, and locations of public meetings.

DATES: Written or emailed comments for scoping for the EIS and on the proposed withdrawal may be submitted through January 15, 2016. In addition, through this Notice the BLM is also announcing that it will hold public meetings in December 2015 to focus on relevant issues and environmental concerns, identify possible alternatives, help determine the scope of the EIS, and provide an opportunity for public comments on the proposed withdrawal. For dates and locations for the scoping meetings, please see the **SUPPLEMENTARY INFORMATION** section below.

ADDRESSES: Written comments should be sent to the BLM Director, 1849 C Street NW. (WO–200), Washington, DC 20240 or emailed to *sagebrush_withdrawals@blm.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Mark Mackiewicz, BLM, by telephone at 435–636–3616. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to reach the BLM contact person. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM filed an application requesting the Assistant Secretary of the Interior for Land and Minerals Management to withdraw, subject to valid existing rights, approximately 10 million acres of BLM-managed public and National Forest System lands located in the States of Idaho, Montana, Nevada, Oregon, Utah and Wyoming from location and entry under the United States mining law, but not from leasing under the mineral or geothermal leasing or mineral materials laws.

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), the BLM will prepare an EIS and conduct public scoping meetings on the withdrawal from the mining law of approximately 10 million acres of BLM- and United States Forest Service-administered public lands, in 6 western states as identified in the **Federal Register** notice of September 24, 2015 (80 FR 57635). The period for initial scoping comments from the public has been extended from December 23, 2015, to January 15, 2016. These public scoping meetings will also meet the requirements under 43 CFR 2310 to provide public meetings for comment on the Notice of Proposed Withdrawal that published on September 24, 2015.

The dates, times, and locations of the meetings are as follows:

Dates & times	Locations	BLM contact
Dec. 14, 2051:		
5 p.m. to 7 p.m.	Harney County Chamber of Commerce, 484 North Broadway, Burns, OR 97720.	Jody Weil, 503–808–6287.
5 p.m. to 7 p.m.	Lakeview BLM District Office, 1301 South G Street, Lakeview, OR 97630.	Jody Weil, 503–808–6287.
5 p.m. to 7 p.m.	Salt Lake City BLM Office, 2370 South Decker Lake Drive, West Valley City, UT 84119.	Megan Crandall, 801–539–4020.
Dec. 15, 2015:		
4 p.m. to 6 p.m.	Best Western Vista Inn & Conference Center, 2645 Airport Way, Boise, ID 83709.	Erin Curtis, 208–373–4016.
5 p.m. to 7 p.m.	Rock Springs BLM Field Office, 280 Highway 191 North, Rock Springs, WY 82901.	Kristen Lenhardt, 307–775–6015.
5 p.m. to 7 p.m.	The Nugget, 1100 Nugget Avenue, Sparks, NV 89431	Steve Clutter, 775–861–6629.
Dec. 16, 2015.		
2 p.m. to 4 p.m.	Great Northern Hotel, 2 South 1st Street East, Malta, MT 59538	Al Nash, 406–896–5260.
4 p.m. to 6 p.m.	Shiloh Suites Conference Hotel, 780 Lindsay Blvd., Idaho Falls, ID 83402.	Erin Curtis, 208–373–4016.

Dates & times	Locations	BLM contact
5 p.m. to 7 p.m.	Elko Conference Center, 724 Moren Way, Elko, NV 89801	Steve Clutter, 775–861–6629.

The EIS will consider a No Action alternative and consider reasonably foreseeable mineral development activities. The EIS does not support a land-use plan or a land-use plan amendment. It will provide a comprehensive programmatic NEPA analysis for the proposed action of the Secretary of the Interior withdrawing these public lands from operation of the mining law for the conservation benefit of the Greater Sage-grouse.

The BLM has initially identified the following issues for analysis in this EIS: Air quality/climate, American Indian resources, cultural resources, wilderness and wilderness characteristics, mineral resources, public health and safety, recreation, social and economic conditions, soil resources, soundscapes, special status species, vegetation resources, visual resources, water resources, and fish and wildlife habitat.

In addition, the BLM expects to address economic effects of withdrawing these public lands from operation of the mining law, wildlife habitat conservation; improvement, restoration of ecosystem processes; protection of cultural resources, watershed and vegetative community health, new listings of threatened and endangered species and consideration of other sensitive and special status species.

Steve Ellis,

Deputy Director, Bureau of Land Management.

[FR Doc. 2015–28877 Filed 11–12–15; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVC00000.L16100000.DR0000; 14–08807; MO# 4500080864]

Opportunity To Comment on Changes to the Nevada and California Greater Sage-Grouse Bi-State Distinct Population Segment Carson City Field Office Consolidated Resource Management Plan and the Tonopah Field Office Resource Management Plan Amendment, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) is soliciting comments on significant changes to the Proposed Plan as set forth in the Greater Sage-Grouse Bi-State Distinct Population Segment (BSSG) Forest Plan Amendment and Final Environmental Impact Statement (EIS), announced on February 13, 2015. Following consideration of any comments on these changes, the BLM intends to issue a Record of Decision (ROD) amending the Carson City Field Office Consolidated Resource Management Plan and the Tonopah Field Office Resource Management Plan.

DATES: Written comments on the changes to the Proposed Plan will be accepted until December 14, 2015.

ADDRESSES: You may submit comments related to the significant changes to the Proposed Plan by any of the following methods:

- *Email: blm_nv_ccdowebmail@blm.gov.*
- *Fax:* 775–885–6147.
- *Mail:* BLM Carson City District, Attn: Colleen Sievers, Project Manager, 5665 Morgan Mill Rd., Carson City, NV 89701.

FOR FURTHER INFORMATION CONTACT: Colleen Sievers, Project Manager, telephone: 775–885–6168; address: 5665 Morgan Mill Rd., Carson City, NV 89701; email: *blm_nv_ccdowebmail@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The United States Forest Service (USFS) was the lead agency for preparing the BSSG Forest Plan Amendment (Plan Amendment) and Final EIS. As part of that effort and based on the analysis in the Final EIS, the BLM, a cooperating agency, proposes to amend the Carson City Field Office Consolidated Resource Management Plan and the Tonopah Field Office Resource Management Plan. Following the release of the Proposed Plan and the conclusion of the protest process, the BLM identified changes and a clarification for the Proposed Plan as explained below and determined, pursuant to the applicable authorities (43 CFR 1610.2(f)(5) and 43 CFR 1610.5–1(b)), that public comment on those measures is necessary. The environmental consequences of the proposed changes and clarification have been analyzed as part of the Plan Amendment and Final EIS. After considering any comments on these changes, the BLM expects to issue a ROD amending the Carson City Field Office Consolidated Resource Management Plan and the Tonopah Field Office Resource Management Plan.

The Environmental Protection Agency (EPA) published the Notice of Availability (NOA) for the BSSG Forest Plan Amendment/Draft EIS in the **Federal Register** on August 23, 2013 (78 FR 52524), which initiated a 90-day comment period. An NOA for the BSSG Forest Plan Amendment/Revised Draft EIS was published by the EPA on July 11, 2014 (79 FR 40100), which initiated a second 90-day comment period. The EPA published the NOA for the BSSG Forest Plan Amendment and Final EIS in the **Federal Register** on February 13, 2015 (80 FR 8081), which initiated a 30-day BLM protest period and 60-day Governors consistency review period. The Plan Amendment and Final EIS identified the BLM Plan as the Proposed Plan. The BLM received three protest letters. In response to those protests and based on additional policy discussions, the BLM has determined that it will clarify and make changes to the Proposed Plan.

The clarification and changes include: (1) Identifying disturbance levels within BSSG habitat; (2) Adjusting buffers for tall structures near active or pending leks; (3) Adding a restriction for new high-power transmission lines; and (4) Changing on-the-ground management for habitat connectivity. This notice identifies those clarifications and changes and initiates a 30-day public comment period (43 CFR 1610.2(f)(5) and 43 CFR 1610.5–1(b)).

Habitat Disturbance—Proposed Change

The BLM is changing the Proposed Plan, as it was set forth in the Plan Amendment and Final EIS, to set a total anthropogenic disturbance of no more than 3 percent of the total BSSG habitat on Federal lands within the Bodie Mountain/Grant, Desert Creek/Fales, and White Mountains population management unit boundaries (C–Wild–S–04), and a total anthropogenic disturbance of no more than 1.5 percent of the total BSSG habitat on Federal lands within the Pine Nut Mountains population management unit (PMU)

boundaries (C–Wild–S–05), due to higher presence of risk factors in the PMU as analyzed under Final EIS Alternative C. This change is being made in response to issues raised during the protest period and based on additional policy discussions.

Concerns were raised by the public that the BLM action was not adequate to protect BSSG and its habitat. Disturbance levels identified in the Final EIS will require site-specific project mitigation to insure no unmitigated net loss of habitat. This requires assessing habitat availability at the landscape scale.

Tall Structure Buffer—Proposed Change

As part of the protest process, the BLM found that it needed to correct an error in the Proposed Plan Amendment and Final EIS. The BLM found that it should have identified the buffer distance for tall structures as 4 miles from active or pending leks. This is consistent with management prescriptions proposed by the USFS. Specifically, the BLM proposes to adopt the action from Alternative C which states that tall structures, which could serve as predator perches, will not be authorized within 4 miles of an active or pending lek (C–LUSU–S–04). The 4-mile lek buffer accords with other prescriptions of surface disturbance in sage-grouse habitat and is consistent with best science available.

High-Voltage (≥120kV) Transmission Line—Proposed Change

The BLM is designating exclusion areas for new high-power (≥120kV) transmission lines in BSSG habitat. Specifically, new high-power (≥120kV) transmission line corridors, rights-of-way, facilities, or construction areas in habitat (outside of existing corridors) will not be authorized (C–Min–S–09). This change is being made in response to issues raised during the protest period and based on additional policy discussions and was analyzed under Alternative C in the EIS.

Connectivity Habitat—Proposed Change

The BLM is clarifying language from Alternative C to provide for management of connectivity habitat. The BSSG landscape is fragmented by areas of agriculture and urbanization, as well as areas of naturally occurring and encroaching pinyon-juniper vegetation. Sage-grouse habitats within and between PMU are often separated by stretches of unsuitable areas that may inhibit sage-grouse movements across the landscape. Alternative C provides a limited amount of management direction to maintain or enhance suitability of connective area. Alternative C includes a goal about habitat and movement and an objective of improving degraded habitat, including areas with conifer encroachment (*i.e.,* pinyon-juniper). Actions and Best Management Practices relating to connectivity apply primarily to mineral uses. Alternative C states that where valid existing rights exist, in connective habitat areas, vegetation characteristics suitable to sage-grouse should be maintained to the extent technically feasible (C–Min–S–01). In addition, Alternative C provides additional direction not specific to connectivity which states, ''Vegetation treatments and post-disturbance restoration should seed and/or transplant sagebrush to restore large patches of sagebrush cover and connect existing patches'' (C–Wild–S–02). Given the fragmented nature of the bi-state landscape and the level of apparent isolation of subpopulations, additional management direction for connective habitat area is necessary to facilitate sage-grouse movement, reduce isolation, and increase genetic interchange between subpopulations. This change is being made in response to policy discussions.

Please note that public comments and information submitted including names, street addresses, and email addresses of persons who submit comments will be available for public review and disclosure at the above address during regular business hours (7:30 a.m. to 4:30 p.m.), Monday through Friday, except holidays.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2

John F. Ruhs,

Acting State Director, Nevada.

[FR Doc. 2015–28876 Filed 11–12–15; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCA932000.L13400000.DQ0000. LXSSB0020000.16X]

Notice of Availability of the Desert Renewable Energy Conservation Plan Proposed Land Use Plan Amendment to the California Desert Conservation Plan and the Bakersfield and Bishop Resource Management Plans and Final Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) has prepared a Proposed Land Use Plan Amendment (LUPA) and Final Environmental Impact Statement (EIS) for the Desert Renewable Energy Conservation Plan (DRECP). This LUPA would amend the California Desert Conservation Area (CDCA) Plan and the Bakersfield and Bishop Resource Management Plans (RMPs). By this notice, the BLM is announcing the availability of the Proposed LUPA and Final EIS.

DATES: BLM planning regulations state that any person who meets the conditions as described in the regulations may protest the BLM's Proposed LUPA/Final EIS. A person who meets the conditions and files a protest must do so within 30 days of the date that the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**.

ADDRESSES: Copies of the DRECP Proposed LUPA and Final EIS have been sent to affected Federal, State, and local government agencies, affected tribal governments, and to other stakeholders. The Proposed LUPA and Final EIS are available for review online at *www.drecp.org* and *www.blm.gov/ca/drecp.* See the **SUPPLEMENTARY INFORMATION** section below for a list of locations where copies of the Proposed LUPA and Final EIS are available for public inspection.

All protests must be in writing and mailed to one of the following addresses: Regular Mail: BLM Director (210), Attention: Protest Coordinator, P.O. Box 71383, Washington, DC 20024–1383; Overnight Delivery: BLM Director (210), Attention: Protest Coordinator, 20 M Street SE., Room 2134LM, Washington, DC 20003.

FOR FURTHER INFORMATION CONTACT: Vicki Campbell, Program Manager,

DRECP, telephone 916–978–4401; address BLM California State Office, 2800 Cottage Way, Suite W–1623, Sacramento, CA; email *vlcampbell@blm.gov*. To request a DVD, please send an email to *drecp.info@energy.ca.gov* or call 1–866–936–7477 to provide a mailing address. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1 800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM developed the DRECP to: (1) Advance Federal and State natural resource conservation goals and other Federal land management goals; (2) Meet the requirements of the Federal Endangered Species Act, Omnibus Public Land Management Act of 2009 (OPLMA), California Endangered Species Act, Natural Community Conservation Planning Act, and FLPMA in the Mojave and Colorado/Sonoran desert region of Southern California; and (3) Facilitate the timely and streamlined permitting of renewable energy projects. The Draft DRECP includes a strategy that identifies and maps potential areas for renewable energy development and areas for long-term natural resource conservation. The Draft DRECP was published on September 26, 2014 (79 FR 57971), and comments were accepted until February 23, 2015.

In March 2015, the DRECP partner agencies (the BLM, California Energy Commission, U.S. Fish and Wildlife Service, and California Department of Fish and Wildlife) announced a phased approach to completing the DRECP. As part of this approach, the BLM's component of the DRECP is being finalized first in Phase I, outlining important designations for conservation and renewable energy on public lands.

The Proposed DRECP LUPA would amend the CDCA Plan for the entire CDCA, and the RMPs for portions of the Bishop and Bakersfield Field Offices, which includes the Mojave Desert and Colorado/Sonoran Desert ecoregion subareas in California. The DRECP Plan Area includes all or a portion of the following counties: Imperial, Inyo, Kern, Los Angeles, Riverside, San Bernardino, and San Diego. The DRECP Plan Area covers approximately 22,585,000 acres, of which approximately 9,784,000 acres are BLM-administered lands. An additional 1,085,000 acres of BLM-administered lands are within the CDCA but outside of the DRECP Plan Area.

The BLM's objectives for the Proposed DRECP LUPA and Final EIS are to:

- Conserve biological, physical, cultural, social, and scenic resources;
- Promote renewable energy and transmission development, consistent with Federal renewable energy and transmission goals and policies, in consideration of State renewable energy targets;
- Comply with all applicable Federal laws, including the BLM's obligation to manage the public lands consistent with FLPMA;
- ''Preserve the unique and irreplaceable resources, including archaeological values, and conserve the use of the economic resources'' of the CDCA (FLPMA 601(a)(6), 43 U.S.C. 1781(a)(6));
- Incorporate goals, objectives, and allowable uses on areas of the public lands managed for conservation purposes within the CDCA and which the BLM identifies as components of the National Landscape Conservation System, consistent with the Omnibus Public Land Management Act of 2009 (Public Law 111–11);
- Amend land use plans consistent with the criteria in FLPMA and the CDCA Plan;
- Coordinate planning and management activities with other Federal, State, local, and tribal planning and management programs by considering the policies of approved land resource management programs, to the extent consistent with Federal law; and
- Make some land use allocation decisions outside the DRECP area but within the CDCA, including Visual Resource Management Classes and land use allocations to replace multiple-use classes.

Following the publication of the Proposed LUPA and Final EIS, the BLM expects to issue a decision that will identify the public lands in the CDCA that Congress included in the National Landscape Conservation System under Section 2002(b)(2)(D) of Public Law 111–11. The Proposed LUPA and Final EIS would define the goals, objectives, and allowable uses within those lands. It would also identify areas suitable for renewable energy development (Development Focus Areas or DFAs); Areas of Critical Environmental Concern and Wildlife Allocation Areas; areas suitable for an emphasis on recreation (Special Recreation Management Areas and Extensive Recreation Management Areas), and areas that would continue to be managed for other uses. In addition, the Proposed LUPA and Final EIS contemplate modifications in the management of recreation (including the establishment of Special Recreation Management Areas and Extensive Recreation Management Areas), allowing for continued exploration of mineral resources, establishment of Visual Resource Management Classes, and grazing. The Proposed LUPA and Final EIS also incorporate proposed mitigation measures to be considered in relation to future authorized uses on the public lands and activities on non-public lands that could adversely affect public land resources. The BLM consulted with tribes and carefully considered tribal comments when developing proposed DFAs and conservation areas and other elements of the proposed LUPA.

The Proposed DRECP LUPA and Final EIS include the BLM's proposed alternative, four additional action alternatives, and a no action alternative. Action alternatives analyzed in detail are the result of integrating varying locations and configurations for renewable energy and conservation on BLM-managed lands. These alternatives were developed through the interagency process that led to the development of the Draft DRECP. The preferred alternative in the draft DRECP/Draft EIS has been modified based on public comment.

The alternatives differ in the following ways:

- Areas suitable for renewable energy: The alternatives range from 81,000 acres of Development Focus Areas (Alternative 1) to 718,000 acres of Development Focus Areas (Alternative 2). Under the No Action Alternative, 2,804,000 acres would be open to some form of renewable energy development. The Proposed Alternative identifies 388,000 acres of Development Focus Areas. The alternatives include Conservation and Management Actions for development in these areas.
- Conservation Designations: With respect to lands to be included in the National Landscape Conservation System, the alternatives range from 3,264,000 acres (Alternative 1) to 5,113,000 acres (Alternative 2). Under the No Action Alternative, no lands would be identified as National Conservation Lands, although 2,966,000 acres would remain as Areas of Critical Environmental Concern. The Proposed Alternative would identify 3,856,000 acres of National Conservation Lands. The alternatives also analyze a range of management actions for National Conservation Lands. In addition, the Proposed LUPA and Final EIS would identify new and expanded Areas of Critical Environmental Concern. The Proposed Alternative would identify approximately 4,717,000 acres of

ACECs, although approximately 3,337,000 acres would overlap with proposed National Conservation Lands.

• Recreation: The Proposed LUPA and Final EIS would identify Special Recreation Management Areas (SRMAs) and Extensive Recreation Management Areas (ERMAs). The alternatives range from 2,537,000 acres of SRMA (Alternative 1) and 2,458,000 acres of SRMA (Proposed Alternative). The Proposed Alternative would also include 946,000 acres of ERMAs. Under the No Action Alternative, there would be zero acres of ERMA, 193,000 acres of SRMA, and 1,465,000 acres managed for recreation emphasis.

Comments on the Draft RMP/Draft EIS received from the public and internal BLM review were considered and incorporated as appropriate into the proposed plan. Public comments resulted in the addition of clarifying text, but did not significantly change proposed land use plan decisions.

Instructions for filing a protest with the Director of the BLM regarding the Proposed LUPA/Final EIS may be found in the ''Dear Reader'' Letter of the DRECP Proposed LUPA and Final EIS and at 43 CFR 1610.5–2. All protests must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section above. Emailed protests will not be accepted as valid protests unless the protesting party also provides the original protest by either regular or overnight mail postmarked by the close of the protest period. Under these conditions, the BLM will consider the emailed protest as an advance copy and it will receive full consideration. If you wish to provide the BLM with such advance notification, please direct emails to: *protest@blm.gov.*

Copies of the Proposed LUPA and Final EIS are available for public inspection at the following locations:

• BLM California State Office, 2800 Cottage Way, Suite W–1623, Sacramento, CA 95825;

• BLM California Desert District Office, 22835 Calle San Juan De Los Lagos, Moreno Valley, CA 92553;

• BLM Barstow Field Office, 2601 Barstow Road, Barstow, CA 92311;

• BLM El Centro Field Office, 1661 S. 4th Street, El Centro, CA 92243;

• BLM Needles Field Office, 1303 S. Highway 95, Needles, CA 92363;

• BLM Palm Springs South Coast Field Office, 1201 Bird Center Drive, Palm Springs, CA 92262;

• BLM Ridgecrest Field Office, 300 S. Richmond Road, Ridgecrest, CA 93555;

• BLM Bakersfield Field Office, 3801 Pegasus Drive, Bakersfield, CA 93308;

• BLM Bishop Field Office, 351 Pacu Lane, Suite 100, Bishop, CA 93514; and

• FWS Palm Springs Fish and Wildlife Office, 777 East Tahquitz Canyon Way, Suite 208, Palm Springs, CA 92262.

Electronic copies will also be available at public libraries throughout the Planning Area. See the project Web site above or contact the BLM for further information on other locations.

Before including your phone number, email address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2, 43 CFR 1610.5.

Thomas Pogacnik,

Deputy State Director, Bureau of Land Management.

[FR Doc. 2015–28791 Filed 11–12–15; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–19542;PPWOCRADN0–PCU00RP15.R50000]

Native American Graves Protection and Repatriation Review Committee: Notice of Nomination Solicitation

AGENCY: National Park Service, Interior.

ACTION: Notice of request for nominations.

SUMMARY: The National Park Service is seeking nominations for one member of the Native American Graves Protection and Repatriation Review Committee (Review Committee). The Secretary of the Interior will appoint the member from nominations submitted by Indian tribes, Native Hawaiian organizations, and traditional Native American religious leaders. The nominee need not be a traditional Indian religious leader.

DATES: Nominations must be received by December 14, 2015.

ADDRESSES: Melanie O'Brien, Program Manager, National NAGPRA Program (2253), National Park Service, 1849 C Street NW., Washington, DC 20240, or via email *nagpra_dfo@nps.gov.*

SUPPLEMENTARY INFORMATION: The Review Committee was established by the Native American Graves Protection and Repatriation Act of 1990 (NAGPRA), at 25 U.S.C. 3006, 5 U.S.C. Appendix 2.

The Review Committee is responsible for:

1. Monitoring the NAGPRA inventory and identification process;

2. reviewing and making findings related to the identity or cultural affiliation of cultural items, or the return of such items;

3. facilitating the resolution of disputes;

4. compiling an inventory of culturally unidentifiable human remains and developing a process for disposition of such remains;

5. consulting with Indian tribes and Native Hawaiian organizations and museums on matters within the scope of the work of the Review Committee affecting such tribes or organizations;

6. consulting with the Secretary of the Interior in the development of regulations to carry out NAGPRA; and

7. making recommendations regarding future care of repatriated cultural items.

The Review Committee consists of seven members appointed by the Secretary of the Interior. The Secretary may not appoint Federal officers or employees to the Review Committee. Three members are appointed from nominations submitted by Indian tribes, Native Hawaiian organizations, and traditional Native American religious leaders. At least two of these members must be traditional Indian religious leaders. Three members are appointed from nominations submitted by national museum or scientific organizations. One member is appointed from a list of persons developed and consented to by all of the other members.

Members serve as Special Government Employees, which requires completion of annual ethics training. Members are appointed for 4-year terms and incumbent members may be reappointed for 2-year terms. The Review Committee's work takes place during public meetings. The Review Committee normally meets in person two times per year, normally for two or three days. The Review Committee may also hold one or more public teleconferences of several hours duration.

Review Committee members serve without pay but shall be reimbursed for each day the member participates in Review Committee meetings. Review Committee members are reimbursed for travel expenses incurred in association with Review Committee meetings (25 U.S.C. 3006(b)(4)). Additional information regarding the Review Committee, including the Review Committee's charter, meeting protocol, and dispute resolution procedures, is available on the National NAGPRA

Program Web site, at *www.nps.gov/NAGPRA/REVIEW/.*

Individuals who are federally registered lobbyists are ineligible to serve on all FACA and non-FACA boards, committees, or councils in an individual capacity. The term ''individual capacity'' refers to individuals who are appointed to exercise their own individual best judgment on behalf of the government, such as when they are designated Special Government Employees, rather than being appointed to represent a particular interest.

Nominations should:

1. Be submitted on the official letterhead of the tribe or organization.
2. Affirm that the signatory is the official authorized by the tribe or organization to submit the nomination.
3. Nominations by a traditional religious leader must explain that he or she is a traditional religious leader.
4. Include the nominee's full legal name, home address, home telephone number, and email address.
5. Include the nominee's resume or a brief biography of the nominee, in which the nominee's NAGPRA experience and ability to work as a member of a Federal advisory committee are addressed.

FOR FURTHER INFORMATION CONTACT: Melanie O'Brien, Program Manager, National NAGPRA Program (2253), National Park Service, 1849 C Street NW., Washington, DC 20240, or via email *nagpra_dfo@nps.gov.*

Dated: October 30, 2015.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2015–28826 Filed 11–12–15; 8:45 am]

BILLING CODE 4310–EE–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Aquarium Fittings and Parts Thereof, DN 3098;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at EDIS [1], and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at USITC.[2] The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at EDIS.[3] Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of HYDOR USA Inc. on November 6, 2015. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain aquarium fittings and parts thereof. The complaint names as a respondent JEBAO CO., LTD of China. The complainant requests that the Commission issue a general exclusion order, a limited exclusion order, a cease and desist order, and a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3098'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures[4]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such

[1] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[2] United States International Trade Commission (USITC): *http://edis.usitc.gov.*

[3] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[4] Handbook for Electronic Filing Procedures: *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf.*

treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[5]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: November 6, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–28800 Filed 11–12–15; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–15–038]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 13, 2015 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote in Inv. Nos. 701–TA–548 and 731–TA–1298 (Preliminary)(Welded Stainless Steel Pressure Pipe from India). The Commission is currently scheduled to complete and file its determinations on November 16, 2015; views of the Commission are currently scheduled to be completed and filed on November 23, 2015.
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: November 4, 2015.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2015–29142 Filed 11–10–15; 4:15 pm]

BILLING CODE 7020–02–P

LEGAL SERVICES CORPORATION

Notice of Intent To Award—Grant Awards for the Provision of Civil Legal Services to Eligible Low-Income Clients in February 2016

AGENCY: Legal Services Corporation.

ACTION: Announcement of intention to make FY 2016 Grant Awards for Service Area MI–13 in southeastern Michigan.

SUMMARY: The Legal Services Corporation (LSC) hereby announces its intention to award grants to provide economical and effective delivery of high quality civil legal services to eligible low-income clients in southeastern Michigan in February 2016.

DATES: All comments and recommendations must be received on or before the close of business on December 14, 2015.

ADDRESSES: Legal Services Corporation—Grants Awards, Legal Services Corporation; 3333 K Street NW., Third Floor; Washington, DC 20007.

FOR FURTHER INFORMATION CONTACT: Reginald Haley, Office of Program Performance, at (202) 295–1545, or *haleyr@lsc.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to LSC's announcement of funding availability on September 22, 2015, 80 FR 57235, LSC intends to award funds to provide civil legal services in southeastern Michigan. The service area is comprised of Macomb, Oakland, and Wayne Counties. The applicants for the service area are listed below. The amounts below reflect the funding amounts for 2015 grant awards to each service area. These amounts will change based on the 2016 census adjustment and the final FY2016 appropriation. LSC will post all updates and/or changes to this notice at *http://www.grants.lsc.gov/grants-grantee-resources.* Interested parties are asked to visit *http://www.grants.lsc.gov/grants-grantee-resources* regularly for updates on the LSC grants process.

Name of applicant organization	State	Service area	Estimated annualized 2016 funding
Lakeshore Legal Aid	MI	MI–13	$ 4,368,810
Legal Aid and Defender Association	MI	MI–13	4,368,810

The grant will be awarded under the authority conferred on LSC by section 1006(a)(1) of the Legal Services Corporation Act, 42 U.S.C. 2996e(a)(l). The award will be made so that the service area is served, although no listed organization is guaranteed an award. The grant will become effective and grant funds will be distributed in February 2016.

This notice is issued pursuant to 42 U.S.C. 2996f(f). Comments and recommendations concerning potential grantees are invited, and should be delivered to LSC within thirty (30) days from the date of publication of this notice.

Dated: November 9, 2015.

Stefanie K. Davis,

Assistant General Counsel.

[FR Doc. 2015–28812 Filed 11–12–15; 8:45 am]

BILLING CODE 7050–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act: Notice of Agency Meeting

TIME AND DATE: 3:00 p.m., Wednesday, November 18, 2015.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed Credit Union/Bank Merger. Closed pursuant to Exemption (8).

[5] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

RECESS: 3:30 p.m.

TIME AND DATE: 10:00 a.m., Thursday, November 19, 2015.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street (All visitors must use Diagonal Road Entrance), Alexandria, VA 22314–3428.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Corporate Stabilization Fund Quarterly Report.
2. 2016/2017 Annual Performance Plan.
3. NCUA Rules and Regulations, Chartering and Fields of Membership.
4. NCUA's 2016/2017 Operating Budget and 2016/2017 Corporate Stabilization Fund Oversight Budget.
5. 2016 Overhead Transfer Rate.
6. 2016 Operating Fee Assessment Scale.

FOR FURTHER INFORMATION CONTACT: Gerard Poliquin, Secretary of the Board, Telephone: 703–518–6304.

Gerard Poliquin,

Secretary of the Board.

[FR Doc. 2015–29187 Filed 11–10–15; 4:15 pm]

BILLING CODE 7535–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings; National Science Board

The National Science Board, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of meetings for the transaction of National Science Board business, as follows:

DATE AND TIME: November 18, 2015 from 8 a.m. to 5 p.m. and November 19, 2015 from 8:30 a.m. to 2:10 p.m. (EST).

PLACE: These meetings will be held at the National Science Foundation, 4201Wilson Blvd., Room 1235, Arlington, VA 22230. All visitors must contact the Board Office (call 703–292–7000 or send an email message to *nationalsciencebrd@nsf.gov*) at least 24 hours prior to the meeting and provide name and organizational affiliation. Visitors must report to the NSF visitor desk located in the lobby at the 9th and N. Stuart Streets entrance to receive a visitor's badge.

WEBCAST INFORMATION: Public meetings and public portions of meetings will be webcast. To view the meetings, go to *http://www.tvworldwide.com/events/nsf/151118/* and follow the instructions.

UPDATES: Please refer to the National Science Board Web site for additional information. Meeting information and schedule updates (time, place, subject matter or status of meeting) may be found at *http://www.nsf.gov/nsb/meetings/notices.jsp.*

AGENCY CONTACT: Ron Campbell, *jrcampbe@nsf.gov,* (703) 292–7000.

PUBLIC AFFAIRS CONTACT: Nadine Lymn, *nlymn@nsf.gov,* (703) 292–2490.

STATUS: Portions open; portions closed.

OPEN SESSIONS:

November 18, 2015

8–8:30 a.m. (Plenary introduction, Chair and Director Reports)
8:30–9 a.m. (AO)
9:55–11:55 a.m. (CPP)
12:55–2 p.m. (SEI)

November 19, 2015

8:30–9:15 a.m. (AB)
9:15–9:35 a.m. (SCF)
9:35–10:10 a.m. (CSB)
11:50 a.m.–12:10 p.m. (NPP)
1:10–1:55 p.m. (CEH)
1:55–2:10 p.m. (Plenary)

CLOSED SESSIONS:

November 18, 2015

9–9:45 a.m. (AO)
2–2:45 p.m. (NPP)
3–3:50 p.m. (CPP)
3:50–4:30 p.m. (Plenary closed)
4:30–5 p.m. (Plenary executive closed)

November 19, 2015

10:20–11:50 a.m. (CPP/SCF joint meeting)

MATTERS TO BE DISCUSSED:

Wednesday, November 18, 2015

Plenary Board Meeting

Open Session: 8–8:30 a.m.

- Introduction and NSB Chair's Report
- NSF Director's Report

Committee on Audit & Oversight (AO)

Open Session: 8:30–9 a.m.

- AO Chair's opening remarks
- Approval of August 2015 open meeting minutes
- Approval of OIG Semiannual Report to Congress
- Inspector General's update
- Chief Financial Officer's update
- AO Chair's closing remarks

Audit and Oversight Committee

Closed Session: 9–9:45 a.m.

- AO Chair's opening remarks
- Approval of August 2015 closed AO meeting minutes
- Report on status of National Academy of Public Administration (NAPA) study
- AO Chair's closing remarks

Committee on Programs and Plans (CPP)

Open Session: 9:55–11:55 a.m.

- CPP Chair's opening remarks
  - Update: CY 2015 schedule of planned action and information items; update for the August 2015 meeting
  - CY 2016 Schedule of Planned Action and Information Items
  - Update: National Nanotechnology Coordinated Infrastructure (NNCI)
  - iPlant Status update
- Approval of open CPP meeting minutes for the August 2015 meeting
- Overview of Geosciences Infrastructure Investments: Status and Timelines
- Information Item: High Performance Computing (HPC)
- NSB Recompetition Policy and Statement
- Report on NSB Antarctic Site Visit
- CPP Chair's closing remarks

Committee on Science & Engineering Indicators (SEI)

Open Session: 12:55–2 p.m.

- SEI Chair's opening remarks
- Approval of the open SEI August 2015 meeting minutes
- Discussion and approval of the 2016 Overview and Digest
- Update on the 2016 digital *Indicators*
- Discussion of 'companion briefs' (formerly 'vignettes')
- Discussion of *Indicators* future directions: possible 2016 workshop
- SEI Chair's closing remarks

Ad hoc Task Force on NEON Performance and Plans (NPP)

Closed Session: 2–2:45 p.m.

- NPP Chair's opening remarks
- Approval of closed teleconference minutes of October 8 and October 23, 2015
- NSF Director's update on NEON
- Update on NPP Task Force activities and next steps
- NPP Chair's closing remarks

Committee on Programs and Plans (CPP)

Closed Session: 3–3:50 p.m.

- CPP Chair's opening remarks
- Approval of closed CPP minutes for August 2015 meeting
- Action Item: National Radio Astronomy Observatory (NRAO)
- CPP Chair's closing remarks

Plenary Board Meeting

Closed Session: 3:50–4:30 p.m.

- NSB Chair's opening remarks
- Approval of closed plenary minutes for August 2015

- Approval of NRAO preliminary resolution
- NSF Director's report
- Closed committee reports
- NSB Chair's closing remarks

Plenary Board Meeting

Executive Closed Session: 4:30–5 p.m.

- NSB Chair's opening remarks
- Approval of executive closed session minutes for August 2015
- Elect four members to the Elections Committee (to nominate candidates for May 2016 elections of NSB Chair, Vice-Chair, and two Executive Committee members)
- Approval of Honorary Awards recommendations
- Report from the NOMS Committee
- Board member NSF grant awards
- NSB Chair's closing remarks

MATTERS TO BE DISCUSSED:

Thursday, November 19, 2015

Working Group on Administrative Burdens (AB)

Open Session: 8:30–9:15 a.m.

- AB Working Group Chair's opening remarks
- Approval of open AB working group minutes for August 2015
- Discussion of National Academies of Science Report
- AB Working Group Chair's closing remarks

Subcommittee on Facilities (SCF)

Open Session: 9:15–9:35 a.m.

- SCF Chair's opening remarks
- Approval of open SCF teleconference minutes from November 2, 2015
- Discussion of SCF's role and charge
- SCF Chair's closing remarks

Committee on Strategy and Budget (CSB)

Open Session: 9:35–10:10 a.m.

- CSB Chair's opening remarks
- Approval of CSB open minutes for the August 2015 meeting
- Approval of the 2014 Annual Portfolio Review
- Information Item: NSF International Strategy

CPP/SCF Joint Meeting

10:20–11:50 a.m.

- CPP Chair's opening remarks
- Discussion: The Evolving Needs of Science and Engineering Infrastructure
- Antarctic Infrastructure Modernization for Science (AIMS) update

Ad hoc Task Force on NEON Performance and Plans (NPP)

Open Session: 11:50 a.m.–12:10 p.m.

- NPP Chair's opening remarks
- NPP Chair's report on NPP activities
- Discussion: New NSB product for monitoring large facilities

Committee on Education and Human Resources (CEH)

Open Session: 1:10–1:55 p.m.

- CEH Chair's opening remarks
- Approval of CEH open minutes for the August 2015 meeting
- Vision and plan for grand challenges in STEM education
- CEH Chair's closing remarks

Plenary Board Meeting

Open Session: 1:55–2:10 p.m.

- NSB Chair's opening remarks
- NSF Director's remarks
- Approval of plenary open session minutes for August 2015 meeting
- Approval of the 2014 Annual Portfolio Review
- Confirm *ad hoc* Honorary Awards Committee as a standing committee
- Approval of the 2016 SEI Overview and Digest
- Approval of the OIG Semiannual Report to Congress
- Open committee reports
- NSB Chair's closing remarks

MEETING ADJOURNS: 2:10 p.m.

Kyscha Slater-Williams,

Program Specialist, National Science Board.

[FR Doc. 2015–29167 Filed 11–10–15; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of permit applications received under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 Part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by December 14, 2015. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Division of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, at the above address or *ACApermits@nsf.gov* or (703) 292–7149.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

1. Applicant

Permit Application: 2016–019

Dr. Diana H. Wall, School of Global Environmental Sustainability, Colorado State University, Fort Collins, CO 80523–1036.

Activity for Which Permit Is Requested

ASPA entry, Import. Applicant wishes to enter Cape Royds ASPA 121 to collect soil samples and associated invertebrates as well as benthic algal mats and underlying soil. This project follows up on several past surveys of orthinogenic soils conducted in this ASPA which examined invertebrate genetic distribution, and also explores the influence of climate change on soil invertebrate populations. The algae sampling is to also follow up on previous surveys, to examine the temporal stability of lake algal communities in the region. Soil samples of approximately 600 grams each would be collected at up to 30 sites within the ASPA using sterile collecting techniques. For benthic algae, at 6 sites along the shore of Poly Lake, the applicant and team would use a sanitized 2 cm copper coring apparatus to collect, by hand, 4 replicates of surface algal mats and 1–2 cm of underlying sediment. Samples would be transported back to the US for further study.

Location

ASPA 121 Cape Royds

Dates

January 1, 2016 to February 15, 2016

Nadene G. Kennedy,

Polar Coordination Specialist, Division of Polar Programs.

[FR Doc. 2015–28799 Filed 11–12–15; 8:45 am]

BILLING CODE 7555–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–14 and CP2016–17; Order No. 2809]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Express & Priority Mail Contract 21 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:* November 16, 2015.

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:

Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Express & Priority Mail Contract 21 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, 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 Nos. MC2016–14 and CP2016–17 to consider the Request pertaining to the proposed Priority Mail Express & Priority Mail Contract 21 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 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 November 16, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–14 and CP2016–17 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than November 16, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2015–28881 Filed 11–12–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Express and Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* November 13, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 6, 2015, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 21 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–14, CP2016–17.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2015–28783 Filed 11–12–15; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76390; File No. SR–NSX–2015–05]

Self-Regulatory Organizations; National Stock Exchange, Inc.; Notice of Filing of Proposed Rule Change Amending Rule 11.1, Hours of Trading, To Rescind Interpretations and Policies .01, ''Cessation of Trading Operations on NSX;'' Adopting Rule 11.25 Relating to Use of Market Data Feeds; Amending NSX Rule 11.13 Relating to the Order Delivery Mode of Order Interaction; Amending NSX Rule 11.11 To Remove Certain Order Types and Correct Technical Deficiencies in the Numbering of Certain Sections of the Rule; and Amending Rule 11.12, Cross Message and Making Conforming Amendments to NSX Rules 11.11(c) and 16.2

November 9, 2015.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Exchange Act'' or ''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 3, 2015, National Stock Exchange, Inc. (''NSX®'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change, as described in Items I and II below, which Items have been substantially prepared by the Exchange. The Commission is publishing this notice to solicit comments on the

[1] Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 21 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, November 6, 2015 (Request).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend NSX Rule 11.1, Hours of Trading, to rescind Interpretations and Policies .01, ''Cessation of Trading Operations on NSX.'' The Exchange is also proposing to: (i) Adopt new Rule 11.25, Use of Market Data Feeds; (ii) amend NSX Rule 11.13 and Interpretations and Policies .01 with respect to the order delivery mode of order interaction with the Exchange's trading system (''Order Delivery''); (iii) amend NSX Rule 11.11, Orders and Modifiers, to remove descriptions of certain order types that the Exchange will not offer upon a resumption of trading and to correct technical deficiencies in the numbering of certain subparagraphs of the rule; and (v) amend Rule 11.12, Cross Message, to delete the rule in its entirety and make conforming amendments to NSX Rules 11.11(c) and 16.2.

The text of the proposed rule change is available on the Exchange's Web site at *www.nsx.com*, at the Exchange's principal office, and at the Commission's public reference room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization 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 those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NSX, a corporation organized under the laws of the State of Delaware,[3] is a registered national securities exchange under Section 6 of the Exchange Act[4] and operates as a self-regulatory organization governed by the requirements of Section 19 of the Exchange Act.[5] The Exchange is filing this rule proposal to rescind Interpretations and Policies .01 of Rule 11.1 (hereinafter referred to as ''I&P.01''), ''Cessation of Trading Operations on the Exchange.'' I&P.01 currently states that, as of the close of business on May 30, 2014 (the ''Closing Date''), NSX shall cease trading activity on its trading system (the ''System'');[6] that all NSX Rules will remain in full force and effect through and after the Closing Date; and that the Exchange shall file a proposed rule change pursuant to Rule 19b–4 of the Exchange Act prior to any resumption of trading on the Exchange pursuant to Chapter XI (Trading Rules).[7] Rescinding I&P.01 will permit the Exchange to resume trading activity on the System as soon as practicable after the instant rule amendment is operative, thereby restoring NSX to its status as an operating, all-electronic national securities exchange as it had been for many years prior to ceasing trading operations

In connection with the proposed resumption of trading on the System, the Exchange is proposing several other rule amendments. Specifically, the Exchange is proposing in new Rule 11.25 to describe the Exchange's use of certain data feeds for order handling and execution, order routing and regulatory compliance. The Exchange is also proposing amendments to: (i) Rule 11.11 to eliminate the Double Play and Auto-Ex Only Order types; (ii) Rule 11.13 and the Interpretations and Policies under the rule to eliminate rule text relating to Order Delivery; and (iii) Rule 11.16, Cross Message, to rescind the rule text in its entirety. The Exchange is further proposing non-substantive or conforming amendments to Rules 11.11 and 16.2.

The details of these proposed rule changes are discussed below.

Proposed Resumption of Trading on NSX

At the time that NSX ceased trading operations, the Exchange operated as a wholly-owned subsidiary of CBOE Stock Exchange, LLC (''CBSX'').[8] Thereafter, on February 13, 2015,[9] the Commission issued an Order granting its approval of a transaction in which National Stock Exchange Holdings, Inc. (''NSX Holdings''), a Delaware corporation, purchased all of the outstanding shares of NSX from the CBSX (the ''Approval Order''). The Commission noted in the Approval Order that ''[t]he Exchange is, and will remain, registered as a national securities exchange under Section 6 of the Act[10] and a self-regulatory organization [''SRO''] . . . as defined in [S]ection 3(a)(26) of the Act[11]after the Closing [of the Transaction].'' The Commission further noted that ''. . . [t]he Exchange states that it plans to reopen its trading operations as soon as practicable after the Closing and plans to operate the Exchange using its existing . . . [S]ystem pursuant to the rules of the Exchange currently in effect . . . .''[12]

After the Closing of the Transaction up to the date of the instant rule filing, the Exchange has continued to discharge its applicable SRO responsibilities in anticipation of resuming trading operations on the Exchange. Specifically, as outlined below, the Exchange has continued as a party to the National Market System (''NMS'') Plans[13] and has updated its

[3] NSX was founded in 1885 as the Cincinnati Stock Exchange and changed its name to ''National Stock Exchange'' in 2003. *See* Securities Exchange Act Release No. 48774 (November 12, 2003), 68 FR 65332 (November 19, 2003) (SR–CSE–2003–12). In 2006, the Exchange de-mutualized and changed its corporate organizational structure from a non-stock, not-for-profit Ohio corporation to a Delaware for-profit stock corporation. *See* Securities Exchange Act Release No. 53963 (June 8, 2006), 71 FR 34660 (June 15, 2006) (SR–NSX–2006–03).

[4] 15 U.S.C. 78f.

[5] 15 U.S.C. 78s.

[6] Exchange Rule 1.5S.(4) defined the term ''System'' as ''. . . the electronic securities communications and trading facility designated by the Board [of Directors] through which orders . . . are consolidated for ranking and execution.''

[7] *See* Securities Exchange Act Release No. 72107 (May 6, 2014), 79 FR 27017 (May 12, 2014) (SR–NSX–2014–14).

[8] *See* Securities Exchange Act Release No. 66071 (December 29, 2011); 77 FR 521 (January 5, 2012)(SR–CBOE–2011–107 and SR–NSX–2011–14), *Order Granting Accelerated Approval to Proposed Rule Changes in Connection with the Proposed Acquisition of the National Stock Exchange, Inc. by the CBOE Stock Exchange, LLC.*

[9] *See* Securities Exchange Act Release No. 74270 (February 13, 2015), 80 FR 9286 (February 20, 2015) (SR–NSX–2014–017), *Order Granting Approval of Proposed Rule Change in Connection With a Proposed Transaction in Which National Stock Exchange Holdings, Inc. Will Acquire Ownership of the Exchange from the CBOE Stock Exchange, LLC.* The Approval Order described in detail, *inter alia*, the ownership structure of the Exchange upon its acquisition by NSX Holdings and the requirement that NSX Holdings give due regard to the preservation of the independence of the Exchange's self-regulatory function.

[10] *See* 15 U.S.C. 78f.

[11] *See* 15 U.S.C. 78s.

[12] *See Order Granting Approval of Proposed Rule Change in Connection With a Proposed Transaction in Which National Stock Exchange Holdings, Inc. Will Acquire Ownership of the Exchange from the CBOE Stock Exchange, LLC,* 80 FR at 9287.

[13] *See, e.g.,* Securities Exchange Act Release No. 74323 (February 19, 2015), 80 FR 10169 (February 25, 2015) (File No. 4–631), *Order Approving the Eighth Amendment to the National Market System Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'');* Securities Exchange Act Release No. 75192 (June 17, 2015), 80 FR 36028 (June 23, 2015) (File No. 4–668), *Order Approving Amendment No. 1 to the National Market System Plan Governing the Process of Selecting a Plan Processor and Developing a Plan for the Consolidated Audit Trail;* Securities Exchange Act Release No. 75505 (July 22, 2015), 80

rules as appropriate.[14] The Exchange also filed with the Commission an amendment to NSX Rule 2.5, Application Procedures for an ETP Holder or to become an Associated Person of an ETP Holder, adding Interpretations and Policies .01, Expedited Process for Reinstatement as an ETP Holder.[15] The amendment provided an expedited procedure, available for a period of 90 days from the date the rule amendment became operative, for ETP Holders in good standing as of the close of business on May 30, 2014 to reinstate their status as such and to register Associated Persons.[16]

As noted above, the Exchange will operate using the existing System and pursuant to the rules in effect. The Exchange has maintained the System's operability and has not made any modification to the System's functionality, except to the extent necessary to comply with regulatory requirements.[17] The functionality relating to order entry and execution, order routing, clearance and settlement and market data distribution, as further described below, remains the same. The Exchange does not currently list any securities and trades equity securities on an Unlisted Trading Privileges basis.[18]

The Exchange has implemented and continues to execute a rigorous testing process, including tests with industry participants, to assure that all components of the System function effectively, that the Exchange has full operational capability to re-open its marketplace for the trading of equity securities, and that the Exchange will operate in compliance with all applicable rules and regulations. This testing plan included three weekend tests of NSX's interfaces with the securities information processors, or ''SIPs'' (*i.e.*, the Consolidated Quote System or ''CQS;'' the Consolidated Tape System or ''CTS;'' the UTP Quotation Data Feed, or ''UQDF;'' and the UTP Trade Data Feed, or ''UTDF''). These tests, which were completed on August 29, 2015, confirmed that NSX will be ready to receive quote and trade data and relevant national market system plan information from, and transmit its quote and trade information to, the securities information processors when it resumes trading operations on the System.

The Exchange also tested for proper functioning of client communication systems with NSX, client order entry connections, and depth of book. Moreover, the Exchange tested its matching engines, market data, trade reporting, quote publication and trade messages, and clearing systems. The tests were conducted with actual market data and clearing data. The Exchange has also re-certified its connection with the Depository Trust & Clearing Corporation (''DTCC'') to assure complete and accurate trade clearing and settlement functions.

The Exchange has also performed a thorough review of the hardware and software components of the System and has resumed the production status of the System on a daily basis. Furthermore, the Exchange made enhancements to its connectivity and certification processes. The Exchange has created an automated certification process, providing ETP Holders and Users with a more efficient process of connecting to the System. The Exchange has also made enhancements to certain internal processes and monitoring tools. These enhancements include a message bus upgrade and security master file upgrade. The Exchange has also enhanced its System monitoring tools to provide for more effective monitoring of System health to allow quicker response within operations support.

Having conducted these tests and made these enhancements and upon receiving regulatory approval to resume trading on the System, the Exchange will execute a staged roll-out plan to reach full operational capacity.[19] Beginning one week and one day prior to the date trading will resume on the System, the Exchange will test the System using only test symbols. On the first day of trading the Exchange will allow for trading in symbols within a defined alphabetic range (for example, symbols within the letter range X–Z). After three days of trading in this range, the Exchange will activate trading in additional symbols within an alphabetic range (for example, adding symbols within the letter range A–K). Two days later the Exchange will activate trading in all remaining symbols and be fully operational. The Exchange will provide ETP Holders with advance notice of the dates and the symbol ranges that will comprise the staged roll-out.

The Exchange will also take affirmative steps to assure that the date that it intends to resume trading operations is communicated broadly to market participants and to the investing public. Specifically, the Exchange has a target date of on or about December 1, 2015 to resume trading operations on the System. The Exchange will provide timely written notice of the date and other information concerning its resumption of trading operations directly to the following parties: (1) ETP Holders; (2) other national securities exchanges that trade NMS securities; (3) the SIPs; and, (4) the operating committees for the various NMS plans (*e.g.*, the Consolidated Tape Association Plan/Consolidated Quote Plan; the Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privileges Basis;

FR 45254 (July 29, 2015) (File No. S7–24–89), *Order Approving Amendment No. 35 to the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privileges Basis;* Securities Exchange Act Release No. 75504 (July 22, 2015), 80 FR 45252 (July 29, 2015) (SR–CTA/CQ 2015–01), *Order Approving the Twenty Second Substantive Amendment to the Second Restatement of the CTA Plan and Sixteenth Substantive Amendment to the Restated CQ Plan;* Securities Exchange Act Release No. 75660 (August 11, 2015), 80 FR 48940 (August 14, 2015), (SR–CTA–2015–02), *Order Approving the Twenty Third Substantive Amendment to the Second Restatement of the CTA Plan;* Securities Exchange Act Release No 75980 (September 25, 2015), 80 FR 58796 (September 30, 2015),*Order Approving Amendment No. 2 to the National Market System Plan Governing the Process of Selecting a Plan Processor and Developing a Plan for the Consolidated Audit Trail.*

[14] *See* Securities Exchange Act Release No. 72434 (June 19, 2014), 79 FR 36110 (June 25, 2014) (SR–NSX–2014–08), *Order Granting Approval of Proposed Rule Changes Relating to Clearly Erroneous Executions;* Securities Exchange Act Release No. 72914 (August 26, 2014), 79 FR 52089 (September 2, 2014) (SR–NSX–2014–16), *Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Rule 15.5 to Provide Additional Clarity and Precision, Correct Certain Citations, and Align the Rule with the Rules of Other Exchanges With Respect to the Original and Continued Listing Standards for Issuers' Compensation Committees;* Securities Exchange Act Release No. 75355 (July 2, 2015), 80 FR 39460 (July 9, 2015) (SR–NSX–2015–03), *Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Rule 4.3, Record of Written Complaints;* Securities Exchange Act Release No. 75554 (July 30, 2015), 80 FR 46620 (August 5, 2015) (SR–NSX–2015–04), *Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Exchange Rule 11.21, Short Sales, to Describe the Exchange's Implementation of Rule 201 of Regulation SHO Under the Securities Exchange Act of 1934 and Relocate Certain Text from Rule 11.11, Orders and Modifiers; and Amending Rule 13.2 to Incorporate By Reference Rules 200,203 and 204 of Regulation SHO.*

[15] The term ''ETP Holder'' refers to registered brokers or dealers that have been issued an Equity Trading Permit by the Exchange for effecting approved securities transactions on the Exchange's trading facilities. *See* Exchange Rule 1.5E.(1).

[16] *See* Securities Exchange Act Release No. 75098 (June 3, 2015), 80 FR 32644 (June 9, 2015) (SR–NSX–2015–02).

[17] For example, the Exchange has made System changes to comply with the new timestamp requirements under the July 2015 amendments to the UTP Plan and the Consolidated Tape and Consolidated Quote Plans. *See* footnote 13, above.

[18] *See* NSX Rule 15.9.

[19] The Exchange will issue a notice to ETP Holders with the precise details of the roll-out plan prior to initiating the plan.

and the Plan to Address Extraordinary Market Volatility). Furthermore, the Exchange will provide timely notice to the public as a whole by way of widely-disseminated press releases issued by the Exchange and notification through the Exchange's Web site and through communications with financial and industry press.

As required by Section 6(b)(1) of the Act,[20] the Exchange has the capacity to be able to carry out the purposes of the Act and to comply and to enforce compliance by ETP Holders and persons associated with ETP Holders, with the provisions of the Act, the rules and regulations thereunder, and the rules of the Exchange. The Exchange has the financial, technology and staff resources to effectively surveil its marketplace and to regulate ETP Holders' trading on NSX upon the resumption of trading operations on the System. The Exchange will continue to regularly assess its regulatory resources to assure that they continue to be sufficient to discharge its SRO responsibilities. The Exchange notes that, throughout the period from the date that it ceased trading operations through the date of the instant rule filing, it has continued to be a party to certain 17d–2 Plans for the Allocation of Regulatory Responsibilities pursuant to Section 17(d)(1) of the Exchange Act [21] and Rules 17d–1 and 17d–2 thereunder,[22] specifically the 17d–2 Plan relating to the surveillance, investigation and enforcement of insider trading rules [23] and the 17d–2 Plan relating to Regulation NMS Rules.[24] The Exchange will continue as a party to these plans going forward.

In summary, since ceasing trading operations on the System as of the close of business on May 30, 2014, the Exchange (i) continued to maintain the operability of the System; (ii) implemented and successfully executed a rigorous internal testing program to assure that the System will function as designed and subject to NSX rules in effect; (iii) successfully tested connectivity to the securities information processors and to DTCC; (iv) continued to discharge its SRO responsibilities through, among other things, remaining a party to NMS plans and in the multi-party 17d–2 plans for insider trading surveillance and certain Regulation NMS requirements; and (v) amended its rules to keep current with industry regulatory initiatives (*e.g.*, amendments to the market-wide rules governing clearly erroneous executions), and is proposing additional rule changes in the instant rule proposal, described below, that will align with the System's functionality when trading operations resume. Further, the Exchange has sufficient financial, technology and staff resources to effectively regulate ETP Holder activity in the NSX marketplace and meet its compliance obligations under the Act.

In view of the foregoing, the Exchange is positioned to successfully reopen its marketplace for the trading of equity securities and accordingly is proposing to rescind I&P.01 to allow the NSX to resume trading operations as soon as practicable after the instant rule proposal becomes operative.

Adoption of NSX Rule 11.25

The Exchange is proposing to adopt NSX Rule 11.25 to describe the sources of market data used for purposes of order handling and execution, order routing, and regulatory compliance. Paragraph (a) of the proposed Rule will specify which data feeds the Exchange utilizes for the handling, execution, and routing of orders, as well as for surveillance necessary to monitor compliance with applicable securities laws and Exchange rules. Proposed paragraph (b) will state that the Exchange may adjust its calculation of the NBBO based on information about orders sent to other venues with protected quotations, execution reports received from those venues, and certain orders received by the Exchange. With this rule and other functionalities in place, the system will use market data as follows.

Order Handling and Execution

In order to calculate the national best bid and offer (''NBBO'') [25] the Exchange uses only SIP data disseminated through CQ and UQDF for all exchanges. NSX does not use any exchange's proprietary data feeds. The Exchange does not include its own quotes in the calculation of the Exchange's NBBO because the system is designed such that all incoming orders are separately compared to the Exchange's Protected Best Bid or Offer (''PBBO'') [26] and the Exchange-calculated NBBO, which together create a complete view of the NBBO, prior to order display, execution, or routing.

The Exchange offers three types of ''pegged'' Zero Display Reserve Orders, which may be ''pegged'' to the buy-side of the PBBO, the sell-side of the PBBO or the midpoint of the PBBO.[27] The System calculates the PBBO using the quotes from the SIPs, excluding quotes disseminated by the SIPs that originated from the NSX Book.[28]

Order Routing

When the Exchange has a marketable order eligible to be routed and the System identifies that there is no matching price available on the Exchange, but there is a matching price represented at another trading center displaying protected quotes, the System will cause the order to be routed to that trading center. The Exchange uses data received from the SIPs to update the System's calculation of the NBBO for purposes of routing decisions.

Regulatory Compliance

Locked or Crossed Markets: The System determines whether the display of an order would lock or cross the market. At the time an order is entered into the System, it will establish, based upon its calculation of the NBBO from SIP feeds, whether the order will lock or cross the prevailing NBBO for a security. In the event that the order would produce a locking or crossing condition, the System will cancel the order or route the order based on the ETP Holder's order handling instructions.

Pursuant to Regulation NMS, a declaration of self-help can occur when an exchange displaying protected quotes is slow, as defined in Regulation NMS, or non-responsive to the Exchange's routed orders. In this circumstance, according to Rule 611(b) of Regulation NMS,[29] the Exchange may declare self-help against that exchange and display a quotation that may lock or cross the market that the Exchange invoked self-help against.[30] The Exchange may also

[20] 15 U.S.C. 78(f)(b)(1).

[21] 15 U.S.C. 78q(d)(1).

[22] 17 CFR 240.17d–1 and 17 CFR 240.17d–2, respectively.

[23] *See* Securities Exchange Act Release No. 65991 (December 16, 2010), 76 FR 79714 (December 22, 2011) (File No. 4–566), *Notice of Filing and Order Approving and Declaring Effective an Amendment to the Plan for the Allocation of Regulatory Responsibilities . . . Relating to the Surveillance, Investigation, and Enforcement of Insider Trading Rules.*

[24] *See* Securities Exchange Act Release No. 63430 (December 3, 2010), 75 FR 76758 (December 9, 2010) (File No. 4–618), *Order Approving and Declaring Effective a Plan for the Allocation of Regulatory Responsibilities . . . Relating to Regulation NMS Rules.*

[25] NSX Rule 1.5P.(2) defines the ''Protected NBBO'' as the national best bid or offer that is a protected quotation.

[26] NSX Rule 1.5P.(3) defines the ''Protected BBO'' as the Protected NBBO or the displayed Top of Book on NSX.

[27] *See* NSX Rule 11.11(c)(2)(A).

[28] NSX Rule 1.5N.(1) defines the NSX Book as the System's electronic file of orders.

[29] *See* 17 CFR 242.611.

[30] *See also* Question 5.03 in the ''Division of Trading and Markets, Responses to Frequently Asked Questions Concerning Rule 611 and Rule 610 of Regulation NMS'' (last updated April 4, 2008) *available at http://www.sec.gov/divisions/marketreg/nmsfaq610-11.htm.*

declare self-help where another exchange's SIP quotes are slow or non-responsive resulting in a locked or crossed market. Once the Exchange declares self-help, the System will ignore the quotes generated from that exchange in its calculation of the NBBO for execution and routing determinations in compliance with Regulation NMS. The Exchange will also disable all routing to that exchange. However, the System will continue to receive and process that exchange's quotes in order to immediately include the quote in the NBBO calculation and enable routing once self-help is revoked.

Order Protection Rule: Pursuant to Rule 611 of Regulation NMS,[31] the Exchange is required to establish, maintain, and enforce written policies and procedures that are reasonably designed to prevent trade-throughs of protected quotations in NMS stocks that do not fall within a valid exception and, if relying on such an exception, that are reasonably designed to ensure compliance with the terms of the exception. The System does not permit an execution on the Exchange if there are better-priced protected quotations displayed in the market unless the order is an ISO. At the time an order is entered on NSX, the System uses the SIP data to determine if the NBBO is priced better than what is on the NSX Book. If the Exchange does not match such order on the NSX Book,[32] and based on the ETP Holder's order handling instructions, the System cancels or routes the order.

Regulation SHO: The Exchange is required to establish, maintain and enforce written policies and procedures reasonably designed to prevent the execution of a Short Sale Order in a covered security at a price that is equal to or below the current National Best Bid (''NBB'') when a short sale price restriction is in effect pursuant to Rule 201 of Regulation SHO under the Exchange Act (''Short Sale Circuit Breaker'').[33] When a Short Sale Circuit Breaker is in effect, the Exchange utilizes information received from SIP feeds and what is on the NSX Book, to prevent the execution of a sell short order in contravention of Rule 201 of Regulation SHO.[34]

Limit Up-Limit Down: As stated in Rule 11.24(c), the Exchange is a participant in, and subject to the applicable requirements of, the Limit Up-Limit Down Plan. The System uses price band data received through the SIP to comply with the requirements of the Limit Up-Limit Down Plan. Specifically, as provided in Rule 11.24(e) the System will not execute or display orders for an NMS stock at prices that are outside of a specified price band (*i.e.*, below the lower price band or above the higher price band).

Amendments to NSX Rules 11.13 and 11.11

The Exchange is further proposing to amend NSX Rule 11.13, Proprietary and Agency Orders; Modes of Order Interaction, to eliminate text relating to two modes of order interaction available to Users.[35] The Exchange is also: (i) Proposing a conforming amendment to NSX Rule 11.11(c)(2)(C) to remove text relating to a Zero Display Reserve Order[36] entered through the order delivery mode; and (ii) proposing to amend NSX Rule 11.11, Orders and Modifiers, to eliminate the Auto-Ex Only Order[37] and the Double Play Order[38] and make non-substantive amendments to correct a numbering defect with respect to certain subparagraphs of NSX Rule 11.11(c).

On August 31, 2006, the Commission approved amendments to NSX's trading rules to provide for a price-time priority market with two modes of order interaction: (1) Automatic execution (''Auto-Ex Mode'') and (2) order delivery and automated response (previously referred to herein as ''Order Delivery'').[39] Every User is eligible to use the Auto-Ex Mode, under which the System matches and executes like-priced orders, including against Order Delivery Orders resting on the NSX Book. To use Order Delivery a User must demonstrate that it can meet certain eligibility criteria; specifically, a User must demonstrate that its system can automatically process the inbound order and respond immediately. If no response to an inbound order is received within 300 milliseconds, the User's displayed order will be canceled. Interpretations and Policies .01 of Rule 11.13 provides that, in determining whether a User's system can automatically process the inbound order and respond immediately, the Exchange requires that Users selecting Order Delivery have system response times that generally meet or exceed industry standards (subject to exceptions for occasional systems malfunctions that do not, in the Exchange's judgment, materially impair the User's ability to process and respond to inbound orders immediately).[40]

The Exchange maintained Order Delivery as a mode of interaction with the System through the cessation of trading as of the close of business on May 30, 2014. The Exchange has now determined that, upon resuming trading operations on the System, it will not offer Order Delivery as a mode of order interaction with the System and the only mode of order interaction with the System will be Auto-Ex Mode. The Exchange made this decision as a business judgment based on its assessment of customer interest and market structure considerations. The Exchange proposes to amend Rule 11.13 to delete paragraph (b) and Interpretations and Policies .01 relating to Order Delivery as a mode of order interaction.

The Exchange is further proposing to amend Rule 11.11(c)(2)(C) to remove certain text related to a Zero Display Reserve Order entered through Order Delivery. The relevant rule text currently states that, if a Zero Display Reserve Order is not designated as a Post Only Order[41] and is entered using the Order Delivery and such order is immediately marketable upon entry into the System, the order will have its mode of order interaction converted to Automatic Execution as described in Rule 11.13(b)(1). This rule text is no longer apposite in view of the Exchange's decision to eliminate Order Delivery upon a resumption of trading on the System.

The Exchange is also proposing to amend Rule 11.11 to eliminate the Auto-Ex Only Order, which was implemented by the Exchange in May 2013.[42] An

[31] 17 CFR 242.611.

[32] NSX Rule 1.5N.(1) defines the term ''NSX Book'' as the ''System's electronic file of orders.''

[33] 17 CFR 242.201.

[34] *See Id.*

[35] A ''User'' is any ETP Holder or Sponsored Participant that is authorized to obtain access to the System pursuant to NSX Rule 11.9. *See* NSX Rule 1.5U.(1).

[36] NSX Rule 11.11(c)(2) defines a reserve order as ''[a] limit order with a portion of the quantity displayed . . . and with a reserve portion of the quantity . . . that is not displayed.'' Rule 11.11(c)(2)(A) provides a Reserve Order may be entered with a zero display quantity, in which case the Reserve Order is known as a Zero Display Reserve Order.

[37] *See* NSX Rule 11.11(c)(13).

[38] *See* NSX Rule 11.11(c)(10).

[39] *See* Securities Exchange Act Release No. 54391 (August 31, 2006), 71 FR 52836 (September 7, 2006) (SR–NSX–2006–08), *Order Approving a Proposed Rule Change and Amendment No. 1 Thereto and Notice of Filing and Order Granting Accelerated Approval to Amendment Nos. 2 and 3 Thereto to Amend Its Trading Rules to Provide for a Price-Time Priority Market and Other Related Changes.*

[40] The Exchange considered 100 milliseconds to be the industry standard for response time to an inbound order.

[41] NSX Rule 11.11(c)(5) defines a Post Only Order as ''[a] limit order that is to be posted on the Exchange and not routed away to another trading center.''

[42] *See* Securities Exchange Act Release No. 69519 (May 6, 2013), 78 FR 27461 (May 10, 2013) (SR–NSX–2013–02), *Order Granting Approval of Proposed Rule Change to Adopt a New Order Type*

Continued

Auto-Ex Only Order is an ''immediate or cancel'' (''IOC'') Limit or Market Order[43] that the System will automatically execute exclusively against other Auto-Ex Orders at a marketable price. An Auto-Ex Only Order does not interact with an Order Delivery order or route away to other Trading Centers. The System cancels any shares remaining after executing against all marketable Auto-Ex Orders. An Auto-Ex Only Order cannot be used to comply with Rule 611 of Regulation NMS pursuant to the Exchange Act because the Auto-Ex Only Order did not interact with Order Delivery orders that may be protected quotations.

The Exchange notes that the Auto-Ex Only order was implemented to offer Users of the System the option of interacting with marketable orders on the NSX Book without having to incur delays associated with Order Delivery. Such delays could result from sending an incoming order to an Order Delivery participant and receiving a response thereto. However, since NSX will no longer offer Order Delivery the underlying rationale for the Auto-Ex Only Order will no longer exist.

The Exchange is also proposing to amend NSX Rule 11.11(c)(10) to eliminate the Double Play Order type. The Double Play Order was implemented by the Exchange in November 2012.[44] A Double Play Order is a market or limit order for which a User instructs the System to route to designated away trading centers which are approved by the Exchange from time to time without first exposing the order to the NSX Book. A Double Play Order that does not execute in full after routing away receives a new time stamp upon return to the Exchange and is ranked and maintained in the NSX Book in accordance with NSX Rule 11.14, Priority of Orders.

After assessing the use of the Double Play Order since November 2012, the Exchange has determined that the Double Play Order was infrequently used and that it is not an efficient use of its resources to maintain and support the Double Play Order as an active order type.

Finally, the Exchange proposes certain technical, non-substantive amendments to NSX Rule 11.11 to correct defective numbering. The Exchange added the Midpoint Seeker Order in March 2013 under NSX Rule 11.11(c)(13).[45] As a result of an administrative error by the Exchange, the Auto-Ex Only order was assigned the same subparagraph number (c)(13) of Rule 11.11 when it was implemented in May 2013. The Exchange is proposing to renumber the Midpoint Seeker Order as subparagraph (c)(12), which is currently a ''reserved'' subparagraph. With the proposed elimination of the Auto-Ex Only Order, subparagraph (c)(13) will now be ''reserved.''

Amendments to Rule 11.12

Currently, NSX Rule 11.12, Cross Message, provides that subject to the certain restrictions described in the rule, Users are permitted to enter a cross message instructing the System to match for execution the identified buy-side of the cross message with the identified sell side of the cross message at a specified price (a ''Cross Trade'').[46] Pursuant to NSX Rule 11.12(b), the price of the Cross Trade must, on the buy side, be at least $0.01 less than the lowest displayed order to sell on the NSX Book and is at a price equal to or less than the Protected NBBO offer; on the sell side of the cross, the price must be at least $0.01 greater than the highest displayed order to buy on the NSX Book and is at a price equal to or greater than the Protected NBBO bid.

Rule 11.12 provides for three types of Cross Trades: A Midpoint Cross, at which the Cross Trade is priced at the midpoint of the Protected NBBO and improves each side of the NSX Top of Book[47] by at least the minimum price increment for the subject security;[48] a Clean Cross, in which the Cross Trade is for at least 5,000 shares with an aggregate value of at least $100,000 and is executed at a price that is equal to or better than each side of the NSX Top of Book and equal to or better than the Protected NBBO;[49] and, a Cross/Sweep, in which the System, upon receipt of a Cross/Sweep message from a user, will enter a Protected Sweep Order[50] for the User's account in an amount necessary to execute against all protected quotations that, if not swept, would prohibit the Cross Trade from being executed by the System. Pursuant to NSX Rule 11.12(f)(1), the Cross Trade will be executed on the System simultaneously with the Protected Sweep Order, unless the size of such order would exceed the size of the Cross Trade, in which event both the Protected Sweep Order and the order for the Cross Trade would be canceled without an execution.

The Exchange has determined in its business judgment that, upon a resumption of trading on the System, it will not support the functionality for Users to enter a Cross into the System. This determination is based on the Exchange's assessment of its current market structure requirements and the technology resources needed to support the functionality. In the event that the Exchange determines to offer Cross Message functionality in the future, it will file a proposed rule change pursuant to Rule 19b–4 of the Exchange Act.

In view of the determination to no longer offer Cross Message functionality, the Exchange is proposing other conforming amendments to its rules. First, the Exchange proposes to delete subparagraph (c)(7)(iii) of NSX Rule 11.11, which currently states that ''[a] Sweep Order entered as part of a Cross/Sweep message pursuant to Rule 11.12 shall be treated identically to a Sweep Order designated 'Sweep and Cancel' except as otherwise provided in Rule 11.12.'' Similarly, the Exchange proposes to rescind in its entirety the text of NSX Rule 16.2, Crosses, which currently provides that ''[c]rosses executed in Tape ''A'', ''B'' and ''C'' securities will not be subject to any transaction fees.'' The elimination of the Cross Message functionality renders this rule inapposite.

2. Statutory Basis

The Exchange's proposed rule changes are consistent with the Exchange Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b)[51] of the Exchange Act. Specifically, the proposed rule change is consistent with

Called the ''Auto-Ex Only'' Order and Add New Definitions Regarding Automatic Execution Mode and Automatic Execution Orders.

[43] NSX Rule 11.11(a), General Order Types, defines a market order as an order to buy or sell a stated amount of a security that is to be executed at the best price obtainable when the order reaches the Exchange (NSX Rule 11.11(a)(1)); a limit order is defined as an order to buy or sell a stated amount of a security at a specified price or better (NSX Rule 11.11(a)(2)); NSX Rule 11.11(b), Time-in-Force, defines an IOC order as a limit order that is to be executed in whole or in part as soon as such order is received and the portion not so executed is canceled. IOC orders are not eligible to be routed to an away trading center pursuant to NSX Rule 11.15, Order Execution.

[44] *See* Securities Exchange Act Release No. 68317 (November 29, 2012), 77 FR 72423 (December 5, 2012) (SR–NSX–2012–22).

[45] *See* Securities Exchange Act Release No. 69009 (February 28, 2013), 78 FR 14867 (March 7, 2013) (SR–NSX–2013–07).

[46] The Commission approved NSX Rule 11.12 in August 2006. *See* footnote 39, *supra.*

[47] The NSX Top of Book is the best-ranked order to buy or sell in the NSX Book. *See* NSX Rule 1.5T.(1).

[48] *See* NSX Rule 11.12(c).

[49] *See* NSX Rule 11.12(d).

[50] A Protected Sweep Order is a limit order that instructed the System to ''sweep'' the market with sizes equal to the order sizes in the NSX Book and the order sizes at away trading centers. *See* NSX Rule 11.11(c)(7)(i)(A).

[51] 15 U.S.C. 78f(b).

the requirement of Section 6(b)(5)[52] of the Exchange Act that the rules of an exchange be designed to, among other things, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange submits that the proposed rescission of I&P.01, which will operate to permit the re-opening of the System for quoting and trading equity securities, fulfills the purposes of Section 6(b)(5).[53] The Exchange's rule proposal will restore the Exchange to the status of a fully operational national securities exchange, as it was prior to the close of business on May 30, 2014. Notably, throughout the period from the date that it ceased trading operations up to the date of the instant rule filing, the Exchange has continued to maintain its status as a registered national securities exchange and as an SRO. It has continued its participation as a party in the national market system plans.[54]

Upon the resumption of trading on the System, the Exchange will operate its marketplace pursuant to rules currently in effect, as amended by the rule changes proposed in this rule filing. The Exchange has completed a rigorous testing process, including tests with the SIPs and market participants, to assure that the System continues to send and receive quote and trade data and other information necessary to assure the Exchange's compliance with the national market system plans. Restoring NSX to its status as an operating Exchange will promote the protection of investors and the public interest by providing an additional trading venue, operating pursuant to an approved rule set, and available to market participants and the investing public for the trading of equity securities. The Exchange has sufficient financial and staff resources to continue to discharge its obligations as a national securities exchange and as an SRO. The Exchange submits that the proposed amendment will thus further the purposes of Section 6(b)(5) of the Act[55] in that it will operate to promote just and equitable principles of trade and perfect the mechanism of a free and open market and a national market system by providing investors with the ability to execute trades in equity securities on a regulated marketplace operating pursuant to rules approved by the Commission and subject to regulatory oversight.

Additionally, the Exchange's proposal to describe the Exchange's use of data feeds as a part of this filing and through the adoption of NSX Rule 11.25 is consistent with the Section 6(b)(5) of the Act.[56] Further, the proposal removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest because it provides additional specificity and transparency. The Exchange's proposal will enable investors to better assess the quality of the Exchange's execution and routing services. The proposal does not change the operation of the Exchange or its use of data feeds; rather it describes how, and for what purposes, the Exchange uses the quotes disseminated from data feeds to calculate the NBBO for a security for purposes of Regulation NMS, Regulation SHO and various order types that update based on changes to the applicable NBBO. The additional transparency into the operation of the Exchange as described in the proposal will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest.

The Exchange's proposed amendments to conform certain of its rules to the planned operation of the System upon a resumption of trading are consistent with the Section 6(b)(5) of the Act.[57] Specifically, the Exchange is proposing to amend NSX Rules 11.11 and 11.13, and Interpretations and Policies .01 of Rule 11.13, to remove text relating to Order Delivery, which will not be available to Users as a mode of order interaction with the System upon a resumption of trading. The Exchange is further proposing to amend Rule 11.11 to eliminate the Auto-Ex Only Order, which relates to the handling of certain orders when interacting with Order Delivery, and the Double Play Order, which was an infrequently used order type that the Exchange no longer wishes to support. The Exchange is also proposing to correct defective numbering in Rule 11.11, which will promote clarity and ease of reference in its rules. These proposed amendments are consistent with Section 6(b)(5) of the Act[58] in that they will operate to align the Exchange's rules with the planned operation of the System upon a resumption of trading, thereby promoting just and equitable principles of trade and the protection of investors and the public interest.

The Exchange's proposals to amend NSX Rule 11.12 to rescind the rule text governing Cross Trades on the System, and making conforming amendments to NSX Rules 11.11(c)(7)(iii), regarding a Cross/Sweep Order, and 16.2, providing that Cross Trades in Tape A, B, and C securities are not subject to transaction fees, are consistent with Section 6(b)(5) of the Exchange Act because they will remove from the NSX rule book provisions that address a System functionality that will not be supported operationally upon a resumption of trading on the System. The amendments are designed to align the Exchange's rules with the System's planned functionality. The Exchange believes that the amendments will further promote just and equitable principles of trade and the protection of investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. The Exchange believes that reopening the System for the trading of equity securities will enhance competition in the national market system by providing investors with the opportunity to trade on a competitive trading venue that was available to them prior to the close of business May 30, 2014. The Exchange submits that the proposed rule amendment will thus operate to enhance rather than burden competition in the equity securities markets.

The Exchange's proposed rule changes to: (i) Eliminate Order Delivery-related rule text; (ii) Eliminate the Auto-Ex Only and Double Play Orders; (iii) eliminate the Cross Trade rule; and (iv) make other conforming rule amendments and correct defecting numbering of certain paragraphs of NSX Rule 11.11, have no competitive impact in that they are designed to assure that the Exchange's rules and its System functionality align and to promote clarity and transparency in the Exchange's rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited or received comments on the proposed rule change from market participants or others.

[52] 15 U.S.C. 78f(b)(5).

[53] 15 U.S.C. 78f(b)(5).

[54] *See* footnote 13, *supra*.

[55] 15 U.S.C. 78f(b)(5).

[56] 15 U.S.C. 78f(b)(5).

[57] 15 U.S.C. 78f(b)(5).

[58] *Id.*

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the 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–NSX–2015–05 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–NSX–2015–05. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NSX–2015–05 and should be submitted on or before December 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[59]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28811 Filed 11–12–15; 8:45 am]

BILLING CODE 8011–01–P

[59] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76384; File No. SR–NASDAQ–2015–131]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Regarding NASDAQ Last Sale Plus

November 6, 2015.

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 October 30, 2015, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NASDAQ Rule 7039 (NASDAQ Last Sale and NASDAQ Last Sale Plus Data Feeds) with language clarifying that the data consolidation component of the fees for NASDAQ Last Sale Plus (''NLS Plus''), a comprehensive data feed offered by NASDAQ OMX Information LLC,[3] will be charged solely to firms that are Internal Distributors and External Distributors (collectively, ''Distributors'' of the data feed) that receive a NLS Plus direct data feed.[4]

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposal is to amend NASDAQ Rule 7039 with language clarifying that the data consolidation component of the fees for NLS Plus will be charged solely to firms that are Distributors that receive an NLS Plus direct data feed.[5]

NLS Plus[6] allows data distributors to access last sale products offered by each

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] NASDAQ OMX Information LLC is a subsidiary of Nasdaq, Inc. (formerly, The NASDAQ OMX Group, Inc.), separate and apart from The NASDAQ Stock Market LLC. The primary purpose of NASDAQ OMX Information LLC is to combine publicly available data from the three filed last sale products of the exchange subsidiaries of Nasdaq, Inc. and from the network processors for the ease and convenience of market data users and vendors, and ultimately the investing public. In that role, the function of NASDAQ OMX Information LLC is analogous to that of other market data vendors, and it has no competitive advantage over other market data vendors; NASDAQ OMX Information LLC performs precisely the same functions as Bloomberg, Thomson Reuters, and other market data vendors.

[4] ''Internal Distributors'' are Distributors that receive NASDAQ Last Sale Plus data and then distribute that data to one or more Subscribers within the Distributor's own entity. ''External Distributors'' are Distributors that receive NASDAQ Last Sale Plus data and then distribute that data to one or more Subscribers outside the Distributor's own entity. Internal Distributors and External Distributors are together known as ''Distributors''. Proposed NASDAQ Rule 7039(d)(1).

[5] Thus, the fee does not apply to persons that receive the NLS Plus data feed indirectly, through an Internal Distributor or External Distributor.

[6] *See* Securities Exchange Act Release Nos. 75257 (June 22, 2015), 80 FR 36862 (June 26, 2015) (SR–NASDAQ–2015–055) (order approving proposed rule change regarding NLS Plus); 75600 (August 4, 2015), 80 FR 47968 (August 10, 2015) (SR–NASDAQ–2015–088) (notice of filing and immediate effectiveness regarding fees for NLS

of Nasdaq, Inc.'s three U.S. equity exchanges.[7] NLS Plus includes all transactions from these exchanges, as well as FINRA/NASDAQ TRF data that is included in the current NLS product. In addition, NLS Plus features total cross-market volume information at the issue level, thereby providing redistribution of consolidated volume information (''consolidated volume'') from the securities information processors (''SIPs'') for Tape A, B, and C securities.[8] Thus, NLS Plus covers all securities listed on NASDAQ and New York Stock Exchange (''NYSE'') (now under the Intercontinental Exchange (''ICE'') umbrella), as well as US ''regional'' exchanges such as NYSE MKT, NYSE Arca, and BATS (also known as BATS/Direct Edge).[9]

NLS Plus is currently codified in NASDAQ Rule 7039(d). The fees for NLS Plus are set forth in NASDAQ Rule 7039(d)(1)–(d)(3) as follows:

(1) Firms that receive NASDAQ Last Sale Plus shall pay the annual administration fees for NASDAQ Last Sale, BX Last Sale, and PSX Last Sale,[10] and a data consolidation fee of $350 per month.

(2) Firms that receive NASDAQ Last Sale Plus would either be liable for NASDAQ Last Sale fees or NASDAQ Basic fees.

(3) In the event that NASDAQ OMX BX and/or NASDAQ OMX PHLX adopt user fees for BX Last Sale and/or PSX Last Sale, firms that receive NLS Plus would also be liable for such fees.

The Exchange now proposes to clarify how the data consolidation fee in NASDAQ Rule (d)(1) will be charged. Specifically, the Exchange proposes to clarify that firms that are Distributors that receive a NASDAQ Last Sale Plus direct data feed shall pay a data consolidation fee of $350 per month. Thus, only Distributors that receive NLS Plus would be charged the data consolidation fee. As proposed to be amended, NASDAQ Rule 7039(d)(1) would state:

(1) Firms that receive NASDAQ Last Sale Plus shall pay the annual administrative fees for NASDAQ Last Sale, BX Last Sale, and PSX Last Sale. Additionally, Internal Distributors or External Distributors shall pay a data consolidation fee of $350 per month.[11] ''Internal Distributors'' are Distributors that receive NASDAQ Last Sale Plus data and then distribute that data to one or more Subscribers within the Distributor's own entity. ''External Distributors'' are Distributors that receive NASDAQ Last Sale Plus data and then distribute that data to one or more Subscribers outside the Distributor's own entity.[12]

The NLS Plus fee structure as amended continues to be designed to ensure that vendors could compete with the Exchange by creating a product similar to NLS Plus.[13] The proposed fee structure reflects the cost of the data feeds underlying NLS Plus (including user fees and annual administrative fees), as well as the incremental cost of the aggregation and consolidation function (the ''consolidation function'') for NLS Plus. Accordingly, the Exchange believes that the fee structure would not result in charges for NLS Plus that are lower than the cost to a vendor creating a competing product, including the cost of receiving the underlying data feeds and consolidating them. The data consolidation fee recognizes that NLS Plus is created from data derived from NASDAQ Last Sale, BX Last Sale, PSX Last Sale, and data from the SIPs to which a consolidation function is applied. Charging the consolidation fee will not impede an entity receiving the underlying direct data feeds from creating a competing product to the NLS Plus feed based on combining individual data feeds, and charging its clients a fee that it believes reflects the value of the consolidation function. The Exchange believes that the incremental cost of aggregation to an entity that wants to re-create NLS Plus will be factored into the entity's revenue opportunity and may be inconsequential where the vendor has in place systems to perform these functions as part of creating its proprietary market data products and allocating costs over numerous products and customer relationships. For these reasons, the Exchange believes that vendors could readily offer a product similar to the NLS Plus on a competitive basis at a similar cost.

The amendment to clarify that the consolidation fee applies to Distributors that receive the NLS Plus data feed directly but does not apply to persons that receive NLS Plus indirectly through a Distributor is designed to ensure that the Exchange charges the fee only to those persons that directly benefit from the consolidation function. Specifically, if a person wished to combine the products that underlie NLS Plus and distribute them to customers or internal users, it would incur its own consolidation costs. By purchasing NLS Plus for distribution, a Distributor foregoes these costs and instead opts to pay the Exchange to perform the consolidation function for it. Thus, imposing this fee upon Distributors is a logical corollary to the service being provided. By contrast, imposing the fee upon persons receiving the product through Distributors would effectively impose a duplicative charge, since such persons consume the data but are not in the business of distributing it and therefore do not forego consolidation costs when receiving the product. The

Plus) (the ''NLS Plus fee proposal''); 75763 (August 26, 2015), 80 FR 52817 (September 1, 2015) (SR–Phlx–2015–72) (notice of filing and immediate effectiveness regarding NLS Plus on PSX); 75890 (September 10, 2015), 80 FR 55692 (September 16, 2015) (SR–Phlx–2015–76) (notice of filing and immediate effectiveness regarding fees for NLS Plus on PSX); 75709 (August 14, 2015), 80 FR 50671 (August 20, 2015) (SR–BX–2015–047) (notice of filing and immediate effectiveness regarding NLS Plus on BX); and 75830 (September 3, 2015), 80 FR 54640 (September 10, 2015) (SR–BX–2015–054) (notice of filing and immediate effectiveness regarding fees for NLS Plus on BX).

[7] The NASDAQ OMX U.S. equity markets include the Exchange NASDAQ OMX BX (''BX''), and NASDAQ OMX PSX (''PSX'') (together known as the ''NASDAQ OMX equity markets''). PSX and BX are filing companion proposals similar to this one. NASDAQ's last sale product, NASDAQ Last Sale, includes last sale information from the FINRA/NASDAQ Trade Reporting Facility (''FINRA/NASDAQ TRF''), which is jointly operated by NASDAQ and the Financial Industry Regulatory Authority (''FINRA''). *See* Securities Exchange Act Release No. 71350 (January 17, 2014), 79 FR 4218 (January 24, 2014) (SR–FINRA–2014–002). For proposed rule changes submitted with respect to NASDAQ Last Sale, BX Last Sale, and PSX Last Sale, *see, e.g.,* Securities Exchange Act Release Nos. 57965 (June 16, 2008), 73 FR 35178, (June 20, 2008) (SR–NASDAQ–2006–060) (order approving NASDAQ Last Sale data feeds pilot); 61112 (December 4, 2009), 74 FR 65569, (December 10, 2009) (SR–BX–2009–077) (notice of filing and immediate effectiveness regarding BX Last Sale data feeds); and 62876 (September 9, 2010), 75 FR 56624, (September 16, 2010) (SR–Phlx–2010–120) (notice of filing and immediate effectiveness regarding PSX Last Sale data feeds).

[8] Tape A and Tape B securities are disseminated pursuant to the Security Industry Automation Corporation's (''SIAC'') Consolidated Tape Association Plan/Consolidated Quotation System, or CTA/CQS (''CTA''). Tape C securities are disseminated pursuant to the NASDAQ Unlisted Trading Privileges (''UTP'') Plan. NLS Plus reflects real-time trading activity for Tape C securities and 15-minute delayed information for Tape A and Tape B securities.

[9] Registered U.S. exchanges are listed at *http://www.sec.gov/divisions/marketreg/mrexchanges.shtml.*

[10] Annual administrative fees are in BX Rule 7035, NASDAQ Rule 7035, and NASDAQ OMX PSX Fees Chapter VIII. These remain unchanged at: $1,000 for NASDAQ, $1,000 for BX, and $1,000 for PSX. For purposes of conformity, ''administration'' is changed to ''administrative'' in NASDAQ Rule 7039(d)(1), discussed below.

[11] The Exchange notes that those that have received NLS Plus directly from the Exchange have all, in fact, been firms. While the NLS Plus feed is available to all that subscribe and pay the requisite costs, the Exchange believes that in light of such costs it will continue to experience only firms receiving the feed directly from the Exchange.

[12] NASDAQ Rule 7039(d)(2) would remain unchanged. For conformity with Rule 7039 language, ''NLS'' in Rule 7039(d)(3) would be changed to ''NASDAQ Last Sale''.

[13] For additional discussion regarding potential competition with NLS Plus, *see* supra note 6 and filings cited therein.

Exchange further notes that the consolidation fee for BATS One, an analogous product of competing exchanges, is charged solely to external distributors of that product.[14]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[15] in general, and with Sections 6(b)(4) and (5) of the Act,[16] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities, and does not unfairly discriminate between customers, issuers, brokers or dealers. All recipients of the NLS Plus data offering continue to pay the underlying data feed fees and annual administrative fees for NLS, BX Last Sale, and PSX Last Sale. The Exchange is simply clarifying that the data consolidation component of the fees for NLS Plus will be charged solely to firms that receive a NASDAQ Last Sale Plus direct data feed and are Distributors.

This change is reasonable and consistent with an equitable allocation of fees because it is designed to ensure that the Exchange charges the fee only to those persons that directly benefit from the consolidation function. Specifically, if a person wished to combine the products that underlie NLS Plus and distribute them to customers or internal users, it would incur its own consolidation costs. By purchasing NLS Plus for distribution, a Distributor foregoes these costs and instead opts to pay the Exchange to perform the consolidation function for it. Thus, imposing this fee upon Distributors is a logical corollary to the service being provided. The change is also not unfairly discriminatory. Indeed, imposing the fee upon persons receiving NLS Plus indirectly through Distributors would effectively impose a duplicative charge upon them, since such persons consume the data but are not in the business of distributing it and therefore do not forego consolidation costs when receiving the product. The Exchange further notes that the consolidation fee for BATS One, an analogous product of competing exchanges, is charged solely to external distributors of that product.[17] Accordingly, the exchanges that distribute BATS One take an analogous approach, in that they do not charge a consolidation fee to indirect recipients of the product, but rather charge the fee only to a subset of its distributors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The change proposed herein is designed to ensure that the consolidation fee for NLS Plus is appropriately assessed to Distributors of the product that benefit from the consolidation function performed by NASDAQ OMX Information LLC in creating the product and insures that a duplicative charge is not also assessed against indirect recipients of the product. Thus, the change will avoid the imposition of fees on certain product recipients, while not increasing fees for any recipients.

The market for data products is extremely competitive and firms may freely choose alternative venues and data vendors based on the aggregate fees assessed, the data offered, and the value provided. This rule proposal does not burden competition, which is reflected in the offerings of other exchanges that sell alternative data products[18] and in the ability of competing data feed vendors to combine underlying data feeds in direct competition with NLS Plus. NASDAQ OMX Information LLC was constructed specifically to establish a level playing field with market data vendors and to preserve fair competition between them. NASDAQ OMX Information LLC receives NLS, BX Last Sale, and PSX Last Sale from each NASDAQ-operated exchange in the same manner, at the same speed, and reflecting the same fees as for all market data vendors. Therefore, NASDAQ OMX Information LLC has no competitive advantage with respect to these last sale products and NASDAQ commits to maintaining this level playing field in the future. In other words, NASDAQ will continue to disseminate separately the underlying last sale products to avoid creating a latency differential between NASDAQ OMX Information LLC and other market data vendors, and to avoid creating a pricing advantage for NASDAQ OMX Information LLC.

NLS Plus exists in a market for proprietary last sale data products that is currently competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data and strict pricing discipline for the proprietary products themselves. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. This proprietary data is produced by each individual exchange, as well as other entities, in a vigorously competitive market. Similarly, with respect to the FINRA/NASDAQ TRF data that is a component of NLS and NLS Plus, allowing exchanges to operate TRFs has permitted them to earn revenues by providing technology and data in support of the non-exchange segment of the market. This revenue opportunity has also resulted in fierce competition between the two current TRF operators, with both TRFs charging extremely low trade reporting fees and rebating the majority of the revenues they receive from core market data to the parties reporting trades.

Transaction execution and proprietary data products are complementary in that market data is both an input and a byproduct of the execution service. In fact, market data and trade execution are a paradigmatic example of joint products with joint costs. The decision whether and on which platform to post an order will depend on the attributes of the platform where the order can be posted, including the execution fees, data quality and price, and distribution of its data products. Without trade executions, exchange data products cannot exist. Moreover, data products are valuable to many end users only insofar as they provide information that end users expect will assist them or their customers in making trading decisions.

The costs of producing market data include not only the costs of the data distribution infrastructure, but also the costs of designing, maintaining, and operating the exchange's transaction execution platform and the cost of regulating the exchange to ensure its fair operation and maintain investor confidence. The total return that a trading platform earns reflects the revenues it receives from both products and the joint costs it incurs. Moreover, the operation of the exchange is characterized by high fixed costs and low marginal costs. This cost structure

[14] *See, e.g.,* Securities Exchange Act Release No. 73918 (December 23, 2014), 79 FR 78920 (December 31, 2014) (SR–BATS–2014–055; SR–BYX–2014–030; SR–EDGA–2014–25; SR–EDGX–2014–25) (order approving market data product called BATS One Feed being offered by four affiliated exchanges).

[15] 15 U.S.C. 78f.

[16] 15 U.S.C. 78f(b)(4) and (5).

[17] *See, e.g.,* Securities Exchange Act Release No. 73918 (December 23, 2014), 79 FR 78920 (December 31, 2014) (SR–BATS–2014–055; SR–BYX–2014–030; SR–EDGA–2014–25; SR–EDGX–2014–25) (order approving market data product called BATS One Feed being offered by four affiliated exchanges).

[18] *Id.*

is common in content and content distribution industries such as software, where developing new software typically requires a large initial investment (and continuing large investments to upgrade the software), but once the software is developed, the incremental cost of providing that software to an additional user is typically small, or even zero (*e.g.,* if the software can be downloaded over the internet after being purchased).[19] In NASDAQ's case, it is costly to build and maintain a trading platform, but the incremental cost of trading each additional share on an existing platform, or distributing an additional instance of data, is very low. Market information and executions are each produced jointly (in the sense that the activities of trading and placing orders are the source of the information that is distributed) and are each subject to significant scale economies. In such cases, marginal cost pricing is not feasible because if all sales were priced at the margin, NASDAQ would be unable to defray its platform costs of providing the joint products. Similarly, data products cannot make use of TRF trade reports without the raw material of the trade reports themselves, and therefore necessitate the costs of operating, regulating,[20] and maintaining a trade reporting system, costs that must be covered through the fees charged for use of the facility and sales of associated data.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A)(ii) of the Act,[21] the Exchange has designated this proposal as establishing or changing a due, fee, or other charge imposed on any person, whether or not the person is a member of the self-regulatory organization, which renders the proposed rule change effective upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2015–131 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2015–131. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–NASDAQ–2015–131 and should be submitted on or before December 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28808 Filed 11–12–15; 8:45 am]

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[19] *See* William J. Baumol and Daniel G. Swanson, ''The New Economy and Ubiquitous Competitive Price Discrimination: Identifying Defensible Criteria of Market Power,'' *Antitrust Law Journal,* Vol. 70, No. 3 (2003).

[20] It should be noted that the costs of operating the FINRA/NASDAQ TRF borne by NASDAQ include regulatory charges paid by NASDAQ to FINRA.

[21] 15 U.S.C. 78s(b)(3)(A)(ii).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76381; File No. SR–MSRB–2015–09]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Order Granting Approval of a Proposed Rule Change Consisting of Proposed Amendments to Rule G–20, on Gifts, Gratuities and Non-Cash Compensation, and Rule G–8, on Books and Records To Be Made by Brokers, Dealers, Municipal Securities Dealers, and Municipal Advisors, and the Deletion of Prior Interpretive Guidance

November 6, 2015.

I. Introduction

On September 2, 2015, the Municipal Securities Rulemaking Board (the ''MSRB'' or ''Board'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change consisting of proposed amendments to MSRB Rule G–20 on gifts, gratuities and non-cash compensation, proposed amendments to MSRB Rule G–8, on books and records to be made by brokers, dealers, municipal securities dealers, and municipal advisors, and the deletion of prior interpretive guidance that would be codified by proposed amended Rule G–20 (the ''proposed rule change'').

The proposed rule change was published for comment in the **Federal Register** on September 22, 2015.[3] The Commission received three comment letters on the proposed rule change.[4] On

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 75932 (September 16, 2015), 80 FR 57240 (September 22, 2015) (the ''Notice'').

[4] *See* Letters from Tamara K. Salmon, Senior Associate Counsel, Investment Company Institute

Continued

November 2, 2015, the MSRB submitted a response to these comments.[5] This order approves the proposed rule change.

II. Description of the Proposed Rule Change

Existing Rule G–20 is designed, in part, to minimize the conflicts of interest that arise when a dealer attempts to induce organizations active in the municipal securities market to engage in business with such dealers by means of personal gifts or gratuities given to employees of such organizations.[6] According to the MSRB, the proposed rule change addresses improprieties and conflicts that may arise when municipal advisors and/or their associated persons[7] give gifts or gratuities to employees who may influence the award of municipal advisory business.[8] In summary, the MSRB has proposed amendments to Rule G–20 that would:

- Extend the relevant existing provisions of Rule G–20 to municipal advisors and their associated persons and to gifts given in relation to municipal advisory activities;
- Consolidate and codify interpretive guidance, including interpretive guidance published by the Financial Industry Regulatory Authority, Inc. (''FINRA'') and adopted by the MSRB and delete prior interpretive guidance that would be codified by proposed amended Rule G–20;
- Add a new provision prohibiting a regulated entity from seeking or obtaining reimbursement of certain entertainment expenses from the proceeds of an offering of municipal securities; and
- Make several revisions that are designed to assist brokers, dealers, and municipal securities dealers (''dealers'') and municipal advisors (dealers, together with municipal advisors, ''regulated entities'') and their associated persons with their understanding of and compliance with Rule G–20.

In summary, the MSRB has proposed amendments to Rule G–8 that would:

- Extend to municipal advisors the recordkeeping requirements related to Rule G–20 that currently apply to dealers; and
- Amend the rule language contained in Rule G–8(a)(xvii)(A), (B), and (C) applicable to dealers to reflect the revisions to proposed amended Rule G–20.

Extension of Rule G–20 to Municipal Advisors and Municipal Advisory Activities

The MSRB has proposed to extend to municipal advisors and their associated persons: (i) The general dealer prohibition of gifts or gratuities in excess of $100 per person per year in relation to the municipal securities activities of the recipient's employer (the ''$100 limit''); (ii) the exclusions contained in the existing rule from that general prohibition (including certain consolidations and the codifications of prior interpretive guidance) and the addition of bereavement gifts to those exclusions; and (iii) the existing exclusion relating to contracts of employment or compensation for services. Proposed section (g) of Rule G–20, on non-cash compensation in connection with primary offerings, is not being extended to municipal advisors or to associated persons thereof.

(i) General Prohibition of Gifts or Gratuities in Excess of $100 per Year

The MSRB has proposed section (c) of Rule G–20 which extends to a municipal advisor and its associated persons the provision that currently prohibits a dealer and its associated persons, in certain circumstances, from giving directly or indirectly any thing or service of value, including gratuities (''gifts''), in excess of $100 per year to a person (other than an employee of the dealer). The prohibited payments or services by a regulated entity or associated persons would be those provided in relation to the municipal securities activities or municipal advisory activities of the employer of the recipient (other than an employee of the regulated entity).

(ii) Exclusions From the $100 Limit

The MSRB has proposed section (d) of Rule G–20 which extends to a municipal advisor and its associated persons the provision that excludes certain gifts from the $100 limit of proposed section (c) as long as the conditions articulated by proposed section (d) and the relevant subsection, as applicable, are met. Section (d) states that gifts, in order to be excluded from the $100 limit, must not give rise to any apparent or actual material conflict of interest.

Proposed section (d) of Rule G–20 includes subsections (d)(i) through (d)(iv) and (d)(vi) which consolidate and codify interpretive guidance that the MSRB provided in MSRB Notice 2007–06 (the ''2007 MSRB Gifts Notice'').[9] The 2007 MSRB Gifts Notice's interpretive guidance also included FINRA guidance that the MSRB had adopted by reference.[10] Further, proposed subsection (d)(v) would codify FINRA interpretive guidance relating to bereavement gifts that the MSRB previously had not adopted.[11]

The MSRB has proposed subsection (d)(i) of Rule G–20 which extends to a municipal advisor and its associated persons the current exclusion of a gift of meals or tickets to theatrical, sporting, and other entertainment given by a dealer or its associated persons from the $100 limit if they are a ''normal business dealing.'' Such exclusion is subject to the limitations as described in proposed subsection (d)(i).

Proposed subsections (d)(ii) through (iv) establish three categories of gifts that were previously excluded from the $100 limit under the category of ''reminder advertising'' in the rule language regarding ''normal business dealings'' in existing section (b) of Rule G–20. The MSRB has proposed to delete the concept of ''reminder advertising'' from the ''normal business dealings'' exclusion under current paragraph (b). This amendment would clarify the types of gifts in the nature of reminder advertising that would be excluded from the $100 limit. These changes conform draft amended paragraph (d) with current FINRA interpretive guidance that the MSRB has stated applies to Rule G–20.[12] These three categories are:

- Gifts commemorative of a business transaction, such as a desk ornament or

(''ICI''), dated September 25, 2015 (''ICI Letter''); Leslie M. Norwood, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association (''SIFMA''), dated October 13, 2015 (''SIFMA Letter''); and Terri Heaton, President, National Association of Municipal Advisors (''NAMA''), dated October 16, 2015 (''NAMA Letter'').

[5] *See* Letter from Michael L. Post, General Counsel—Regulatory Affairs, MSRB, dated November 2, 2015 (''MSRB Response Letter'').

[6] *See* MSRB Notice 2004–17 (June 15, 2004).

[7] MSRB Rule D–11 defines ''associated persons'' as follows: Unless the context otherwise requires or a rule of the Board otherwise specifically provides, the terms ''broker,'' ''dealer,'' ''municipal securities broker,'' ''municipal securities dealer,'' ''bank dealer,'' and ''municipal advisor'' shall refer to and include their respective associated persons. Unless otherwise specified, persons whose functions are solely clerical or ministerial shall not be considered associated persons for purposes of the Board's rules.

[8] *See supra* note 3 at 57240–41.

[9] *See* Dealer Payments in Connection with the Municipal Issuance Process, MSRB Notice 2007–06 (Jan. 29, 2007).

[10] *See* 2007 MSRB Gifts Notice (reminding dealers of the application of Rule G–20 and Rule G–17 in connection with certain payments made and expenses reimbursed during the municipal bond issuance process, and stating that the National Association of Securities Dealers, Inc.'s (''NASD'') guidance provided in NASD Notice to Members 06–69 (Dec. 2006) to assist dealers in complying with NASD Rule 3060 applies as well to comparable provisions of Rule G–20).

[11] *See supra* note 3 at 57242.

[12] *Id.* at 57241.

Lucite tombstone (proposed subsection (d)(ii));

• de minimis gifts, such as pens and notepads (proposed subsection (d)(iii)); and

• promotional gifts of nominal value that bear an entity's corporate or other business logo and that are substantially below the $100 limit (proposed subsection (d)(iv)).

Proposed subsection (d)(v) of Rule G–20 excludes bereavement gifts which are reasonable and customary for the circumstances from the $100 limit. According to the MSRB, proposed subsection (d)(v) of Rule G–20 codifies FINRA interpretive guidance currently applicable to dealers relating to bereavement gifts that the MSRB previously had not adopted.[13]

Finally, the MSRB has proposed subsection (d)(vi) of Rule G–20 which excludes personal gifts given upon the occurrence of infrequent life events, such as a wedding gift or a congratulatory gift for the birth of a child. According to the MSRB, this proposed subsection consolidates and codifies the FINRA personal gift guidance currently applicable to dealers.[14]

The ''frequency'' and ''extensiveness'' limitations applicable to proposed subsection (d)(i) of Rule G–20 would not apply to proposed subsections (d)(ii) through (vi). The MSRB has proposed to modify those limitations to better reflect the characteristics of the gifts described in proposed subsections (d)(ii) through (vi).[15] According to the MSRB, gifts described in those subsections in the proposed rule change are by their nature given infrequently and/or are of such nominal value that retaining the requirement that such gifts be ''not so frequent or extensive'' would be unnecessarily duplicative of the description of these gifts and could result in confusion.[16]

To assist regulated entities with their understanding of the exclusions described and with their compliance with the rule, the MSRB has provided guidance in the Supplementary Material. Paragraph .03 of the Supplementary Material provides guidance regarding promotional gifts and ''other business logos'' including what would constitute an ''other business logo.'' Paragraph .04 of the Supplementary Material provides guidance regarding personal gifts including factors that should be considered when determining whether a gift is given in connection with the municipal securities or municipal advisory services of the employer of the recipient.

(iii) Exclusion for Compensation Paid as a Result of Contracts of Employment or Compensation for Services

The MSRB has proposed section (f) which extends to municipal advisors the exclusion from the $100 limit in existing Rule G–20(c) for contracts of employment with or compensation for services that are rendered pursuant to a prior written agreement meeting certain content requirements. The MSRB has stated that proposed section (f) would clarify that the exclusion applies only to the compensation paid as a result of certain employment contracts, and does not apply to the existence or creation of employment contracts. The MSRB further stated that proposed section (f) is only a clarification and would not alter the requirements currently applicable to dealers.[17]

Consolidation and Codification of MSRB and FINRA Interpretive Guidance

As discussed, the MSRB has proposed to consolidate and codify existing FINRA interpretive guidance previously adopted by the MSRB and incorporate additional relevant FINRA interpretive guidance that has not previously been adopted by the MSRB in both Rule G–20 text and the Supplementary Material. While FINRA's interpretive guidance regarding bereavement gifts was not formerly adopted by the MSRB, the MSRB believes that this guidance will be appropriate for regulated entities as it is consistent with the purpose and scope of proposed amended Rule G–20. Further, the MSRB stated its belief that the consolidation and codification of the applicable interpretive guidance will promote compliance with the rule and create efficiencies for regulated entities and regulatory enforcement agencies.[18]

In addition to the interpretive guidance discussed above, proposed paragraphs .01, .02, and .05 of the Supplementary Material would provide guidance relating to the valuation and the aggregation of gifts and to the applicability of state laws. Proposed paragraph .01 of the Supplementary Material would state that a gift's value should be determined generally according to the higher of its cost or market value. Proposed paragraph .02 of the Supplementary Material would state that regulated entities must aggregate all gifts that are subject to the $100 limit given by the regulated entity and each associated person of the regulated entity to a particular recipient over the course of a year however ''year'' is selected to be defined by the regulated entity. Proposed paragraphs .01 and .02 reflect existing FINRA interpretive guidance regarding the aggregation of gifts for purposes of its gift rules, which the MSRB has previously adopted.

Proposed paragraph .05 of the Supplementary Material would remind regulated entities that, in addition to all the requirements of proposed amended Rule G–20, regulated entities may also be subject to other duties, restrictions, or obligations under state or other laws and that proposed amended Rule G–20 would not supersede any more restrictive provisions of state or other laws applicable to regulated entities or their associated persons.

Prohibition of Reimbursement for Entertainment Expenses

The MSRB has also proposed section (e) of Rule G–20 which provides that a regulated entity is prohibited from requesting or obtaining reimbursement for certain entertainment expenses from the proceeds of a municipal securities offering. The MSRB stated its belief that this provision would address a matter highlighted by a recent FINRA enforcement action. Proposed section (e) provides that an entertainment expense excludes ''ordinary and reasonable expenses for meals hosted by the regulated entity and directly related to the offering for which the regulated entity was retained.'' The MSRB has stated that proposed section (e) is intended to allow the continuation of the generally accepted market practice of a regulated entity advancing normal travel costs to personnel of a municipal entity or obligated person for business travel related to a municipal securities issuance and obtaining reimbursement for such costs.[19]

Additional Proposed Amendments to Rule G–20

In addition to the previously discussed proposed amendments to Rule G–20, the MSRB proposed several amendments which it believes will assist readers with their understanding of and compliance with Rule G–20.[20] These proposed amendments include (i) a revised rule title, (ii) a new provision stating the rule's purpose, and (iii) a re-ordering of existing provisions and additional defined terms.

[13] *Id.* at 57242.

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] *Id.*

Recordkeeping Requirements

The MSRB has proposed amendments to Rule G–8 which extend to municipal advisors the recordkeeping requirements related to Rule G–20 that currently apply to dealers. Municipal advisor recordkeeping requirements would be identical to the recordkeeping requirements to which dealers would be subject in proposed amended Rule G–8(a)(xvii)(A) and (B).

The MSRB has proposed to amend the language contained in Rule G–8(a)(xvii)(A), (B), and (C) applicable to dealers, to reflect the revisions to proposed amended Rule G–20. Proposed amended paragraph (a)(xvii)(A) provides that a separate record of any gift or gratuity *subject to the general limitation of* proposed amended Rule G–20(c) must be made and kept by dealers (emphasis added to amended rule text). Paragraph (a)(xvii)(B) would be amended to clarify that dealers must make and keep records of all agreements referred to in proposed amended Rule G–20(f) and *records of* all compensation paid as a result of those agreements (emphasis added to proposed amended rule text). The proposed amendments would also track the reordering of sections in proposed amended Rule G–20 and provide greater specificity as to the records that a dealer must maintain by referencing the terms used in proposed amended Rule G–20.

The proposed rule change would extend the provisions of existing Rule G–8 to require that municipal advisors as well as dealers make and keep records of: gifts given that are subject to the $100 limit; and all agreements referred to in proposed section (f) (on compensation for services) and records of compensation paid as a result of those agreements.

Implementation Date

The MSRB requested that the proposed rule change be approved with an implementation date six months after the Commission approval date for all changes.

III. Summary of Comments Received and the MSRB's Response

As noted previously, the Commission received three comment letters on the proposed rule change.[21] The commenters generally support the proposed rule change.[22] However, some commenters asked for further clarification and provided suggestions to the proposed rule change.[23] In response to an earlier request for comment by the MSRB on the draft amendments to Rules G–20 and G–8,[24] the MSRB received eight comment letters and responded to the comments in the Notice. In the MSRB Response Letter, the MSRB incorporated by reference its response to comments made in the Notice noting that the three comments received on the proposed rule change were the same or substantially similar to the comments made in response to the MSRB Request for Comment.[25] The MSRB believes the proposed rule change is appropriately tailored and responded to the commenters as discussed below.

A. Application of Proposed Amended Rule G–20(c) to Certain Recipients

NAMA commented that under the MSRB's proposed Rule G–20, the $100 limit would seem not to apply to gifts given to employees or officials of municipal entities or obligated persons because such persons, for the most part, do not engage in ''municipal advisory activities.'' [26] NAMA noted that the MSRB indicated in the Notice that prior interpretive guidance made clear issuer personnel are considered to engage in ''municipal securities activities'' and requested that the MSRB codify this guidance in Rule G–20.[27] The MSRB responded to NAMA stating that the language of both existing Rule G–20 and proposed amended Rule G–20 applies to gifts given in relation to this broad term ''municipal securities activities.'' [28]

NAMA also commented that many municipal official and governing board members are not employees of municipal entities or obligated persons, and therefore it appears that G–20 does not apply to gifts given to non-employee officials of municipal entities and obligated persons.[29] The MSRB responded by stating that it believes for purposes of existing and proposed amended Rule G–20, elected and appointed officials are considered employees of the governmental entity on behalf of which they act as agent or representative.[30]

B. Changing the Amount of the $100 Limit

In its comments, NAMA proposed that the $100 limit be raised to $250 per person per year which would aid in limiting conflicts of interest and also align Rule G–20 with MSRB Rule G–37.[31] NAMA stated that in Rule G–37 the MSRB determined that the contribution level of $250 was sufficient to address the needs of individuals seeking to give political contributions while not allowing those contributions to be so excessive as to allow the contributor to gain undue influence.[32] NAMA proposed that supplementary material be added to state, in effect, that occasional gifts of meals or tickets to theatrical, sporting, and other entertainments that are hosted by the regulated entity would be presumed to be so extensive as to raise a question of propriety if they exceed $250 in any year in conjunction with any gifts provided under Rule G–20(c).[33] NAMA asserted that because the purposes of Rule G–20 and Rule G–37 both are meant to limit a dealer's or a municipal advisor's ability to gain undue influence through the giving of gifts or contributions that the rules should be written similarly.[34]

The MSRB responded to NAMA by stating that Rule G–37 is designed to address potential political corruption that may result from pay-to-play practices,[35] and as such, is tailored in light of First Amendment concerns. Existing Rule G–20 is designed to address commercial bribery by minimizing the conflicts of interest that arise when a dealer attempts to induce organizations active in the municipal securities market to engage in business with such dealer by means of gifts or gratuities given to employees of such organizations.[36] The MSRB stated that Rules G–37 and G–20 address substantially different regulatory needs in different legal contexts, and therefore the dollar amounts are likewise justifiably different.[37]

C. ''Normal Business Dealings''

NAMA commented that proposed amended Rule G–20(d), which sets forth the exclusions from the $100 limit, leaves open opportunities for abuse.[38] NAMA expressed specific concern regarding proposed subsection (d)(i), which would, under certain circumstances, exclude from the $100 limit the giving of occasional meals or tickets to theatrical, sporting or

[21] *See supra* note 4.

[22] *Id.*

[23] *Id.*

[24] Request for Comment on Draft Amendments to MSRB Rule G–20, on Gifts, Gratuities and Non-Cash Compensation, to Extend its Provisions to Municipal Advisors, MSRB Notice 2014–18 (Oct. 23, 2014) (''MSRB Request for Comment'').

[25] *See supra* note 5.

[26] *See* NAMA Letter.

[27] *Id.*

[28] *See supra* notes 5 and 24.

[29] *See* NAMA Letter.

[30] *See supra* notes 5 and 24.

[31] *See* NAMA Letter.

[32] *Id.*

[33] *Id.*

[34] *Id.*

[35] *See supra* notes 5 and 24.

[36] *Id.*

[37] *Id.*

[38] *See* NAMA Letter.

entertainment events.[39] In NAMA's view, regulated entities would be able to engage in otherwise impermissible gift giving under the guise of ''normal business dealings,'' and such gift giving likely would result in the improper influence that Rule G–20 was designed to curtail.[40] NAMA suggested modifying the amended rule to impose an aggregate limit of $250 on all gifts given as part of ''normal business dealings'' and gifts and gratuities given under proposed subsection (c) believing the aggregate limit would be consistent with the dollar threshold used in MSRB Rule G–37.[41]

The MSRB responded that in order to curtail any abuse of the exception to the $100 limit, proposed amended Rule G–20 places conditions on the excluded gifts, including those that fall under ''normal business dealings.''[42] All of the gifts described in proposed section (d) would be excluded only if they do not ''give rise to any apparent or actual material conflict of interest,'' and, under proposed section (d)(i), ''normal business dealing'' gifts would be excluded only if they are not ''so frequent or so extensive as to raise any question of propriety.''[43] The MSRB further stated that dealers and municipal advisors are subject to the fundamental fair-dealing obligations of MSRB Rule G–17.[44] The MSRB stated that Rule G–17 likely addresses at least some of the concerns raised by NAMA by prohibiting regulated entities from characterizing excessive or lavish expenses for the personal benefit of issuer personnel as an expense of the issue, as such behavior could possibly constitute a deceptive, dishonest or unfair practice.[45]

D. Incorporation of Applicable FINRA Interpretive Guidance

ICI commented that the MSRB should incorporate the relevant portions of certain NASD guidance regarding the value of promotional items into Rule G–20.[46] ICI also encouraged the MSRB to do so in order to ease the compliance burden on regulated entities as well as make clear that the monetary limits in Rule G–20 do not apply to ''customary Lucite tombstones, plaques or other similar solely decorative items commemorating a business transaction, even when such items have a cost of more than $100.''[47]

In response to ICI, the MSRB stated that such interpretive guidance published by NASD has been incorporated into proposed amended Rule G–20.[48] The MSRB also stated that proposed Rule G–20(d)(ii) provides that the general $100 limitation does not apply to ''[g]ifts that are solely decorative items commemorating a business transaction, such as a customary plaque or desk ornament (*e.g.,* Lucite tombstone).''[49] The MSRB noted that this description does not contain a monetary limit, and therefore the provision fully addresses ICI's comment.[50]

E. Recordkeeping Requirements

NAMA commented that a regulated entity should be required to maintain records for gifts that are subject to either the normal business dealing exclusion under proposed amended Rule G–20(c) or Rule G–20(d)(i).[51] NAMA noted that gifts that constitute normal business dealings under proposed amended Rule G–20(d)(i) require recordkeeping to comply with certain requirements of the Internal Revenue Service and of various municipalities.[52] Therefore, according to NAMA, imposing a recordkeeping requirement would not be an entirely new burden, would provide protection against pay-to-play activities and would provide a means to determine whether such gifts give rise to questions of impropriety or conflicts of interest.[53] NAMA also commented that to allow for meaningful enforcement the MSRB should require a regulated entity to keep records of any personal gifts given pursuant to proposed amended Rule G–20(d)(iv) that were paid for, directly or indirectly, by the regulated entity.[54]

The MSRB responded to NAMA stating that it believes that the recordkeeping requirements of Rule G–8(h) that relate to Rule G–20 should be limited to items that are subject to the $100 limit so as to continue to align recordkeeping under Rule G–20 with existing FINRA recordkeeping requirements for dealers.[55] The MSRB further stated that significant safeguards are already in place, including Rules G–27, G–44, and G–17, which weigh against imposing the additional recordkeeping burdens on regulated entities.[56] The MSRB further noted that it reminded dealers in its 2007 MSRB Gifts Notice on Rule G–20 that they must have supervisory policies and procedures in place under Rule G–27 that are reasonably designed to prevent and detect violations of Rule G–20 (and of other applicable securities laws).[57] The MSRB also stated that recently adopted Rule G–44, on supervision and compliance obligations of municipal advisors, imposes similar supervisory requirements on municipal advisors.[58] Finally, the MSRB notes that they reminded dealers in 2007 in particular contexts that the making of payments that might not otherwise be subject to Rule G–20 could constitute separate violations of Rule G–17, which currently applies to municipal advisors and dealers.[59]

SIFMA commented that it objects to the requirement that brokers, dealers and municipal securities dealers keep records related to Rule G–20 for a period of six years because municipal advisors only need to retain them for five years.[60] The MSRB responded to SIFMA stating that this topic is addressed in MSRB Rule G–9 which was not included as part of the proposed rule change and therefore no revision to the proposed rule change is necessary.[61]

V. Discussion and Commission Findings

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the MSRB. In particular, the proposed rule change is consistent with Sections 15B(b)(2) and 15B(b)(2)(C) of the Act. Section 15B(b)(2) of the Act provides that the MSRB shall propose and adopt rules to effect the purposes of that title with respect to transactions in municipal securities effected by brokers, dealers, and municipal securities dealers and advice provided to or on behalf of municipal entities or obligated persons by brokers, dealers, municipal securities dealers, and municipal advisors with respect to municipal financial products, the issuance of municipal securities, and solicitations of municipal entity or obligated persons undertaken by brokers, dealers, municipal securities dealers, and municipal advisors.[62] Section 15B(b)(2)(C) of the Act requires that the MSRB's rules shall be designed to

[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] *See supra* notes 5 and 24.
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *See* ICI Letter.
[47] *Id.*
[48] *See supra* note 5.
[49] *Id.*
[50] *Id.*
[51] *See* NAMA Letter.
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *See supra* notes 5 and 24.
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] *Id.*
[60] *See* SIFMA Letter.
[61] *See supra* note 5.
[62] 15 U.S.C. 78o–4(b)(2).

prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities and municipal financial products, to remove impediments to and perfect the mechanism of a free and open market in municipal securities and municipal financial products, and, in general, to protect investors, municipal entities, obligated persons, and the public interest.'' [63]

The proposed rule change would help prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade and protect investors, municipal entities, obligated persons, and the public interest by reducing, or at least exposing, the potential for conflicts of interests in municipal advisory activities by extending the policies embodied in existing Rule G–20 to municipal advisors and their associated persons and establishing a common standard for all regulated entities that operate in the municipal securities market. The proposed rule change would help ensure that engagements of municipal advisors, as well as engagements of dealers, are awarded on the basis of merit and not as a result of gifts made to employees controlling the award of such business. In addition, by prohibiting the reimbursement of entertainment expenses from the proceeds of a municipal securities issuance, the proposed rule change will provide regulated entities with clear notice and guidance regarding MSRB regulation of such matters. Further, codifying certain applicable MSRB interpretive guidance and adopting and codifying certain FINRA interpretive guidance will increase awareness of such guidance by regulated entities and in turn improve compliance and help prevent inadvertent violations of Rule G–20.

In addition, the proposed amendments to Rule G–8 will assist in the enforcement of Rule G–20 by extending the relevant existing recordkeeping requirements of Rule G–8 that currently are applicable to dealers to municipal advisors. Regulated entities will be required to create and maintain records in a consistent manner which the Commission believes will allow organizations that examine regulated entities to more precisely monitor and promote compliance with the proposed rule change. Increased compliance with the proposed rule change would likely reduce the frequency and magnitude of conflicts of interests that could potentially result in harm to investors, municipal entities, or obligated persons, or undermine the public's confidence in the municipal securities market.

The Commission finds that the proposed rule change is consistent with Section 15B(b)(2)(L)(iv) of the Act, in that it does not impose a regulatory burden on small municipal advisors that is not necessary or appropriate in the public interest and for the protection of investors, municipal entities, and obligated persons, provided that there is robust protection of investors against fraud.[64] While the proposed rule change would affect all municipal advisors, including small municipal advisors, the Commission believes the proposed rule change is a necessary and appropriate regulatory burden in order to limit practices that could harm investors, municipal entities and obligated persons. The proposed rule change will likely reduce the frequency and severity of violations of the public trust by elected officials and others involved in the issuance of municipal securities that might otherwise have their decisions regarding the award of municipal advisory business influenced by the gifts given by regulated entities and their associated persons. Further, codifying certain interpretive guidance will help minimize compliance costs which will benefit all regulated entities, including small municipal advisors. While the proposed rule change would burden some small municipal advisors, the Commission believes that such burden is outweighed by the need to maintain the integrity of the municipal securities market and to preserve investor and public confidence in the municipal securities market, including the bond issuance process.

In addition, the Commission finds that the proposed rule change is consistent with Section 15B(b)(2)(G) of the Act which provides that the MSRB's rules shall prescribe records to be made and kept by municipal securities brokers, municipal securities dealers, and municipal advisors and the periods for which such records shall be preserved.[65] The proposed rule change would extend the provisions of existing Rule G–8 to require that municipal advisors as well as dealers make and keep records related to Rule G–20 as amended by the proposed rule change.

In approving the proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation.[66] The Commission believes the proposed rule change will help promote competition. By extending the relevant current restrictions embodied in existing MSRB Rule G–20 to municipal advisors and their municipal advisory activities, the proposed rule change will promote merit-based and price-based competition for municipal advisory services and limit the selection or retention of a municipal advisor based on the receipt of gifts. A market where regulated entities compete on the basis of price and quality of services is more likely to provide a level playing field for existing regulated entities within which to operate and also encourages the entry of new providers. By extending the policies embodied in existing MSRB Rule G–20 to municipal advisors and their municipal advisory activities, the proposed rule change will also establish common standards for dealers and municipal advisors that operate in the same municipal securities market. The Commission also believes that by codifying certain interpretive guidance, the proposed rule change will clarify the obligations of dealers and municipal advisors and ease compliance burdens. The Commission believes that the effect of the proposed rule is beneficial and the proposed changes will help maintain the integrity of the municipal securities market and preserve investor and public confidence.

As noted above, the Commission received three comment letters on the filing. The Commission believes that the MSRB through its responses has addressed commenters concerns. For the reasons noted above, including those discussed in the MSRB Response Letter, the Commission believes that the proposed rule change is consistent with the Act.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[67] that the proposed rule change (SR–MSRB–2015–09) be, and hereby is, approved.

For the Commission, pursuant to delegated authority.[68]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28806 Filed 11–12–15; 8:45 am]

BILLING CODE 8011–01–P

[63] 15 U.S.C. 78o–4(b)(2)(C).

[64] 15 U.S.C. 78o–4(b)(2)(L)(iv).

[65] 15 U.S.C. 78o–4(b)(2)(G).

[66] 15 U.S.C. 78c(f).

[67] 15 U.S.C. 78s(b)(2).

[68] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76385; File No. SR–FINRA–2015–045]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend FINRA Rule 7640A (Data Products Offered by Nasdaq)

November 6, 2015.

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 October 29, 2015, Financial Industry Regulatory Authority, Inc. (''FINRA'') (f/k/a National Association of Securities Dealers, Inc. (''NASD'')) filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 7640A (Data Products Offered By Nasdaq) to identify the Nasdaq Last Sale Plus (''NLS Plus'') data feed, which distributes FINRA/Nasdaq Trade Reporting Facility (''FINRA/Nasdaq TRF'' or ''TRF'') data to third parties.

Below is the text of the proposed rule change. Proposed new language is in italics.

* * * * *

7000. Clearing, Transaction and Order Data Requirements, and Facility Charges

* * * * *

7600. Data Products and Charges for Trade Reporting Facility Services

7600A. Data Products and Charges for FINRA/NASDAQ Trade Reporting Facility Services

* * * * *

7640A. Data Products Offered by NASDAQ

(a) through (b) No Change.

(c) The following data products offered by Nasdaq pursuant to Nasdaq rules use covered market data:

(1) No Change.

(2) Nasdaq Last Sale *and Nasdaq Last Sale Plus* Data Feeds under Nasdaq Rule 7039; and

(3) No Change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA Rule 7640A describes FINRA's practices relating to the distribution of market data for over-the-counter (''OTC'') transactions in NMS stocks generated through the operation of the FINRA/Nasdaq TRF by Nasdaq, Inc. (''NASDAQ''), the Business Member under the Limited Liability Company agreement governing the FINRA/Nasdaq TRF (the ''LLC Agreement''),[4] and its affiliate, The NASDAQ Stock Market LLC (''Nasdaq''). Rule 7640A was adopted pursuant to SR–FINRA–2014–002, which describes in greater detail the TRF framework and FINRA's oversight of TRF operations and use of FINRA/Nasdaq TRF data in Nasdaq market data products.[5] As described in that filing, although the FINRA/Nasdaq TRF is a facility of FINRA and TRF data is OTC data for which FINRA is responsible under the Act, NASDAQ, as the Business Member, has the contractual right to develop market data products using TRF data. As such, use of FINRA/Nasdaq TRF data is conducted through Nasdaq, is subject to a separate proposed rule change filed with the Commission by Nasdaq in its capacity as a self-regulatory organization (''SRO'') and must satisfy the appropriate statutory standards.

Paragraph (a) of Rule 7640A codifies the contractual arrangement between FINRA and NASDAQ and provides for the overall structure relating to the FINRA/Nasdaq TRF and the permissible use of FINRA/Nasdaq TRF data. Paragraph (b) provides that fees for market data products that use FINRA/Nasdaq TRF data are charged by Nasdaq under Nasdaq rules. Nasdaq must adopt such fees pursuant to a proposed rule change submitted to the Commission under Section 19(b) of the Act, and must demonstrate that the fees are consistent with the requirements of the Act, including that they are reasonable, equitably allocated and not unfairly discriminatory. Paragraph (c) identifies Nasdaq rules relating to products that use FINRA/Nasdaq TRF data, including Nasdaq Rule 7039 relating to the Nasdaq Last Sale (''NLS'') data feeds.[6]

On June 22, 2015, the Commission approved proposed rule change SR–NASDAQ–2015–055, pursuant to which Nasdaq proposed to amend Nasdaq Rule 7039 to fully reflect the NLS Plus data feed and to rename the rule ''Nasdaq Last Sale and Nasdaq Last Sale Plus Data Feeds.''[7] As described in Nasdaq's filing, NLS Plus has been offered since 2010 via NASDAQ OMX Information LLC, a subsidiary of NASDAQ. As further described in Nasdaq's filing, in offering NLS Plus, NASDAQ OMX Information LLC is acting as a redistributor of the last sale products already offered by NASDAQ's three equity exchanges (Nasdaq, NASDAQ OMX BX and NASDAQ OMX PSX), as well as volume information provided by the securities information processors (''SIPs''). As such, NLS Plus includes transactions from all of NASDAQ's equity markets, as well as the FINRA/Nasdaq TRF data that is included in the current NLS product, as contemplated under Rule 7640A. In other words,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] As approved by its board of directors and the Commission [sic], effective September 8, 2015, NASDAQ changed its legal name from The NASDAQ OMX Group, Inc. to Nasdaq, Inc. *See* Nasdaq, Inc. Form 8–K Current Report (filed September 8, 2015) (available at *www.sec.gov/Archives/edgar/data/1120193/000119312515314459/d48431d8k.htm*).

FINRA and NASDAQ are in the process of amending the LLC Agreement to reflect the name change. FINRA will file a separate proposed rule change to update the FINRA manual, including Rule 7640A, accordingly.

[5] *See* Securities Exchange Act Release No. 71350 (January 17, 2014), 79 FR 4218 (January 24, 2014) (Notice of Filing and Immediate Effectiveness; File No. SR–FINRA–2014–002).

[6] Pursuant to Nasdaq Rule 7039, the NLS data feeds combine both Nasdaq Market Center and FINRA/Nasdaq TRF last sale data and provide real-time execution price, volume and time information for each reported sale.

[7] *See* Securities Exchange Act Release No. 75257 (June 22, 2015), 80 FR 36862 (June 26, 2015) (Order Approving File No. SR–NASDAQ–2015–055).

NASDAQ OMX Information LLC redistributes last sale data that has been the subject of a proposed rule change filed with the Commission at prices that have also been the subject of a proposed rule change filed with the Commission.

Because the NLS Plus product provides a subset of the same last sale data that is disseminated by the SIPs, the feed is structured so that data is not provided to the NLS Plus product sooner than it is provided to the SIPs. NASDAQ currently monitors for potential latency by comparing the time of the dissemination of FINRA/Nasdaq TRF data to the SIPs and to the NLS data feeds, including NLS Plus. In that regard, NASDAQ has made specific commitments and undertakings with respect to its products that use FINRA/Nasdaq TRF data, including that, consistent with the Commission's interpretation of Rule 603(a) under SEC Regulation NMS, it will not transmit any FINRA/Nasdaq TRF transactions data to a vendor or user any sooner than the FINRA/Nasdaq TRF transmits the data to the SIPs.[8] Thus, FINRA believes that the NLS Plus product satisfies the requirement that FINRA/Nasdaq TRF transaction data not be disseminated to a vendor or user any sooner than such data is transmitted to the SIPs.

Accordingly, FINRA is proposing to amend Rule 7640A(c)(2) to identify the NLS Plus product in the cross-reference to Nasdaq Rule 7039. FINRA believes that the proposed rule change will ensure that Rule 7640A accurately reflects the Nasdaq products that use FINRA/Nasdaq TRF data.

On July 24, 2015, Nasdaq filed proposed rule change SR–NASDAQ–2015–088 to amend Nasdaq Rule 7039 with language indicating fees for NLS Plus.[9] Specifically, firms that receive the NLS Plus feed pay annual administration fees for applicable NASDAQ equity exchanges ($1,000 for Nasdaq, $1,000 for BX and $1,000 for PSX), are liable for NLS or Nasdaq Basic fees under Nasdaq Rules and, pursuant to SR–NASDAQ–2015–088, pay a data consolidation fee of $350 per month. As stated in Nasdaq's filing, the NLS Plus fee is a codification of the existing NLS Plus fee, with the addition of a monthly data consolidation fee, and as such, meets the requirements of the Act.

FINRA has filed the proposed rule change for immediate effectiveness. FINRA is proposing that the proposed rule change will be operative immediately upon filing.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[10] which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes the proposed rule change will provide greater clarity to members and the public regarding Nasdaq market data products that use FINRA/Nasdaq TRF data by specifically identifying NLS Plus under Rule 7640A. In addition, consistent with SR–NASDAQ–2015–055, NLS Plus is an additional means by which investors may access information about securities transactions, thereby providing investors with additional options for accessing information that may help inform their trading decisions. In approving the NLS Plus product, the Commission specifically determined that it is consistent with the Act.[11]

FINRA also believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,[12] which requires, among other things, that FINRA rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls. As noted above, the fees for the NLS Plus product are not charged by FINRA under FINRA rules, but rather are charged by Nasdaq under Nasdaq rules. Such fees have been adopted pursuant to a proposed rule change submitted to the Commission pursuant to Section 19(b) of the Act.[13] In its rulemaking, Nasdaq was required to demonstrate that the fees are consistent with the requirements of the Act, including that they are reasonable, equitably allocated and not unfairly discriminatory. In its filing, Nasdaq stated that the fees for the NLS Plus product are simply a codification of the existing fee structure, with the addition of the consolidation fee. Nasdaq further stated that the fees apply equally to all firms that choose to subscribe to the NLS Plus product, and no firm is required to use NLS Plus.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As described above, use of FINRA/Nasdaq TRF data is conducted through Nasdaq, is subject to a separate proposed rule change filed with the Commission by Nasdaq in its capacity as an SRO and must satisfy the appropriate statutory standards. As such, Nasdaq has the obligation of assessing the potential impacts of the NLS Plus product in its own rulemaking. As described more fully in SR–NASDAQ–2015–055, Nasdaq's ability to offer and price NLS Plus is constrained by: (1) Competition between exchanges and other trading platforms that compete with each other in a variety of dimensions; (2) the existence of inexpensive real-time consolidated data and market-specific data and free delayed consolidated data; and (3) the inherent contestability of the market for proprietary last sale data.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and Rule 19b–4(f)(6) thereunder.[15]

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. FINRA has asked the Commission to waive the 30-day operative delay so that the proposal may become operative upon filing. The Commission believes that waiver of the

[8] *See* Securities Exchange Act Release No. 71350 (January 17, 2014), 79 FR 4218 (January 24, 2014) (Notice of Filing and Immediate Effectiveness; File No. SR–FINRA–2014–002).

[9] *See* Securities Exchange Act Release No. 75600 (August 4, 2015), 80 FR 47968 (August 10, 2015) (Notice of Filing and Immediate Effectiveness; File No. SR–NASDAQ–2015–088).

[10] 15 U.S.C. 78*o*–3(b)(6).

[11] *See* Securities Exchange Act Release No. 75257 (June 22, 2015), 80 FR 36862 (June 26, 2015) (Order Approving File No. SR–NASDAQ–2015–055).

[12] 15 U.S.C. 78*o*-3(b)(5).

[13] *See* Securities Exchange Act Release No. 75600 (August 4, 2015), 80 FR 47968 (August 10, 2015) (Notice of Filing and Immediate Effectiveness; File No. SR–NASDAQ–2015–088).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b-4(f)(6).

30-day operative delay is appropriate because the proposed rule change merely adds a reference to Nasdaq Last Sale Plus Data Feeds to Rule 7640A to reflect recently approved changes to NASDAQ's rules. Based on the foregoing, the Commission believes that the waiver of the operative delay is consistent with the protection of investors and the public interest.[16] The Commission hereby grants the waiver and designates the proposal operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2015–045 on the subject line.

Paper Comments:

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2015–045. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2015–045 and should be submitted on or before December 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28809 Filed 11–12–15; 8:45 am]

BILLING CODE 8011–01–P

[16] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76383; File No. SR–BX–2015–063]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Regarding NASDAQ Last Sale Plus

November 6, 2015.

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 October 27, 2015, NASDAQ OMX BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend BX Rule 7039 (BX Last Sale and NASDAQ Last Sale Plus Data Feeds) with language clarifying that the data consolidation component of the fees for NASDAQ Last Sale Plus (''NLS Plus''), a comprehensive data feed offered by NASDAQ OMX Information LLC,[3] will be charged solely to firms that are Internal Distributors and External Distributors (collectively, ''Distributors'' of the data feed) that receive a NLS Plus direct data feed.[4]

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxbx.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposal is to amend BX Rule 7039 with language clarifying that the data consolidation component of the fees for NLS Plus will be charged solely to firms that are

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] NASDAQ OMX Information LLC is a subsidiary of Nasdaq, Inc. (formerly, The NASDAQ OMX Group, Inc.), separate and apart from The NASDAQ Stock Market LLC. The primary purpose of NASDAQ OMX Information LLC is to combine publicly available data from the three filed last sale products of the exchange subsidiaries of Nasdaq, Inc. and from the network processors for the ease and convenience of market data users and vendors, and ultimately the investing public. In that role, the function of NASDAQ OMX Information LLC is analogous to that of other market data vendors, and it has no competitive advantage over other market data vendors; NASDAQ OMX Information LLC performs precisely the same functions as Bloomberg, Thomson Reuters, and other market data vendors.

[4] ''Internal Distributors'' are Distributors that receive NASDAQ Last Sale Plus data and then distribute that data to one or more Subscribers within the Distributor's own entity. ''External Distributors'' are Distributors that receive NASDAQ Last Sale Plus data and then distribute that data to one or more Subscribers outside the Distributor's own entity. Internal Distributors and External Distributors are together known as ''Distributors''. Proposed BX Rule 7039(b)(1).

Distributors that receive an NLS Plus direct data feed.[5]

NLS Plus[6] allows data distributors to access last sale products offered by each of Nasdaq, Inc.'s three U.S. equity exchanges.[7] NLS Plus includes all transactions from these exchanges, as well as FINRA/NASDAQ TRF data that is included in the current NLS product. In addition, NLS Plus features total cross-market volume information at the issue level, thereby providing redistribution of consolidated volume information (''consolidated volume'') from the securities information processors (''SIPs'') for Tape A, B, and C securities.[8] Thus, NLS Plus covers all securities listed on NASDAQ and New York Stock Exchange (''NYSE'') (now under the Intercontinental Exchange (''ICE'') umbrella), as well as US ''regional'' exchanges such as NYSE MKT, NYSE Arca, and BATS (also known as BATS/Direct Edge).[9]

NLS Plus is currently codified in BX Rule 7039(b). The fees for NLS Plus are set forth in BX Rule 7039(b)(1)–(b)(3) as follows:

(1) Firms that receive NLS Plus shall pay the annual administration fees for NLS, BX Last Sale, and PSX Last Sale,[10] and a data consolidation fee of $350 per month.

(2) Firms that receive NLS Plus would either be liable for NLS fees or NASDAQ Basic fees.

(3) In the event that NASDAQ OMX BX and/or NASDAQ OMX PHLX adopt user fees for BX Last Sale and/or PSX Last Sale, firms that receive NLS Plus would also be liable for such fees.

The Exchange now proposes to clarify how the data consolidation fee in BX Rule 7039(d)(1) will be charged. Specifically, the Exchange proposes to clarify that firms that are Distributors that receive a NASDAQ Last Sale Plus direct data feed and are Distributors shall pay a data consolidation fee of $350 per month. Thus, only Distributors that receive NLS Plus would be charged the data consolidation fee. As proposed to be amended, BX Rule 7039(b)(1) would state:

(1) Firms that receive NLS Plus shall pay the annual administrative fees for NLS, BX Last Sale, and PSX Last Sale. Additionally, Internal Distributors or External Distributors shall pay a data consolidation fee of $350 per month.[11] ''Internal Distributors'' are Distributors that receive NLS Plus data and then distribute that data to one or more Subscribers within the Distributor's own entity. ''External Distributors'' are Distributors that receive NLS Plus data and then distribute that data to one or more Subscribers outside the Distributor's own entity.[12]

The NLS Plus fee structure as amended continues to be designed to ensure that vendors could compete with the Exchange by creating a product similar to NLS Plus.[13] The proposed fee structure reflects the cost of the data feeds underlying NLS Plus (including user fees and annual administrative fees), as well as the incremental cost of the aggregation and consolidation function (the ''consolidation function'') for NLS Plus. Accordingly, the Exchange believes that the fee structure would not result in charges for NLS Plus that are lower than the cost to a vendor creating a competing product, including the cost of receiving the underlying data feeds and consolidating them. The data consolidation fee recognizes that NLS Plus is created from data derived from NASDAQ Last Sale, BX Last Sale, PSX Last Sale, and data from the SIPs to which a consolidation function is applied. Charging the consolidation fee will not impede an entity receiving the underlying direct data feeds from creating a competing product to the NLS Plus feed based on combining individual data feeds, and charging its clients a fee that it believes reflects the value of the consolidation function. The Exchange believes that the incremental cost of aggregation to an entity that wants to re-create NLS Plus will be factored into the entity's revenue opportunity and may be inconsequential where the vendor has in place systems to perform these functions as part of creating its proprietary market data products and allocating costs over numerous products and customer relationships. For these reasons, the Exchange believes that vendors could readily offer a product similar to the NLS Plus on a competitive basis at a similar cost.

The amendment to clarify that the consolidation fee applies to Distributors that receive the NLS Plus data feed directly but does not apply to persons that receive NLS Plus indirectly through a Distributor is designed to ensure that the Exchange charges the fee only to those persons that directly benefit from the consolidation function. Specifically, if a person wished to combine the products that underlie NLS Plus and distribute them to customers or internal users, it would incur its own consolidation costs. By purchasing NLS Plus for distribution, a Distributor foregoes these costs and instead opts to pay the Exchange to perform the consolidation function for it. Thus, imposing this fee upon Distributors is a logical corollary to the service being provided. By contrast, imposing the fee

[5] Thus, the fee does not apply to persons that receive the NLS Plus data feed indirectly, through an Internal Distributor or External Distributor.

[6] *See* Securities Exchange Act Release Nos. 75709 (August 14, 2015), 80 FR 50671 (August 20, 2015) (SR–BX–2015–047) (notice of filing and immediate effectiveness regarding NLS Plus on BX); 75830 (September 3, 2015), 80 FR 54640 (September 10, 2015) (SR–BX–2015–054) (notice of filing and immediate effectiveness regarding fees for NLS Plus on BX); 75257 (June 22, 2015), 80 FR 36862 (June 26, 2015)(SR–NASDAQ–2015–055) (order approving proposed rule change regarding NLS Plus); 75600 (August 4, 2015), 80 FR 47968 (August 10, 2015)(SR–NASDAQ–2015–088) (notice of filing and immediate effectiveness regarding fees for NLS Plus) (the ''NLS Plus fee proposal''); 75763 (August 26, 2015), 80 FR 52817 (September 1, 2015) (SR-Phlx-2015–72) (notice of filing and immediate effectiveness regarding NLS Plus on PSX); and 75890 (September 10, 2015), 80 FR 55692 (September 16, 2015) (SR-Phlx-2015–76) (notice of filing and immediate effectiveness regarding fees for NLS Plus on PSX).

[7] The NASDAQ OMX U.S. equity markets include the Exchange,· The NASDAQ Stock Market LLC (''NASDAQ''), and NASDAQ OMX PSX (''PSX'') (together known as the ''NASDAQ OMX equity markets''). PSX and NASDAQ are filing companion proposals similar to this one. NASDAQ's last sale product, NASDAQ Last Sale, includes last sale information from the FINRA/NASDAQ Trade Reporting Facility (''FINRA/NASDAQ TRF''), which is jointly operated by NASDAQ and the Financial Industry Regulatory Authority (''FINRA''). *See* Securities Exchange Act Release No. 71350 (January 17, 2014), 79 FR 4218 (January 24, 2014) (SR–FINRA–2014–002). For proposed rule changes submitted with respect to NASDAQ Last Sale, BX Last Sale, and PSX Last Sale, *see, e.g.,* Securities Exchange Act Release Nos. 57965 (June 16, 2008), 73 FR 35178, (June 20, 2008) (SR–NASDAQ–2006–060) (order approving NASDAQ Last Sale data feeds pilot); 61112 (December 4, 2009), 74 FR 65569, (December 10, 2009) (SR–BX–2009–077) (notice of filing and immediate effectiveness regarding BX Last Sale data feeds); and 62876 (September 9, 2010), 75 FR 56624, (September 16, 2010) (SR-Phlx-2010–120) (notice of filing and immediate effectiveness regarding PSX Last Sale data feeds).

[8] Tape A and Tape B securities are disseminated pursuant to the Security Industry Automation Corporation's (''SIAC'') Consolidated Tape Association Plan/Consolidated Quotation System, or CTA/CQS (''CTA''). Tape C securities are disseminated pursuant to the NASDAQ Unlisted Trading Privileges (''UTP'') Plan. NLS Plus reflects real-time trading activity for Tape C securities and 15-minute delayed information for Tape A and Tape B securities.

[9] Registered U.S. exchanges are listed at *http://www.sec.gov/divisions/marketreg/mrexchanges.shtml.*

[10] Annual administrative fees are in BX Rule 7035, NASDAQ Rule 7035, and NASDAQ OMX PSX Fees Chapter VIII. These remain unchanged at: $1,000 for NASDAQ, $1,000 for BX, and $1,000 for PSX. For purposes of conformity, ''administration'' is changed to ''administrative'' in BX Rule 7039(d)(1), discussed below.

[11] The Exchange notes that those that have received NLS Plus directly from the Exchange have all, in fact, been firms. While the NLS Plus feed is available to all that subscribe and pay the requisite costs, the Exchange believes that in light of such costs it will continue to experience only firms receiving the feed directly from the Exchange.

[12] BX Rule 7039(b)(2) and (b)(3) would remain unchanged.

[13] For additional discussion regarding potential competition with NLS Plus, *see* supra note 6 and filings cited therein.

upon persons receiving the product through Distributors would effectively impose a duplicative charge, since such persons consume the data but are not in the business of distributing it and therefore do not forego consolidation costs when receiving the product. The Exchange further notes that the consolidation fee for BATS One, an analogous product of competing exchanges, is charged solely to external distributors of that product.[14]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[15] in general, and with Sections 6(b)(4) and (5) of the Act,[16] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities, and does not unfairly discriminate between customers, issuers, brokers or dealers. All recipients of the NLS Plus data offering continue to pay the underlying data feed fees and annual administrative fees for NLS, BX Last Sale, and PSX Last Sale. The Exchange is simply clarifying that the data consolidation component of the fees for NLS Plus will be charged solely to firms that receive a NASDAQ Last Sale Plus direct datafeed and are Distributors.

This change is reasonable and consistent with an equitable allocation of fees because it is designed to ensure that the Exchange charges the fee only to those persons that directly benefit from the consolidation function. Specifically, if a person wished to combine the products that underlie NLS Plus and distribute them to customers or internal users, it would incur its own consolidation costs. By purchasing NLS Plus for distribution, a Distributor foregoes these costs and instead opts to pay the Exchange to perform the consolidation function for it. Thus, imposing this fee upon Distributors is a logical corollary to the service being provided. The change is also not unfairly discriminatory. Indeed, imposing the fee upon persons receiving NLS Plus indirectly through Distributors would effectively impose a duplicative charge upon them, since such persons consume the data but are not in the business of distributing it and therefore do not forego consolidation costs when receiving the product. The Exchange further notes that the consolidation fee for BATS One, an analogous product of competing exchanges, is charged solely to external distributors of that product.[17] Accordingly, the exchanges that distribute BATS One take an analogous approach, in that they do not charge a consolidation fee to indirect recipients of the product, but rather charge the fee only to a subset of its distributors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The change proposed herein is designed to ensure that the consolidation fee for NLS Plus is appropriately assessed to Distributors of the product that benefit from the consolidation function performed by NASDAQ OMX Information LLC in creating the product and insures that a duplicative charge is not also assessed against indirect recipients of the product. Thus, the change will avoid the imposition of fees on certain product recipients, while not increasing fees for any recipients.

The market for data products is extremely competitive and firms may freely choose alternative venues and data vendors based on the aggregate fees assessed, the data offered, and the value provided. This rule proposal does not burden competition, which is reflected in the offerings of other exchanges that sell alternative data products[18] and in the ability of competing data feed vendors to combine underlying data feeds in direct competition with NLS Plus. NASDAQ OMX Information LLC was constructed specifically to establish a level playing field with market data vendors and to preserve fair competition between them. NASDAQ OMX Information LLC receives NLS, BX Last Sale, and PSX Last Sale from each NASDAQ-operated exchange in the same manner, at the same speed, and reflecting the same fees as for all market data vendors. Therefore, NASDAQ OMX Information LLC has no competitive advantage with respect to these last sale products and NASDAQ commits to maintaining this level playing field in the future. In other words, NASDAQ will continue to disseminate separately the underlying last sale products to avoid creating a latency differential between NASDAQ OMX Information LLC and other market data vendors, and to avoid creating a pricing advantage for NASDAQ OMX Information LLC.

NLS Plus exists in a market for proprietary last sale data products that is currently competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data and strict pricing discipline for the proprietary products themselves. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. This proprietary data is produced by each individual exchange, as well as other entities, in a vigorously competitive market. Similarly, with respect to the FINRA/NASDAQ TRF data that is a component of NLS and NLS Plus, allowing exchanges to operate TRFs has permitted them to earn revenues by providing technology and data in support of the non-exchange segment of the market. This revenue opportunity has also resulted in fierce competition between the two current TRF operators, with both TRFs charging extremely low trade reporting fees and rebating the majority of the revenues they receive from core market data to the parties reporting trades.

Transaction execution and proprietary data products are complementary in that market data is both an input and a byproduct of the execution service. In fact, market data and trade execution are a paradigmatic example of joint products with joint costs. The decision whether and on which platform to post an order will depend on the attributes of the platform where the order can be posted, including the execution fees, data quality and price, and distribution of its data products. Without trade executions, exchange data products cannot exist. Moreover, data products are valuable to many end users only insofar as they provide information that end users expect will assist them or their customers in making trading decisions.

The costs of producing market data include not only the costs of the data distribution infrastructure, but also the costs of designing, maintaining, and operating the exchange's transaction execution platform and the cost of regulating the exchange to ensure its fair operation and maintain investor confidence. The total return that a

[14] *See, e.g.,* Securities Exchange Act Release No. 73918 (December 23, 2014), 79 FR 78920 (December 31, 2014) (SR–BATS–2014–055; SR–BYX–2014–030; SR–EDGA–2014–25; SR–EDGX–2014–25) (order approving market data product called BATS One Feed being offered by four affiliated exchanges).

[15] 15 U.S.C. 78f.

[16] 15 U.S.C. 78f(b)(4) and (5).

[17] *See, e.g.,* Securities Exchange Act Release No. 73918 (December 23, 2014), 79 FR 78920 (December 31, 2014) (SR–BATS–2014–055; SR–BYX–2014–030; SR–EDGA–2014–25; SR–EDGX–2014–25) (order approving market data product called BATS One Feed being offered by four affiliated exchanges).

[18] *Id.*

trading platform earns reflects the revenues it receives from both products and the joint costs it incurs. Moreover, the operation of the exchange is characterized by high fixed costs and low marginal costs. This cost structure is common in content and content distribution industries such as software, where developing new software typically requires a large initial investment (and continuing large investments to upgrade the software), but once the software is developed, the incremental cost of providing that software to an additional user is typically small, or even zero (*e.g.,* if the software can be downloaded over the internet after being purchased).[19] In NASDAQ's case, it is costly to build and maintain a trading platform, but the incremental cost of trading each additional share on an existing platform, or distributing an additional instance of data, is very low. Market information and executions are each produced jointly (in the sense that the activities of trading and placing orders are the source of the information that is distributed) and are each subject to significant scale economies. In such cases, marginal cost pricing is not feasible because if all sales were priced at the margin, NASDAQ would be unable to defray its platform costs of providing the joint products. Similarly, data products cannot make use of TRF trade reports without the raw material of the trade reports themselves, and therefore necessitate the costs of operating, regulating,[20] and maintaining a trade reporting system, costs that must be covered through the fees charged for use of the facility and sales of associated data.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A)(ii) of the Act,[21] the Exchange has designated this proposal as establishing or changing a due, fee, or other charge imposed on any person, whether or not the person is a member of the self-regulatory organization, which renders the proposed rule change effective upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2015–063 on the subject line.

Paper comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC

All submissions should refer to File Number SR–BX–2015–063. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–BX–2015–063 and should be submitted on or before December 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28807 Filed 11–12–15; 8:45 am]

BILLING CODE 8011–01–P

[19] *See* William J. Baumol and Daniel G. Swanson, ''The New Economy and Ubiquitous Competitive Price Discrimination: Identifying Defensible Criteria of Market Power,'' *Antitrust Law Journal,* Vol. 70, No. 3 (2003).

[20] It should be noted that the costs of operating the FINRA/NASDAQ TRF borne by NASDAQ include regulatory charges paid by NASDAQ to FINRA.

[21] 15 U.S.C. 78s(b)(3)(A)(ii).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76386; File No. SR–NASDAQ–2015–128]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Chapter XV, Entitled ''Options Pricing,'' at Section 2 Governing Pricing for NASDAQ Members

November 6, 2015.

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 October 27, 2015, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's transaction fees at Chapter XV, Section 2 entitled ''NASDAQ Options Market—Fees and Rebates,'' which governs pricing for NASDAQ members using the NASDAQ Options Market (''NOM''), NASDAQ's facility for executing and routing standardized equity and index options.

While these amendments are effective upon filing, the Exchange has

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

designated the proposed amendments to be operative on November 2, 2015.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes the following change to the NOM transaction fees set forth at Chapter XV, Section 2 for executing and routing standardized equity and index options under the Penny Pilot [3] options program.

The proposed change is as follows:

Fees for Removing Liquidity in Penny Pilot Options: the Exchange proposes to:

1. Increase the Customer [4] Fee for Removing Liquidity in Penny Pilot Options from $0.48 to $0.50 per contract.

This rule change is described in greater detail below.

Customer Fee for Removing Liquidity in Penny Pilot Options

The Exchange proposes, beginning November 2, 2015, to increase the Customer Fee for Removing Liquidity in Penny Pilot Options from $0.48 per contract to $0.50 per contract. The Exchange notes that the Fees for Removing Liquidity for other Participants in Penny Pilot Options will remain the same.[5]

The purpose of the proposed fee change is to increase the transaction fee for Customers to the same fee level that is assessed today to Professionals,[6] Firms,[7] NOM Market Makers,[8] Non-NOM Market Makers [9] and Broker-Dealers.[10] With this proposal all market participants will be assessed the same Fee for Removing Liquidity in Penny Pilot Options of $0.50 per contract. Despite the increase, the Exchange believes that Customers will continue to send order flow to NOM.

2. Statutory Basis

NASDAQ believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[11] in general, and with Section 6(b)(4) and 6(b)(5) of the Act,[12] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which Nasdaq operates or controls, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Customer Fee for Removing Liquidity in Penny Pilot Options

The Exchange's proposal to increase the Customer Fee for Removing Liquidity in Penny Pilot Options from $0.48 per contract to $0.50 is reasonable because all other market participants are currently assessed a fee of $0.50 per contract today. The Exchange's increase would result in all market participants being assessed the same Fee for Removing Liquidity in Penny Pilot Options.

The Exchange's proposal to increase the Customer Fee for Removing Liquidity in Penny Pilot Options from $0.48 per contract to $0.50 is equitable and not unfairly discriminatory because all market participants would be uniformly assessed the same rate of $0.50 per contract.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange's proposal to increase the Customer Fee for Removing Liquidity in Penny Pilot Options from $0.48 per contract to $0.50 will result in all market participants being uniformly assessed the same fee for transactions in Penny Pilot Options.

The Exchange notes that it operates in a highly competitive market in which

[3] The Penny Pilot was established in March 2008 and has since been expanded and extended through June 30, 2016. *See* Securities Exchange Act Release Nos. 57579 (March 28, 2008), 73 FR 18587 (April 4, 2008) (SR–NASDAQ–2008–026) (notice of filing and immediate effectiveness establishing Penny Pilot); 60874 (October 23, 2009), 74 FR 56682 (November 2, 2009)(SR–NASDAQ–2009–091) (notice of filing and immediate effectiveness expanding and extending Penny Pilot); 60965 (November 9, 2009), 74 FR 59292 (November 17, 2009)(SR–NASDAQ–2009–097) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 61455 (February 1, 2010), 75 FR 6239 (February 8, 2010) (SR–NASDAQ–2010–013) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 62029 (May 4, 2010), 75 FR 25895 (May 10, 2010) (SR–NASDAQ–2010–053) (notice of filing and immediate effectiveness adding seventy-five classes to Penny Pilot); 65969 (December 15, 2011), 76 FR 79268 (December 21, 2011) (SR–NASDAQ–2011–169) (notice of filing and immediate effectiveness [sic] extension and replacement of Penny Pilot); 67325 (June 29, 2012), 77 FR 40127 (July 6, 2012) (SR–NASDAQ–2012–075) (notice of filing and immediate effectiveness and extension and replacement of Penny Pilot through December 31, 2012); 68519 (December 21, 2012), 78 FR 136 (January 2, 2013) (SR–NASDAQ–2012–143) (notice of filing and immediate effectiveness and extension and replacement of Penny Pilot through June 30, 2013); 69787 (June 18, 2013), 78 FR 37858 (June 24, 2013) (SR–NASDAQ–2013–082) (notice of filing and immediate effectiveness and extension and replacement of Penny Pilot through December 31, 2013); 71105 (December 17, 2013), 78 FR 77530 (December 23, 2013) (SR–NASDAQ–2013–154) (notice of filing and immediate effectiveness and extension and replacement of Penny Pilot through June 30, 2014); 79 FR 31151 [sic] (May 23, 2014), 79 FR 31151 (May 30, 2014) (SR–NASDAQ–2014–056) (notice of filing and immediate effectiveness and extension and replacement of Penny Pilot through December 31, 2014); 73686 (December 2, 2014), 79 FR 71477 (November 25, 2014) (SR–NASDAQ–2014–115) (notice of filing and immediate effectiveness and extension and replacement of Penny Pilot through June 30, 2015) and 75283 (June 24, 2015), 80 FR 37347 (June 30, 2015) (SR–NASDAQ–2015–063) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Extension of the Exchange's Penny Pilot Program and Replacement of Penny Pilot Issues That Have Been Delisted.) *See also* NOM Rules, Chapter VI, Section 5.

[4] The term ''Customer'' applies to any transaction that is identified by a Participant for clearing in the Customer range at The Options Clearing Corporation (''OCC'') which is not for the account of [sic] broker or dealer or for the account of a ''Professional'' (as that term is defined in Chapter I, Section 1(a)(48)).

[5] Non-Customers will continue to be assessed a $0.50 per contract Fee for Removing Liquidity in Penny Pilot Options.

[6] The term ''Professional'' means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s) pursuant to Chapter I, Section 1(a)(48). All Professional orders shall be appropriately marked by Participants.

[7] The term ''Firm'' or (''F'') applies to any transaction that is identified by a Participant for clearing in the Firm range at OCC.

[8] The term ''NOM Market Maker'' or (''M'') is a Participant that has registered as a Market Maker on NOM pursuant to Chapter VII, Section 2, and must also remain in good standing pursuant to Chapter VII, Section 4. In order to receive NOM Market Maker pricing in all securities, the Participant must be registered as a NOM Market Maker in at least one security.

[9] The term ''Non-NOM Market Maker'' or (''O'') is a registered market maker on another options exchange that is not a NOM Market Maker. A Non-NOM Market Maker must append the proper Non-NOM Market Maker designation to orders routed to NOM.

[10] The term ''Broker-Dealer'' or (''B'') applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category.

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(4) and (5).

market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow. The Exchange believes that the proposal reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2015–128 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2015–128. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number *SR–NASDAQ–2015–128* and should be submitted on or before December 4, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28810 Filed 11–12–15; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76382; File No. 4–657]

Order Granting Exemption From Compliance With the National Market System Plan To Implement a Tick Size Pilot Program

November 6, 2015.

I. Introduction

Pursuant to Rule 608(e)[1] under the Securities Exchange Act of 1934 (''Exchange Act''), the Securities and Exchange Commission (''Commission'') may exempt from compliance with the provisions of Rule 608, either unconditionally or on specified terms and conditions, any self-regulatory organization, member thereof, or specified security, if the Commission determines that such exemption is consistent with the public interest, the protection of investors, the maintenance of fair and orderly markets and the removal of impediments to, and perfection of the mechanisms of, a national market system. As discussed below, the Commission is exercising its authority under Rule 608(e) to exempt BATS Exchange, Inc., BATS Y-Exchange, Inc., Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc. (''FINRA''), NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, the Nasdaq Stock Market LLC, New York Stock Exchange LLC (''NYSE''), NYSE MKT LLC, and NYSE Arca, Inc., (collectively ''SROs'' or ''Participants''), from implementing the Plan to Implement a Tick Size Pilot Program (''Tick Size Pilot'') until October 3, 2016.

II. Background

On May 6, 2015, the Commission approved the Tick Size Pilot and provided that the Tick Size Pilot be implemented within one year after the publication of the order.[2] The Tick Size Pilot will have a two-year duration (''Pilot Period''),[3] and will include exchange-listed common stocks that have the following characteristics: (1) A market capitalization of less than $3 billion; (2) a closing price of at least $2 per share on the last day of the measurement period (and a closing price of not less than $1.50 per share during the measurement period); (3) a consolidated average daily volume of one million shares or less; and (4) a volume-weighted average price of at least $2 per share (''Pilot Securities'').

The Pilot Securities will be divided into one control group and three test groups. There will be 400 Pilot Securities per test group and the remaining Pilot Securities will be assigned to the control group. Test Group One Pilot Securities will quote in $0.05 per share increments and will trade at any currently permitted increment. Test Group Two Pilot Securities will quote in $0.05 per share increments like those in Test Group One, but will only be permitted to trade in $0.05 per share increments, subject to certain exceptions.[4] Finally, Test Group

[1] 17 CFR 242.608(e).

[2] Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27514 (May 13, 2015).

[3] The term Pilot Period means the operative period of the Tick Size Pilot, lasting two years from the date of implementation. *See* Section I.U of the Tick Size Pilot at 80 FR 27547.

[4] First, executions will be able to at the midpoint between the national (or protected) best bid and the national (or protected) best offer; second, orders involving retail investor orders will be able to trade with price improvement of at least $0.005 per share; and third, negotiated trades (such as a volume-weighted average price trade or a time-weighted average price trade) will be able to trade outside of the $0.05 increment.

Three Pilot Securities will quote in $0.05 per share increments and will trade in $0.05 per share increments consistent with Test Group Two, and in addition be subject to a Trade-At Prohibition, which would generally prevent price matching by a trading center that is not displaying a quotation at the price of the best protected quotation, unless an exception applies. Pilot Securities in the control group would continue to quote and trade in the pricing increments that are currently permitted.

Pursuant to the Tick Size Pilot, Participants will collect data reflecting a variety of market quality metrics with respect to the Pilot Securities and transmit such data to the Commission. The collected data will be publicly available in an aggregated form. In addition, the Participants are required to conduct, and provide the Commission with, a publicly-available impact assessment.

III. Discussion

As discussed in the Approval Order,[5] several actions need to occur prior to the implementation of the Tick Size Pilot, including: (1) The development and testing of applicable trading and compliance systems, (2) the filing and approval of SRO rules related to the Tick Size Pilot's quoting and trading requirements, and (3) the development and implementation of the written policies and procedures by Participants and their members that are reasonably designed to comply with the applicable quoting and trading increments. In addition, the Participants must develop appropriate policies and procedures for collecting and reporting to the Commission the requisite data in connection with the Tick Size Pilot, including the filing and approval of SRO rules requiring the collection and reporting of data from certain member firms. Data is to be collected by the Participants for periods beginning six months prior to the Pilot Period.[6] To date, the requisite SRO rule proposals have not been filed or approved by the Commission, and there has not been an opportunity for the Participants and their members to develop and test applicable trading and compliance systems.[7]

Accordingly, the Commission believes additional time is needed for the Participants and their members to complete their preparations for implementation of the Tick Size Pilot. The Commission believes that extending the implementation date by approximately five months, to October 3, 2016, is sufficient to allow for a smooth yet timely implementation of the Tick Size Pilot, including the approval of applicable SRO rules and the development and testing of new compliance systems.[8]

Therefore, the Commission believes that it is necessary and appropriate to issue an exemption to extend the date by which the Participants must implement the Tick Size Pilot until October 3, 2016. The Commission has determined that such an exemption is consistent with the public interest, the protection of investors, the maintenance of fair and orderly markets and the removal of impediments to, and perfection of the mechanisms of, a national market system.

IV. Conclusion

It is hereby ordered, pursuant to Rule 608(e) of Exchange Act,[9] that the Participants are exempt from implementing the Tick Size Pilot until October 3, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28795 Filed 11–12–15; 8:45 am]

BILLING CODE 8011–01–P

[5] 80 FR at 27545.

[6] *See* Sections IV and VII of the Tick Size Pilot at 80 FR at 27548 and 27552–53.

[7] The Commission notes that the Participants anticipate filing model data collection rule proposals with the Commission no later than November 13, 2015. *See* Letter from Brendon J. Weiss, Co-Head, Government Affairs, Intercontinental Exchange/NYSE, to Brent J. Fields, Secretary, Commission, dated November 4, 2015. In addition, the Commission notes that the Participants issued technical specifications and FAQs related to the data collection requirements on October 12, 2015.

[8] The Commission has received requests to extend the implementation date of the Tick Size Pilot or its data collection requirements for various periods. *See* Letter from Theodore R. Lazo, Managing Director and Associate General Counsel, SIFMA, to Stephen Luparello, Director, Division of Trading and Markets, Commission, dated August 31, 2015 (requesting the data collection period be extended until at least three months after the requisite SRO rules are approved by the Commission and related interpretive guidance is published); Letter from Mary Lou Von Kaenel, Managing Director, Financial Information Forum, to Stephen Luparello, Director, Division of Trading and Markets, Commission, dated September 24, 2015 (requesting the data collection period be extended a minimum of six months); and Letter from Brendon J. Weiss, Co-Head, Government Affairs, Intercontinental Exchange/NYSE, to Brent J. Fields, Secretary, Commission, dated November 4, 2015 (requesting the data collection period be extended until six months after the requisite SRO rules are approved, and the implementation data of the Tick Size Pilot until six months thereafter).

[9] 17 CFR 242.608(e).

[10] 17 CFR 200.30–3(a)(42).

SMALL BUSINESS ADMINISTRATION

Interagency Task Force on Veterans Small Business Development

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Interagency Task Force Meeting.

Date and Time: December 10, 2015, from 9:00 a.m. to 12:00 noon.

ADDRESSES: SBA Headquarters, 409 3rd Street SW., Washington, DC 20416, in the Eisenhower Conference Room B, Concourse Level.

Purpose: This public meeting is to discuss recommendations identified by the Interagency Task Force (IATF) to further enable veteran entrepreneurship policy and programs. In addition, the Task Force will allow public comment regarding the focus areas.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Interagency Task Force on Veterans Small Business Development. The Task Force is established pursuant to Executive Order 13540 and focused on coordinating the efforts of Federal agencies to improve capital, business development opportunities and pre-established Federal contracting goals for small business concerns owned and controlled by veterans (VOB's) and service-disabled veterans (SDVOSB'S). Moreover, the Task Force shall coordinate administrative and regulatory activities and develop proposals relating to ''six focus areas'': (1) Access to capital (loans, surety bonding and franchising); (2) Ensure achievement of pre-established contracting goals, including mentor protégé and matching with contracting opportunities; (3) Increase the integrity of certifications of status as a small business; (4) Reducing paperwork and administrative burdens in accessing business development and entrepreneurship opportunities; (5) Increasing and improving training and counseling services; and (6) Making other improvements to support veteran's business development by the Federal government.

Additional Information: Advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the Task Force must contact Cheryl Simms by November 27, 2015 by email in order to be placed on the agenda. Comments for the record should be applicable to the ''six focus areas'' of the Task Force and emailed prior to the meeting for inclusion in the

public record. Comments will be limited to five minutes in the interest of time and to accommodate as many presenters as possible. Written comments should be emailed to Cheryl Simms, Program Liaison for the Task Force, Office of Veterans Business Development at *vetstaskforce@sba.gov.* If participants need accommodations because of a disability or require additional information, please contact Cheryl Simms, Program Liaison at (202) 205–6773, or by email at *vetstaskforce@sba.gov.* For more information, please visit our Web site at *www.sba.gov/vets.*

Dated: November 4, 2015.

Miguel J. L'Heureux,

SBA Committee Management Officer.

[FR Doc. 2015–28866 Filed 11–12–15; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14532 and #14533]

Texas Disaster #TX–00457

AGENCY: U.S. Small Business Administration.

ACTION: Notice

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Texas dated 11/05/2015.

Incident: Hidden Pines Wildfire.

Incident Period: 10/13/2015 through 10/24/2015.

Effective Date: 11/05/2015.

Physical Loan Application Deadline Date: 01/04/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 08/05/2016.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Bastrop.

Contiguous Counties: Texas: Caldwell, Fayette, Lee, Travis, Williamson.

The Interest Rates are:

For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.750
Homeowners Without Credit Available Elsewhere	1.875
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.625
Non-Profit Organizations Without Credit Available Elsewhere	2.625
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for physical damage is 14532 5 and for economic injury is 14533 0.

The States which received an EIDL Declaration # are Texas.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: November 5, 2015.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2015–28869 Filed 11–12–15; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14534 and #14535]

Alaska Disaster #AK–00034

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 Alaska (FEMA–4244–DR), dated 10/30/2015.

Incident: Severe Storm.

Incident Period: 08/27/2015.

Effective Date: 10/30/2015.

Physical Loan Application Deadline Date: 12/29/2015.

Economic Injury (EIDL) Loan Application Deadline Date: 08/01/2016.

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 10/30/2015, 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 Areas: North Slope Borough.

The Interest Rates are:

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 14534B and for economic injury is 14535B

(Catalog of Federal Domestic Assistance Numbers 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2015–28871 Filed 11–12–15; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14501 and #14502]

South Carolina Disaster Number SC–00032

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 5.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of South Carolina (FEMA–4241–DR), dated 10/15/2015.

Incident: Severe Storms and Flooding.

Incident Period: 10/01/2015 through 10/23/2015.

Effective Date: 11/05/2015.

Physical Loan Application Deadline Date: 12/14/2015.

Economic Injury (EIDL) Loan Application Deadline Date: 07/14/2016.

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: The notice of the President's major disaster

declaration for Private Non-Profit organizations in the State of South Carolina, dated 10/15/2015, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Spartanburg.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Joseph P. Loddo,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2015–28868 Filed 11–12–15; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14499 and #14500]

California Disaster Number CA–00240

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of California (FEMA–4240–DR), dated 10/08/2015.

Incident: Valley Fire and Butte Fire.

Incident Period: 09/09/2015 through 10/30/2015.

Effective Date: 10/30/2015.

Physical Loan Application Deadline Date: 12/07/2015.

Economic Injury (EIDL) Loan Application Deadline Date: 07/08/2016.

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: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of California, dated 10/08/2015, is hereby amended to establish the incident period for this disaster as beginning 09/09/2015 and continuing through 10/30/2015.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2015–28872 Filed 11–12–15; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Advisory Committee on Veterans Business Affairs

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Advisory Committee Meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time, and agenda for the next meeting of the Advisory Committee on Veterans Business Affairs. The meeting will be open to the public.

DATES: Wednesday, December 9, 2015 from 9 a.m. to 4 p.m.

ADDRESSES: U.S. Small Business Administration, 409 3rd Street SW., Washington, DC 20416. ROOM: Eisenhower Conference room B, located on the Concourse Level Floor.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Advisory Committee on Veterans Business Affairs. The Advisory Committee on Veterans Business Affairs serves as an independent source of advice and policy recommendation to the Administrator of the U.S. Small Business Administration.

The purpose of this meeting is scheduled as a full committee. It will focus on strategic planning, updates on past and current events and the ACVBA's objectives for 2016. For information regarding our veterans' resources and partners, please visit our Web site at *www.sba.gov/vets*.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public, however, advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the Advisory Committee must contact Cheryl Simms, by November 27, 2015 by email in order to be placed on the agenda. Comments for the Record should be emailed prior to the meeting for inclusion in the public record, verbal presentations; however, will be limited to five minutes in the interest of time and to accommodate as many presenters as possible. Written comments should be emailed to Cheryl Simms, Program Liaison, Office of Veterans Business Development, U.S. Small Business Administration, 409 3rd Street SW., Washington, DC 20416.

Additionally, if you need accommodations because of a disability or require additional information, please contact Cheryl Simms, Program Liaison at (202) 205–6773; or by email at *vetstaskforce@sba.gov*. For more information, please visit our Web site at *www.sba.gov/vets*.

Dated: November 4, 2015.

Miguel J. L'Heureux,

SBA Committee Management Officer.

[FR Doc. 2015–28867 Filed 11–12–15; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14474 and #14475]

California; Disaster Number CA–00238

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of California (FEMA–4240–DR), dated 09/22/2015.

Incident: Valley Fire and Butte Fire.

Incident Period: 09/09/2015 through 10/30/2015.

Effective Date: 10/30/2015.

Physical Loan Application Deadline Date: 11/23/2015.

EIDL Loan Application Deadline Date: 06/22/2016.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 7615.5.

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: The notice of the President's major disaster declaration for the State of California, dated 09/22/2015 is hereby amended to establish the incident period for this disaster as beginning 09/09/2015 and continuing through 10/30/2015.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2015–28874 Filed 11–12–15; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2015–0008]

Manual for Assessing Safety Hardware (MASH) Transition

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: In issuing Federal-aid eligibility letters for roadside safety hardware, FHWA currently makes determinations of continued eligibility for modifications to devices tested to the National Cooperative Highway Research Program Report 350 (NCHRP 350). In an effort to facilitate the implementation of the Manual for Assessing Safety Hardware (MASH), FHWA intends to discontinue issuing eligibility letters for requests received after December 31, 2015, for modified NCHRP 350-tested devices that do not involve full scale crash testing to the MASH. Modifications to NCHRP 350-tested devices that have, in the past, been based on engineering analysis or finite element modeling will no longer receive FHWA eligibility letters. Effective January 1, 2016, all changes to NCHRP 350-tested devices will require testing under MASH in order to receive a Federal-aid eligibility letter from FHWA.

FOR FURTHER INFORMATION CONTACT: For questions about the program discussed herein, contact Mr. Michael Griffith, Director of Office of Safety Technologies, FHWA Office of Safety, (202) 366–9469 or via email at *mike.griffith@dot.gov.* For legal questions, please contact Ms. Jennifer Mayo, Assistant Chief Counsel, FHWA Office of Chief Counsel (202) 366–1523, or via email at *jennifer.mayo@dot.gov,* Federal Highway Administration, 1200 New Jersey Avenue SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document, all comments, and the request for comments notice may be viewed on line through the Federal eRulemaking portal at: *http://www.regulations.gov.* The docket identification number is FHWA–2015–0008. The Web site is available 24 hours each day, 365 days each year. Anyone is able to search the electronic form of all comments 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, business, or labor union). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, Pages 19477–78), or you may visit *http://DocketsInfo.dot.gov.*

Request for Comments

On May 19, 2015, at 80 FR 28761, FHWA published a Request for Comments soliciting public input on the impact of FHWA no longer issuing Federal-aid eligibility letters after December 31, 2015, for modified NCHRP 350-tested devices that do not involve full scale crash testing to MASH criteria. The FHWA solicited input because modifications to NCHRP 350-tested devices have, in the past, received FHWA Federal-aid eligibility letters based on engineering analysis or finite element modeling.

Summary of Responses

The FHWA received a total of 16 responses to the docket. Of these responses, 11 were from private industry, 2 from State departments of transportation, 2 from private organizations, and 1 anonymous comment. Only three of the commenters addressed FHWA's proposal to discontinue issuing Federal-aid eligibility letters for modified NCHRP 350-tested safety devices that are not tested under the MASH criteria.

The Georgia Department of Transportation, the Illinois Department of Transportation, and the Advocates for Highway and Auto Safety, support FHWA efforts to move towards MASH testing. These three commenters also urged FHWA to move to MASH promptly and set sunset dates for the installation of hardware previously crash tested to NCHRP Report 350. Although FHWA recognizes the commenters' interest in this subject, this is an issue outside the scope of this notice and request for comment. The FHWA is currently working with the American Association of State Highway and Transportation Officials (AASHTO) to set as an aggressive schedule as possible to develop an update to the MASH 2009 Implementation Plan.

The other 13 commenters were from private industry, private organizations, or anonymous. Although none of these respondents commented on the proposed December 31, 2015, deadline to discontinue issuing Federal-aid eligibility letters for modified NCHRP 350-tested safety devices that are not tested under the MASH criteria, these commenters generally objected to the use of MASH to test roadside safety hardware. A summary of the comments in opposition to MASH testing, and FHWA's response to them, follows.

Some commenters expressed their opinion that testing to the MASH criteria is unwarranted and that there are no in-service performance evaluations that show NCHRP Report 350-tested devices are causing serious or fatal injuries. Crash testing has shown that some products tested under NCHRP Report 350 criteria will fail the MASH criteria because passenger vehicles on our roads in general have become larger and heavier than those used for testing in the 1990's. The MASH reflects the change in the vehicle fleet on our Nation's highways and adds the pickup truck as a test vehicle for more devices. The FHWA believes these improvements are justified to improve safety for the traveling public.

Some commenters expressed concern about the high cost of re-testing Category II devices and maintained that MASH-tested products will be more expensive due to testing costs and material costs. Some suggested NCHRP 350 Category II devices should be moved to Category I to be ''self-certified,'' while others proposed that manufacturers be allowed to make minor changes to 350 devices. It must be noted that it is the States' decision whether or not to continue approving NCHRP Report 350 devices that are currently being installed. Approval, installation, and maintenance of safety devices on Federal-aid projects is a State responsibility. The NCHRP 350-tested devices remain eligible for Federal-aid funding. The FHWA will not withdraw an existing Federal-aid eligibility letter for a product that currently meets NCHRP Report 350 criteria. The proposed deadline does not prevent a manufacturer from modifying a device, does not impose any requirements for the installation of MASH-tested devices, nor does it prevent a State DOT from installing a device previously tested to the NCHRP 350 criteria. The proposed deadline only applies to those seeking a Federal-aid eligibility letter for a modified device previously tested to NCHRP 350 criteria. It will be the States' responsibility to determine if all future proposed modifications made to existing 350 devices comply with NCHRP Report 350 criteria.

Other commenters expressed their concern about a lack of MASH tested products and recommended that sunset dates be realistic to provide adequate time to develop products and receive approval. They also stated that sole-sourcing for MASH devices should be allowed if no alternatives are available. Another commenter said that FHWA's delay in issuing Federal-aid eligibility

letters could be a problem and recommended that FHWA streamline the process to bring new MASH products to market. There was also concern about States' delay in adding devices to Qualified Products List. Although FHWA recognizes the commenters' interest in these subjects, these are issues outside the scope of this notice and request for comment. The FHWA is currently working with AASHTO to develop an update to the MASH 2009 Implementation Plan. The FHWA will continue to work on streamlining the process to seek Federal-aid eligibility for MASH tested devices. Finally, the General Material Requirements in 23 CFR 635.411 permits a State to specify sole-source products if it certifies that no equally suitable alternate exists.

Another commenter suggested that FHWA eliminate ''approvals'' based on engineering analysis or finite element analysis. Although FHWA recognizes the commenters' interest in this subject, this is an issue outside the scope of this notice and request for comment. However, FHWA would like to clarify that the agency does not have the authority to ''approve'' safety hardware. Approval, installation and maintenance of safety devices on Federal-aid projects is a State responsibility.

One commenter stated that FHWA should prohibit conflict of interest between labs and manufacturers. Although FHWA recognizes the commenters' interest in this subject, this is an issue outside the scope of this notice and request for comment. The FHWA only issues Federal-aid eligibility letters for roadside hardware devices that have been crash tested at accredited laboratory facilities, pursuant to [23 CFR 637.209(a)(5)].

There was one comment regarding the availability of the MASH to the public. The MASH is neither a Federal regulation nor guidance. The MASH was developed through the National Academy of Science's National Cooperative Highway Research Program and can be purchased from the AASHTO Web site (*http://www.transportation.org/*).

Lastly, a commenter said that FHWA is avoiding its responsibility for ''approving'' safety hardware. The FHWA issues Federal-aid eligibility letters for devices that meet the applicable crash test criteria. While these letters are the most common way for roadside safety hardware to qualify for Federal-aid reimbursement, FHWA eligibility letters are not a requirement for these devices to be eligible for reimbursement on Federal-aid highway projects. The FHWA is charged with implementing the Federal-aid highway program in cooperation with the States and local government. Therefore, FHWA relies on its relationships with State DOTs to ensure roadside hardware satisfies crash test criteria. The FHWA has established strong guidelines and policies in order to encourage all State DOTs to use roadside safety hardware that has successfully met the applicable crash test criteria.

In an effort to facilitate the implementation of the MASH, FHWA intends to discontinue issuing eligibility letters for requests received after December 31, 2015, for modified NCHRP 350-tested devices that do not involve full scale crash testing to the MASH. Modifications to NCHRP 350-tested devices that have, in the past, been based on engineering analysis or finite element modeling will no longer receive FHWA eligibility letters. Effective January 1, 2016, all changes to NCHRP 350-tested devices will require testing under MASH in order to receive a Federal-aid eligibility letter from FHWA.

Authority: 23 U.S.C. 148 and 315.

Dated: October 28, 2015.

Gregory G. Nadeau,

Administrator, Federal Highway Administration.

[FR Doc. 2015–28753 Filed 11–12–15; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0326]

Qualification of Drivers; Application for Exemptions; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces that 15 individuals have applied for a medical exemption from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). In accordance with the statutory requirements concerning applications for exemptions, FMCSA requests public comments on these requests. The statute and implementing regulations concerning exemptions require that exemptions must provide an equivalent or greater level of safety than if they were not granted. If the Agency determines the exemptions would satisfy the statutory requirements and decides to grant theses requests after reviewing the public comments submitted in response to this notice, the exemptions would enable these 15 individuals to operate CMVs in interstate commerce.

DATES: Comments must be received on or before December 14, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2015–0326 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5

p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

The Federal Motor Carrier Safety Administration has authority to grant exemptions from many of the Federal Motor Carrier Safety Regulations (FMCSRs) under 49 U.S.C. 31315 and 31136(e), as amended by Section 4007 of the Transportation Equity Act for the 21st Century (TEA–21) (Pub. L. 105–178, June 9, 1998, 112 Stat. 107, 401). FMCSA has published in 49 CFR part 381, subpart C final rules implementing the statutory changes in its exemption procedures made by section 4007, 69 FR 51589 (August 20, 2004).[1] Under the rules in part 381, subpart C, FMCSA must publish a notice of each exemption request in the **Federal Register**. The Agency must provide the public with an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted and any research reports, technical papers and other publications referenced in the application. The Agency must also provide an opportunity to submit public comment on the applications for exemption.

The Agency reviews the safety analyses and the public comments and determines whether granting the exemption would likely achieve a level of safety equivalent to or greater than the level that would be achieved without the exemption. The decision of the Agency must be published in the **Federal Register**. If the Agency denies the request, it must state the reason for doing so. If the decision is to grant the exemption, the notice must specify the person or class of persons receiving the exemption and the regulatory provision or provisions from which an exemption is granted. The notice must also specify the effective period of the exemption (up to 2 years) and explain the terms and conditions of the exemption. The exemption may be renewed.

The current provisions of the FMCSRs concerning hearing state that a person is physically qualified to drive a CMV if that person

> First perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5–1951.

49 CFR 391.41(b)(11). This standard was adopted in 1970, with a revision in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, 35 FR 6458, 6463 (April 22, 1970) and 36 FR 12857 (July 3, 1971).

FMCSA also issues instructions for completing the medical examination report and includes advisory criteria on the report itself to provide guidance for medical examiners in applying the hearing standard. See 49 CFR 391.43(f). The current advisory criteria for the hearing standard include a reference to a report entitled ''Hearing Disorders and Commercial Motor Vehicle Drivers'' prepared for the Federal Highway Administration, FMCSA's predecessor, in 1993.[2]

FMCSA Requests Comments on the Exemption Applications

FMCSA requests comments from all interested parties on whether a driver who cannot meet the hearing standard should be permitted to operate a CMV in interstate commerce. Further, the Agency asks for comments on whether a driver who cannot meet the hearing standard should be limited to operating only certain types of vehicles in interstate commerce, for example, vehicles without air brakes. The statute and implementing regulations concerning exemptions require that the Agency request public comments on all applications for exemptions. The Agency is also required to make a determination that an exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption before granting any such requests.

Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and in the search box insert the docket number ''FMCSA–2015–0326'' and click the search button. When the new screen appears, click on the blue ''Comment Now!'' button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

Viewing Comments and Documents

To view comments, go to *www.regulations.gov* and in the search box insert the docket number ''FMCSA–2015–0326'' and click ''Search.'' Next, click ''Open Docket Folder'' and you will find all documents and comments related to the proposed rulemaking.

Information on Individual Applicants

Mebrahtu G. Abai

Mr. Abai, 59, holds an operator's license in California.

Tonya Lee Bland

Ms. Bland, 45, holds an operator's license in Maryland.

Robert Dale Burnett

Mr. Burnett, 59, holds an operator's license in California.

Jackson Paul Cummins

Mr. Cummins, 32, holds an operator's license in California.

Jerry Merland Doose

Mr. Doose, 59, holds a class A CDL in Minnesota.

Tiffany Ann Drumel

Ms. Drumel, 51, holds an operator's license in California.

Raoof Hayes

Mr. Hayes, 38, holds an operator's license in Massachusetts.

Donald G. Howton, Jr.

Mr. Howton, 51, holds an operator's license in Alabama.

Michael A. Murrah,

Mr. Murrah, 31, holds an operator's license in Georgia.

[1] This action adopted as final rules the interim final rules issued by FMCSA's predecessor in 1998 (63 FR 67600 (Dec. 8, 2008)), and adopted by FMCSA in 2001 [66 FR 49867 (Oct. 1, 2001)].

[2] This report is available on the FMCSA Web site at *http://www.fmcsa.dot.gov/facts-research/research-technology/publications/medreport_archives.htm.*

Nicholas A. Nugent

Mr. Nugent, 34, holds an operator's license in Louisiana.

Javier Posada

Mr. Posada, 27, holds an operator's license in Florida.

D'Nielle V. Smith

Ms. Smith, 32, holds an operator's license in Ohio.

John C. Taylor

Mr. Taylor, 57, holds an operator's license in Illinois.

Ramarr James Wadley

Mr. Wadley, 36, holds an operator's license in Virginia.

Joseph Albert Woodle, Jr.

Mr. Woodle, 48, holds an operator's license in Alabama.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315(b)(4), FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. The Agency will consider all comments received before the close of business December 14, 2015. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will file comments received after the comment closing date in the public docket, and will consider them to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

Issued on: October 29, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–28902 Filed 11–12–15; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption From the Federal Motor Vehicle Theft Prevention Standard; Mazda Motor Corporation

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full the Mazda Motor Corporation's (Mazda) petition for an exemption of the (confidential) vehicle line in accordance with 49 CFR part 543, *Exemption from Vehicle Theft Prevention Standard.* This petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of 49 CFR part 541, *Federal Motor Vehicle Theft Prevention Standard* (Theft Prevention Standard). Mazda also requested confidential treatment for specific information in its petition. For purposes of this document the confidential information has been redacted until released by the manufacturer.

DATES: The exemption granted by this notice is effective beginning with the 2017 model year (MY).

FOR FURTHER INFORMATION CONTACT: Ms. Carlita Ballard, Office of International Policy, Fuel Economy and Consumer Programs, NHTSA, W43–439, 1200 New Jersey Avenue SE., Washington, DC 20590. Ms. Ballard's phone number is (202) 366–5222. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: In a petition dated June 18, 2015, Mazda requested an exemption from the parts-marking requirements of the Theft Prevention Standard for the Mazda (confidential) vehicle line beginning with MY 2017. The petition requested an exemption from parts-marking pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention Standard,* based on the installation of an antitheft device as standard equipment for the entire vehicle line.

Under 49 CFR 543.5(a), a manufacturer may petition NHTSA to grant an exemption for one vehicle line per model year. In its petition, Mazda provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the (confidential) vehicle line. Mazda stated that its MY 2017 (confidential) vehicle line will be equipped with a passive, transponder based, electronic engine immobilizer antitheft device as standard equipment. Key components of its antitheft device will include a powertrain control module (PCM), immobilizer control module, security indicator light, coil antenna, transmitter with transponder key (transponder key), low frequency (LF) antenna, radio frequency (RF) antenna and low frequency unit (LFU). The device will not provide any visible or audible indication of unauthorized vehicle entry (*i.e.,* flashing lights or horn alarm) as standard equipment however, Mazda stated that its device will incorporate a light-emitting diode (LED) indicator which will provide a visual confirmation on the protection status of the antitheft device.

Mazda's submission is considered a complete petition as required by 49 CFR 543.7, in that it meets the general requirements contained in § 543.5 and the specific content requirements of § 543.6.

In addressing the specific content requirements of § 543.6, Mazda provided information on the reliability and durability of its proposed device. To ensure reliability and durability of the device, Mazda conducted tests based on its own specified standards. Mazda provided a detailed list of the tests conducted (*i.e.,* electromagnetic radiation, electric conduction, and climatic, mechanical and chemical environments) and believes that the device is reliable and durable since it complied with its own specified requirements for each test. Additionally, Mazda stated that its device is extremely reliable and durable because it is computer-based and does not rely on any mechanical or moving parts. Mazda further stated that any attempt to slam-pull its vehicle's ignition will have no effect on a thief's ability to start the vehicle without the correct code being transmitted to the electronic control modules.

According to Mazda, there are two methods of initiating the antitheft device operation process. The first process is used when the transponder key can be detected. Specifically, the immobilizer control unit sends a signal to the transponder key using its LF antenna to request a transponder code. The transponder code is then sent through the RF receiver back to the immobilizer control unit to authenticate the code and determine its validity. The second process is used when the transponder key cannot be detected by the immobilizer control unit (*i.e.,* discharged battery). For this process, communication between the transponder key and the immobilizer control unit begins when the transponder key is passed over the coil antenna located in the ''Engine Start'' pushbutton. The immobilizer control module then communicates with the transponder key to determine key validity. Mazda stated that if the code from the transponder key matches with the code from the immobilizer control module by either process, the immobilizer control module compares its code with the code from the powertrain electronic control module when the ''Engine Start'' pushbutton is pressed and the brake pedal is depressed simultaneously. Mazda stated

that the vehicle's engine can only be started if the immobilizer code matches the code previously programmed into the immobilizer control module.

Mazda stated that activation of the device occurs when the operator disengages the ignition by pressing the ''Engine Start'' pushbutton when the vehicle is parked, and that the integration of the set/unset device (transponder key) into the immobilizer system prevents any inadvertent activation of the system. Deactivation occurs when the ignition is initially engaged by pressing the ''Engine Start'' pushbutton while simultaneously depressing the brake pedal.

Mazda provided data on the effectiveness of other similar antitheft devices installed on vehicle lines in support of its belief that its device will be at least as effective as those comparable devices. Specifically, Mazda stated that its device was installed on certain MY 1996 Ford vehicles as standard equipment, (*i.e.,* all Ford Mustang GT and Cobra models, Ford Taurus LX, and SHO models and Ford Sable LS models). In MY 1997, Mazda installed its immobilizer device on the entire Ford Mustang vehicle line as standard equipment. When comparing 1995 model year Mustang vehicle thefts (without immobilizers) with MY 1997 Mustang vehicle thefts (with immobilizers), Mazda referenced the National Crime Information Center's (NCIC) theft information which showed that there was a 70% reduction in theft experienced when comparing MY 1997 Mustang vehicle thefts (with immobilizers) to MY 1995 Mustang vehicle thefts (without immobilizers). Mazda also stated that the Highway Loss Data Institute's (HLDI) September 1997 Theft Loss Bulletin reported an overall theft loss decrease of approximately 50% for both the Ford Mustang and Taurus models upon installation of an antitheft immobilization device. The agency notes that the theft rate data for MYs' 2010 through 2012 are 2.2392, 1.7365 and 2.2115 respectively for the Ford Mustang vehicle line. Preliminary theft data for MY 2013 show that the theft rate for the Ford Mustang vehicle line is 2.8190, which is still below the median theft rate. Additionally, Mazda referenced a July 2000 Highway Loss Data Institute news release which compared theft loss data before and after equipping vehicles with passive immobilizer devices. The data showed an average theft reduction of approximately 50% for vehicles installed with immobilizer devices.

Based on the supporting evidence submitted by Mazda on its device, the agency believes that the antitheft device for the (confidential) vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541). The agency concludes that the device will provide four of the five types of performance listed in § 543.6(a)(3): promoting activation; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.7(b), the agency grants a petition for exemption from the parts-marking requirements of part 541 either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of part 541. The agency finds that Mazda has provided adequate reasons for its belief that the antitheft device for the Mazda (confidential) vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541). This conclusion is based on the information Mazda provided about its device.

For the foregoing reasons, the agency hereby grants in full Mazda's petition for exemption for the Mazda (confidential) vehicle line from the parts-marking requirements of 49 CFR part 541. The agency notes that 49 CFR part 541, appendix A–1, identifies those lines that are exempted from the Theft Prevention Standard for a given model year. 49 CFR 543.7(f) contains publication requirements incident to the disposition of all part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the Theft Prevention Standard. As a condition to the formal granting of Mazda's petition for exemption from the parts-marking requirements of 49 CFR part 541 for the MY 2017 (confidential) vehicle line, the agency fully expects Mazda to notify the agency of the nameplate for the vehicle line prior to its introduction into the United States Commerce for sale.

If Mazda decides not to use the exemption for this line, it must formally notify the agency. If such a decision is made, the line must be fully marked according to the requirements under 49 CFR 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if Mazda wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Section 543.7(d) states that a part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, § 543.9(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption.''

The agency wishes to minimize the administrative burden that § 543.9(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be *de minimis.* Therefore, NHTSA suggests that if the manufacturer contemplates making any changes, the effects of which might be characterized as *de minimis,* it should consult the agency before preparing and submitting a petition to modify.

Issued in Washington, DC, under authority delegated in 49 CFR 1.95.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2015–28814 Filed 11–12–15; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. EP 670 (Sub-No. 1)]

Notice of Rescheduled Rail Energy Transportation Advisory Committee Meeting

AGENCY: Surface Transportation Board.

ACTION: Notice of rescheduled Rail Energy Transportation Advisory Committee meeting.

SUMMARY: Notice is hereby given of a meeting of the Rail Energy Transportation Advisory Committee (RETAC), pursuant to the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 2 section 10(a)(2). This meeting was originally scheduled for Thursday, October 1, 2015, 80 FR 55712 (Sept. 16, 2015). However, the meeting

was postponed due to the possibility of a Federal Government shutdown.

DATES: The rescheduled meeting will be held on Tuesday, December 1, 2015, at 9:00 a.m., E.S.T.

ADDRESSES: The meeting will be held in the Hearing Room on the first floor of the Board's headquarters at 395 E Street SW., Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: Michael Higgins (202) 245–0284; *Michael.Higgins@stb.dot.gov.* [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at: (800) 877–8339].

SUPPLEMENTARY INFORMATION: RETAC was formed in 2007 to provide advice and guidance to the Board, and to serve as a forum for discussion of emerging issues related to the transportation of energy resources by rail, including coal, ethanol, and other biofuels, *Establishment of a Rail Energy Transportation Advisory Committee,* Docket No. EP 670. The purpose of this meeting is to continue discussions regarding issues such as rail performance, capacity constraints, infrastructure planning and development, and effective coordination among suppliers, carriers, and users of energy resources. Agenda items for this meeting include introduction of new members, a performance measures review, industry segment updates by RETAC members, a presentation on the outlook for U.S. coal consumption, and a roundtable discussion.

The meeting, which is open to the public, will be conducted in accordance with the Federal Advisory Committee Act, 5 U.S.C. app. 2; Federal Advisory Committee Management regulations, 41 CFR part 102–3; RETAC's charter; and Board procedures. Further communications about this meeting may be announced through the Board's Web site at *www.stb.dot.gov.*

Written Comments: Members of the public may submit written comments to RETAC at any time. Comments should be addressed to RETAC, c/o Michael Higgins, Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001 or *Michael.Higgins@stb.dot.gov.*

Authority: 49 U.S.C. 721, 49 U.S.C. 11101; 49 U.S.C. 11121.

Decided: November 9, 2015.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2015–28823 Filed 11–12–15; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35963]

BNSF Railway Company—Temporary Trackage Rights Exemption—Union Pacific Railroad Company

Pursuant to a written temporary trackage rights agreement dated November 1, 2015, Union Pacific Railroad Company (UP) has agreed to grant restricted local temporary trackage rights to BNSF Railway Company (BNSF) as follows: (1) Between UP milepost 93.2 at Stockton, Cal., on UP's Oakland Subdivision, and UP milepost 219.4 at Elsey, Cal., on UP's Canyon Subdivision, a distance of 126.2 miles; and (2) between UP milepost 219.4 at Elsey and UP milepost 280.7 at Keddie, Cal., on UP's Canyon Subdivision, a distance of 61.3 miles.

The transaction is scheduled to be consummated on or after November 29, 2015, the effective date of the exemption (30 days after the exemption is filed).

The purpose of this transaction is to permit BNSF to move empty and loaded ballast trains to and from the ballast pit at Elsey, which is adjacent to the UP rail line. The parties' agreement provides that the trackage rights are temporary in nature and are scheduled to expire on December 31, 2018.

As a condition to this exemption, any employee affected by the 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).

This notice is filed under 49 CFR 1180.2(d)(7).[1] 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 effectiveness of the exemption. Stay petitions must be filed by November 20, 2015 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35963, 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 Karl Morell, Karl Morell & Associates, 655 15th St. NW., Suite 225, Washington, DC 20005.

Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV.*''

Decided: November 9, 2015.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2015–28825 Filed 11–12–15; 8:45 am]

BILLING CODE 4915–01–P

[1] BNSF states that the verified notice is not filed under the Board's class exemption for temporary trackage rights at 49 CFR 1180.2(d)(8), because the trackage rights are local rather than overhead. *See R.R. Consolidation Procedures,* 6 S.T.B. 910 (2003). Instead, BNSF has filed under the trackage rights class exemption at § 1180.2(d)(7) and concurrently has filed, in *BNSF Railway Company—Temporary Trackage Rights Exemption—Union Pacific Railroad Company,* Docket No. FD 35676 (Sub-No. 1), a petition for partial revocation of this exemption to permit these proposed local trackage rights to expire at midnight on December 31, 2018, as provided in the parties' agreement. The Board will address that petition in a separate decision.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Procedure 2002–67

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Revenue Procedure 2002–67, Settlement of Section 351 Contingent Liability Tax Shelter Cases.

DATES: Written comments should be received on or before January 12, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Michael A. Joplin, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of revenue procedure should be directed to Sara Covington, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet, at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Settlement of Section 351 Contingent Liability Tax Shelter Cases.

OMB Number: 1545–1801.

Revenue Procedure Number: Revenue Procedure 2002–67.

Abstract: Revenue Procedure 2002–67 prescribes procedures for taxpayers who elect to participate in a settlement initiative aimed at resolving tax shelter cases involving contingent liability transactions that are the same or similar to those described in Notice 2001–17 (''contingent liability transaction''). There are two resolution methodologies: A fixed concession procedure and a fast track dispute resolution procedure that includes binding arbitration.

Current Actions: There are no changes being made to the revenue procedure at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals.

Estimated Number of Respondents: 150.

Estimated Average Time per Respondent: 50 hours.

Estimated Total Annual Burden Hours: 7,500.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request For Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 3, 2015.

Michael A. Joplin,

IRS Supervisory Tax Analyst.

[FR Doc. 2015–28906 Filed 11–12–15; 8:45 am]

BILLING CODE 4830–01–P

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

Notice of Open Public Hearing; Correction

AGENCY: U.S.-China Economic and Security Review Commission.

ACTION: Notice; correction.

SUMMARY: The U.S.-China Commission published a document in the **Federal Register** on November 4, 2015, concerning notice of the official public release of the Commission's 2015 Annual Report to Congress on November 18, 2015. The meeting location and time is now available.

FOR FURTHER INFORMATION CONTACT: Anthony DeMarino, 202–624–1496.

Correction

In the **Federal Register** of November 4, 2015, in FR Doc. 2015–28055 on page 68385, in the second column, correct the ''Location, Date and Time'' caption to read:

Dates, Times, and Room Locations: Wednesday, November 18, 2015 (9 a.m. to 10 a.m. EST). Location: Dirksen Senate Office Building Room 106. Please check our Web site, *www.uscc.gov,* for possible changes to the public meeting and for information on the meeting location.

Dated: November 4, 2015.

Michael Danis,

Executive Director, U.S.-China Economic and Security Review Commission.

[FR Doc. 2015–28517 Filed 11–12–15; 8:45 am]

BILLING CODE 1137–00–P

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of extension of deadline for public comment regarding the proposed amendment to the sentencing guidelines and commentary published on August 17, 2015 (80 FR 49314).

SUMMARY: On August 17, 2015, the United States Sentencing Commission published a notice in the **Federal Register** (80 FR 49314) requesting comment regarding a proposed amendment to the sentencing guidelines and commentary. The proposed amendment and issues for comment published in the notice were as follows: A proposed amendment to revise the ''crime of violence'' and ''drug trafficking offense'' definitions in the career offender guideline and the illegal reentry guideline, including (A) A proposed amendment to § 4B1.2 (Definitions of Terms Used in Section 4B1.1) to delete the residual clause and revise the list of enumerated offenses in the ''crime of violence'' definition, (B) a proposed amendment to § 4B1.2 to implement an additional requirement related to the state felony classification in determining whether an offense qualifies as a felony under § 4B1.2, and (C) corresponding changes to the ''crime of violence'' and ''drug trafficking offense'' definitions in § 2L1.2 (Unlawfully Entering or Remaining in the United States) to bring them more into parallel with the definitions at § 4B1.2, and related issues for comment. The Commission further requested comment regarding retroactive application of the proposed amendment.

The Commission is issuing this notice to advise the public that the period for public comment has been extended to November 25, 2015. The deadline was initially November 12, 2015.

DATES: Public comment regarding the proposed amendment and issues for comment described in this notice should be received by the Commission not later than November 25, 2015.

ADDRESSES: Public comment should be sent to the Commission by electronic mail or regular mail. The email address for public comment is *Public_Comment@ussc.gov.* The regular mail address for public comment is United States Sentencing Commission, One Columbus Circle NE., Suite 2–500, Washington, DC 20002–8002, Attention: Public Affairs.

FOR FURTHER INFORMATION CONTACT: Office of Legislative and Public Affairs, 202–502–4500, *pubaffairs@ussc.gov.*

SUPPLEMENTARY INFORMATION: The United States Sentencing Commission is an independent agency in the judicial branch of the United States Government. The Commission promulgates sentencing guidelines and policy statements for federal courts pursuant to 28 U.S.C. 994(a). The Commission also periodically reviews and revises previously promulgated guidelines pursuant to 28 U.S.C. 994(o) and submits guideline amendments to the Congress not later than the first day of May each year pursuant to 28 U.S.C. 994(p).

The Commission issued a notice for public comment regarding the proposed amendment and issues for comment described in this notice on August 17, 2015 (80 FR 49314). Comment was initially due to the Commission on November 12, 2015. The Commission hereby invites additional comment from any person or group who has interest in the proposed amendment and issues for comment. Comment must be received by the Commission not later than November 25, 2015.

Additional information pertaining to the proposed amendment described in this notice may be accessed through the Commission's Web site at *www.ussc.gov.*

Authority: 28 U.S.C. 994(a), (o), (p), (x); USSC Rules of Practice and Procedure, Rule 4.4.

Patti B. Saris,

Chair.

[FR Doc. 2015–28879 Filed 11–12–15; 8:45 am]

BILLING CODE 2210–40–P

UNITED STATES SENTENCING COMMISSION

Request for Applications; Victims Advisory Group

AGENCY: United States Sentencing Commission.

ACTION: Notice.

SUMMARY: In view of upcoming vacancies in the membership of the Victims Advisory Group, the United States Sentencing Commission hereby invites any individual who has knowledge, expertise, and/or experience in the area of federal crime victimization to apply to be appointed to the membership of the advisory group. Applications should be received by the Commission not later than December 28, 2015. An applicant for membership of the Victims Advisory Group should apply by sending a letter of interest and résumé to the Commission as indicated in the **ADDRESSES** section below.

DATES: Application materials for membership of the Victims Advisory Group should be received not later than December 28, 2015.

ADDRESSES: An applicant for membership of the Victims Advisory Group should apply by sending a letter of interest and résumé to the Commission by electronic mail or regular mail. The email address is *pubaffairs@ussc.gov.* The regular mail address is United States Sentencing Commission, One Columbus Circle NE., Suite 2–500, South Lobby, Washington, DC 20002–8002, Attention: Public Affairs.

FOR FURTHER INFORMATION CONTACT: Office of Legislative and Public Affairs, 202–502–4500, *pubaffairs@ussc.gov.* More information about the Victims Advisory Group is available on the Commission's Web site at *www.ussc.gov/advisory-groups.*

SUPPLEMENTARY INFORMATION: The Victims Advisory Group of the United States Sentencing Commission is a standing advisory group of the United States Sentencing Commission pursuant to 28 U.S.C. 995 and Rule 5.4 of the Commission's Rules of Practice and Procedure. Under the charter for the advisory group, the purpose of the advisory group is (1) to assist the Commission in carrying out its statutory responsibilities under 28 U.S.C. 994(o); (2) to provide to the Commission its views on the Commission's activities and work, including proposed priorities and amendments, as they relate to victims of crime; (3) to disseminate information regarding sentencing issues to organizations represented by the Victims Advisory Group and to other victims of crime and victims advocacy groups, as appropriate; and (4) to perform any other functions related to victims of crime as the Commission requests. The advisory group consists of not more than nine members, each of whom may serve not more than two consecutive three-year terms. Each member is appointed by the Commission.

The Commission invites any individual who has knowledge, expertise, and/or experience in the area of federal crime victimization to apply to be appointed to the membership of the Victims Advisory Group by sending a letter of interest and a résumé to the Commission as indicated in the **ADDRESSES** section above.

Authority: 28 U.S.C. 994(a), (o), (p), § 995; USSC Rules of Practice and Procedure 5.4.

Patti B. Saris,

Chair.

[FR Doc. 2015–28849 Filed 11–12–15; 8:45 am]

BILLING CODE 2210–40–P

FEDERAL REGISTER

Vol. 80 Friday,

No. 219 November 13, 2015

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 412, et al.

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System; Provider Administrative Appeals and Judicial Review; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 412, 413, 416, and 419

[CMS–1633–FC; CMS–1607–F2]

RIN 0938–AS42; 0938–AS11

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System; Provider Administrative Appeals and Judicial Review

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

ACTION: Final rule with comment period; final rule.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2016 to implement applicable statutory requirements and changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Further, this document includes certain finalized policies relating to the hospital inpatient prospective payment system: Changes to the 2-midnight rule under the short inpatient hospital stay policy; and a payment transition for hospitals that lost their status as a Medicare-dependent, small rural hospital (MDH) because they are no longer in a rural area due to the implementation of the new Office of Management and Budget delineations in FY 2015 and have not reclassified from urban to rural before January 1, 2016.

In addition, this document contains a final rule that finalizes certain 2015 proposals, and addresses public comments received, relating to the changes in the Medicare regulations governing provider administrative appeals and judicial review relating to appropriate claims in provider cost reports.

DATES: *Effective Date:* This final rule with comment period and final rule are effective on January 1, 2016.

Comment Period: To be assured consideration, comments on the payment classifications assigned to HCPCS codes identified in Addenda B, AA, and BB with the ''NI'' comment indicator and on other areas specified throughout this final rule with comment period must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on December 29, 2015.

Application Deadline—New Class of New Technology Intraocular Lenses: Requests for review of applications for a new class of new technology intraocular lenses must be received by 5 p.m. EST on March 1, 2016, at the following address: ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

ADDRESSES: In commenting, please refer to file code CMS–1633–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1633–FC, 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 via express or overnight mail to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1633–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact Carol Schwartz at (410) 786–0576.

Ambulatory Surgical Center (ASC) Payment System, contact Elisabeth Daniel at (410) 786–0237.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia at (410) 786–7236.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Vinitha Meyyur at (410) 786–8819.

Blood and Blood Products, contact Lela Strong at (410) 786–3213.

Cancer Hospital Payments, contact David Rice at (410) 786–6004.

Chronic Care Management (CCM) Hospital Services, contact Twi Jackson at (410) 786–1159.

CPT and Level II Alphanumeric HCPCS Codes—Process for Requesting Comments, contact Marjorie Baldo at (410) 786–4617.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver at (410) 786–9379.

Composite APCs (Extended Assessment and Management, Low Dose Brachytherapy, Multiple Imaging), contact Twi Jackson at (410) 786–1159.

Comprehensive APCs, contact Lela Strong at (410) 786–3213.

Hospital Observation Services, contact Twi Jackson at (410) 786–1159.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Elizabeth Bainger at (410) 786–0529.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur at (410) 786–8819.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson at (410) 786–1159.

Inpatient Only Procedures List, contact Lela Strong at (410) 786–3213.

Medicare Cost Reports: Appropriate Claims and Provider Appeals, contact Kellie Shannon at (410) 786–0416.

New Technology Intraocular Lenses (NTIOLs), contact John McInnes at (410) 786–0791.

No Cost/Full Credit and Partial Credit Devices, contact Carol Schwartz at (410) 786–0576.

OPPS Brachytherapy, contact Elisabeth Daniel at (410) 786–0237.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact David Rice at (410) 786–6004.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Elisabeth Daniel at (410) 786–0237.

OPPS Exceptions to the 2 Times Rule, contact Marjorie Baldo at (410) 786–4617.

OPPS Packaged Items/Services, contact Elisabeth Daniel at (410) 786–0237.

OPPS Pass-Through Devices and New Technology Procedures/Services, contact Carol Schwartz at (410) 786–0576.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova at (410) 786–2682.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact Dexter Dickey at (410) 786–6856.

Rural Hospital Payments, contact David Rice at (410) 786–6004.

Stereotactic Radiosurgery Services (SRS), contact Elisabeth Daniel at (410) 786–0237.

Transition for Former Medicare-Dependent, Small Rural Hospitals, contact Shevi Marciano at (410) 786–4487.

Two-Midnight Policy—General Issues, contact Twi Jackson at (410) 786–1159.

Two-Midnight Policy—Medical Review, contact Steven Rubio at (410) 786–1782.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Marjorie Baldo at (410) 786–4617.

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, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys),* a service of the U.S. Government Printing Office. This database can be accessed via the Internet at *http://www.gpo.gov/fdsys/.*

Addenda Available Only Through the Internet on the CMS Web site

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS Web site. The Addenda relating to the OPPS are available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* The Addenda relating to the ASC payment system are available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html.*

Alphabetical List of Acronyms Appearing in This Federal Register Document

AHA American Hospital Association
AMA American Medical Association
AMI Acute myocardial infarction
APC Ambulatory Payment Classification
APU Annual payment update
ASC Ambulatory surgical center
ASCQR Ambulatory Surgical Center Quality Reporting
ASP Average sales price
AWP Average wholesale price
BBA Balanced Budget Act of 1997, Pub. L. 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Pub. L. 106–113
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106–554
BLS Bureau of Labor Statistics
CAH Critical access hospital
CAHPS Consumer Assessment of Healthcare Providers and Systems
CAP Competitive Acquisition Program
C–APC Comprehensive Ambulatory Payment Classification
CASPER Certification and Survey Provider Enhanced Reporting
CAUTI Catheter-associated urinary tract infection
CBSA Core-Based Statistical Area
CCM Chronic care management
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDC Centers for Disease Control and Prevention
CED Coverage with Evidence Development
CERT Comprehensive Error Rate Testing
CFR Code of Federal Regulations
CI Comment indicator
CLABSI Central Line [Catheter] Associated Blood Stream Infection
CLFS Clinical Laboratory Fee Schedule
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services
CoP Condition of participation
CPI–U Consumer Price Index for All Urban Consumers
CPT Current Procedural Terminology (copyrighted by the American Medical Association)
CR Change request
CRC Colorectal cancer
CSAC Consensus Standards Approval Committee
CT Computed tomography
CV Coefficient of variation
CY Calendar year
DFO Designated Federal Official
DIR Direct or indirect remuneration
DME Durable medical equipment
DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
DRA Deficit Reduction Act of 2005, Pub. L. 109–171
DSH Disproportionate share hospital
EACH Essential access community hospital
EAM Extended assessment and management
EBRT External beam radiotherapy

ECG Electrocardiogram
ED Emergency department
EDTC Emergency department transfer communication
EHR Electronic health record
EJR Expedited judicial review
E/M Evaluation and management
ESRD End-stage renal disease
ESRD QIP End-Stage Renal Disease Quality Improvement Program
FACA Federal Advisory Committee Act, Pub. L. 92–463
FDA Food and Drug Administration
FFS [Medicare] Fee-for-service
FTE Full-time equivalent
FY Fiscal year
GAO Government Accountability Office
GI Gastrointestinal
GME Graduate medical education
HAI Healthcare-associated infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCERA Health Care and Education Reconciliation Act of 2010, Pub. L. 111–152
HCP Health care personnel
HCPCS Healthcare Common Procedure Coding System
HCRIS Healthcare Cost Report Information System
HCUP Healthcare Cost and Utilization Project
HEU Highly enriched uranium
HH QRP Home Health Quality Reporting Program
HHS Department of Health and Human Services
HIE Health information exchange
HIPAA Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191
HOP Hospital Outpatient Payment [Panel]
HOPD Hospital outpatient department
HOP QDRP Hospital Outpatient Quality Data Reporting Program
HPMS Health Plan Management System
IBD Inflammatory bowel disease
ICC Interclass correlation coefficient
ICD Implantable cardioverter defibrillator
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10 International Classification of Diseases, Tenth Revision
ICH In-center hemodialysis
IME Indirect medical education
IDTF Independent diagnostic testing facility
IGI IHS Global Insight, Inc.
IHS Indian Health Service
I/OCE Integrated Outpatient Code Editor
IOL Intraocular lens
IORT Intraoperative radiation treatment
IPFQR Inpatient Psychiatric Facility Quality Reporting
IPPS [Hospital] Inpatient Prospective Payment System
IQR [Hospital] Inpatient Quality Reporting
IRF Inpatient rehabilitation facility
IRF QRP Inpatient Rehabilitation Facility Quality Reporting Program
IT Information technology
LCD Local coverage determination
LDR Low dose rate
LTCH Long-term care hospital
LTCHQR Long-Term Care Hospital Quality Reporting
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. 114–10
MAP Measure Application Partnership
MDH Medicare-dependent, small rural hospital
MedPAC Medicare Payment Advisory Commission
MEG Magnetoencephalography
MFP Multifactor productivity
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006, Pub. L. 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110–275
MLR Medical loss ratio
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Pub. L. 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. 110–173
MPFS Medicare Physician Fee Schedule
MR Medical review
MRA Magnetic resonance angiography
MRgFUS Magnetic Resonance Image Guided Focused Ultrasound
MRI Magnetic resonance imaging
MRSA Methicillin-Resistant Staphylococcus Aures
MS–DRG Medicare severity diagnosis-related group
MSIS Medicaid Statistical Information System
MUC Measure under consideration
NCCI National Correct Coding Initiative
NDC National Drug Code
NEMA National Electrical Manufacturers Association
NHSN National Healthcare Safety Network
NOS Not otherwise specified
NPI National Provider Identifier
NPR Notice of program reimbursement
NPWT Negative Pressure Wound Therapy
NQF National Quality Forum
NQS National Quality Strategy
NTIOL New technology intraocular lens
NUBC National Uniform Billing Committee
OACT [CMS] Office of the Actuary
OBRA Omnibus Budget Reconciliation Act of 1996, Pub. L. 99–509
OIG [HHS] Office of the Inspector General
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPD [Hospital] Outpatient Department
OPO Organ Procurement Organization
OPPS [Hospital] Outpatient Prospective Payment System
OPSF Outpatient Provider-Specific File
OQR [Hospital] Outpatient Quality Reporting
OT Occupational therapy
PAMA Protecting Access to Medicare Act of 2014, Pub. L. 113–93
PCHQR PPS-Exempt Cancer Hospital Quality Reporting
PCR Payment-to-cost ratio
PDC Per day cost
PDE Prescription Drug Event
PE Practice expense
PEPPER Program Evaluation Payment Patterns Electronic Report
PHP Partial hospitalization program
PHSA Public Health Service Act, Pub. L. 96–88
PMA Premarket approval
PN Pneumonia
POS Place of service
PPI Producer Price Index
PPS Prospective payment system
PQRI Physician Quality Reporting Initiative
PQRS Physician Quality Reporting System
PRM Provider Reimbursement Manual
QDC Quality data code
QIO Quality Improvement Organization
RFA Regulatory Flexibility Act
RHQDAPU Reporting Hospital Quality Data for Annual Payment Update
RTI Research Triangle Institute, International
RVU Relative value unit
SAD Self-administered drug
SAMS Secure Access Management Services
SCH Sole community hospital
SCOD Specified covered outpatient drugs
SES Socioeconomic status
SI Status indicator
SIR Standardized infection ratio
SNF Skilled nursing facility
SRS Stereotactic radiosurgery
SSA Social Security Administration
SSI Surgical site infection
TEP Technical Expert Panel
TIP Transprostatic implant procedure
TOPs Transitional Outpatient Payments
USPSTF United States Preventive Services Task Force
VBP Value-based purchasing
WAC Wholesale acquisition cost

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I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this document, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) beginning January 1, 2016. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. We describe these and various other statutory authorities in the relevant sections of this final rule with comment period. In addition, this document updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Further, we are making certain changes relating to the hospital inpatient prospective payment system (IPPS): Changes to the 2-midnight rule under the short inpatient hospital stay policy; and a payment transition for hospitals that lost their MDH status because they are no longer in a rural area due to the implementation of the new OMB delineations in FY 2015 and have not reclassified from urban to rural under 42 CFR 412.103 before January 1, 2016.

In addition, we are finalizing certain 2015 proposed policies, and addressing public comments, relating to the changes in the Medicare regulations governing provider administrative appeals and judicial review relating to appropriate claims in provider cost reports.

2. Summary of the Major Provisions

• *OPPS Update:* For CY 2016, we are decreasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of -0.3 percent. This increase factor is based on the hospital inpatient market basket percentage increase of 2.4 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment of 0.5 percentage point, and minus a 0.2 percentage point adjustment required by the Affordable Care Act. In addition, we are applying a 2.0 percent reduction to the conversion factor to redress the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests that are excepted from our final CY 2014 laboratory packaging policy, as discussed in section II.B. of this final rule with comment period. Under this rule, we estimate that total payments for CY 2016, including beneficiary cost-sharing, to the approximate 4,000 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)), will decrease by approximately $133 million compared to CY 2015 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a proposed reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

• *Rural Adjustment:* We are continuing the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This adjustment will apply to all services paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to cost.

• *Cancer Hospital Payment Adjustment:* For CY 2016, we are continuing to provide additional payments to cancer hospitals so that the cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. Based on those data, a target PCR of 0.92 will be used to determine the CY 2016 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.92 for each cancer hospital.

• *Payment of Drugs, Biologicals, and Radiopharmaceuticals:* For CY 2016, payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals that do not have pass-through status are set at the statutory default of average sales price (ASP) plus 6 percent.

• *Payment of Skin Substitutes:* Payment for skin substitutes will utilize the high/low cost APC structure based on exceeding a threshold based on mean unit cost (MUC) or per day cost (PDC). Further, for CY 2016, skin substitutes with pass-through payment status will be assigned to the high cost category. Skin substitutes with pricing information but without claims data to calculate either an MUC or PDC will be assigned to either the high cost or low cost category based on the product's ASP+6 percent payment rate. Moreover, any new skin substitutes without pricing information will be assigned to the low cost category until pricing information is available to compare to the CY 2016 thresholds.

• *Payment of Biosimilar Biological Products:* For CY 2016, we are paying for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act. We also are extending pass-through payment eligibility to biosimilar biological products and to set payment at the difference between the amount paid under section 1842(o) of the Act (that is, the payment allowance of the product as determined under section 1847A of the Act) and the otherwise applicable HOPD fee schedule amount.

• *Packaging Policies:* In CY 2015, we conditionally packaged certain ancillary services when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service. For CY 2016, we are expanding the set of conditionally packaged ancillary services to include three new APCs.

• *Conditionally Packaged Outpatient Laboratory Tests:* For CY 2016, we are conditionally packaging laboratory tests (regardless of the date of service) on a claim with a service that is assigned status indicator ''S,'' ''T,'' or ''V'' unless an exception applies or the laboratory test is ''unrelated'' to the other HOPD

service or services on the claim. We are establishing a new status indicator ''Q4'' for this purpose. When laboratory tests are the only services on the claim, a separate payment at CLFS payment rates will be made. The ''L1'' modifier will still be used for ''unrelated'' laboratory tests.

• *Comprehensive APCs:* We implemented the comprehensive APCs (C–APCs) policy for CY 2015 with a total of 25 C–APCs. In CY 2016, we are not making extensive changes to the already established methodology used for C–APCs. However, we are creating nine new C–APCs that meet the previously established criteria.

• *APC Restructuring:* Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. For CY 2016, we conducted a comprehensive review of the structure of the APCs and codes and are restructuring the OPPS APC groupings for nine APC clinical families based on the following principles: (1) Improved clinical homogeneity; (2) improved resource homogeneity; (3) reduced resource overlap in longstanding APCs; and (4) greater simplicity and improved understandability of the OPPS APC structure.

• *New Process for Device Pass-Through Payment:* Beginning in CY 2016, we are adding a rulemaking component to the current quarterly device pass-through payment application process. Specifically, we are supplementing the quarterly process by including a description of applications received as well as our rationale for approving the application in the next applicable OPPS proposed rule. Applications that we do not approve based on the evidence available during the quarterly review process will be described in the next applicable OPPS proposed rule, unless the applicant withdraws its application. The addition of rulemaking to the device pass-through application process will help achieve the goals of increased transparency and stakeholder input. In addition, this change will align a portion of the OPPS device pass-through payment application process with the already established IPPS application process for new medical services and new technology add-on payments. We also are establishing policy that a device that requires FDA premarket approval or clearance is eligible to apply for device pass-through payment only if it is ''new,'' meaning that the pass-through payment application is submitted within 3 years from the date of the initial FDA premarket approval or clearance, or, in the case of a delay of market availability, within 3 years of market availability.

• *Two-Midnight Rule:* The 2-midnight rule was adopted effective October 1, 2013. Under the 2-midnight rule, an inpatient admission is generally appropriate for Medicare Part A payment if the physician (or other qualified practitioner) admits the patient as an inpatient based upon the expectation that the patient will need hospital care that crosses at least 2 midnights. In assessing the expected duration of necessary care, the physician (or other practitioner) may take into account outpatient hospital care received prior to inpatient admission. If the patient is expected to need less than 2 midnights of care in the hospital, the services furnished should generally be billed as outpatient services. In this final rule, we are modifying our existing ''exceptions'' policy under which previously the only exceptions to the 2-midnight benchmark were cases involving services designated by CMS as inpatient only, and those published on the CMS Web site or other subregulatory guidance. Specifically, we are finalizing our proposal to also allow exceptions to the 2-midnight benchmark to be determined on a case-by-case basis by the physician responsible for the care of the beneficiary, subject to medical review. However, we continue to expect that stays under 24 hours would rarely qualify for an exception to the 2-midnight benchmark. In addition, we revised our medical review strategy to have Quality Improvement Organization (QIO) contractors conduct reviews of short inpatient stays rather than the Medicare administrative contractors (MACs), and the QIOs assumed medical responsibility for hospital stays affected by the 2-midnight rule on October 1, 2015.

• *Advanced Care Planning (ACP):* For CY 2016, we are conditionally packaging payment for the service described by CPT code 99497 (Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate). Consequently, this code is assigned to a conditionally packaged payment status indicator of ''Q1.'' When this service is furnished with another service paid under the OPPS, payment will be package; when it is the only service furnished, payment will be made separately. CPT code 99498 (Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes (List separately in addition to code for primary procedure)) is an add-on code and therefore payment for the service described by this code is unconditionally packaged (assigned status indicator ''N'') in the OPPS in accordance with 42 CFR 419.2(b)(18).

• *Chronic Care Management (CCM):* For CY 2016, we are adding additional requirements for hospitals to bill and receive OPPS payment for CCM services described by CPT code 99490. These requirements include scope of service elements analogous to the scope of service elements finalized as requirements in the CY 2015 Medicare Physician Fee Schedule (MPFS) final rule with comment period (79 FR 6715 through 67728).

• *National Electrical Manufacturers Association (NEMA) Modifier:* Effective for services furnished on or after January 1, 2016, section 218(a) of the PAMA amended section 1834 of the Act by establishing a new subsection 1834(p), which reduces payment for the technical component (TC) (and the TC of the global fee) under the MPFS and the OPPS (5 percent in 2016 and 15 percent in 2017 and subsequent years) for applicable computed tomography (CT) services identified by certain CPT HCPCS codes furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled ''Standard Attributes on CT Equipment Related to Dose Optimization and Management.'' The provision requires that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable CT service was furnished that was not consistent with the NEMA CT equipment standard. To implement this provision, we are establishing a new modifier that will be reported with specific CPT codes, effective January 1, 2016.

• *New Process for Requesting Comments on New and Revised Category I and III CPT Codes:* In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66842 through 66844), we finalized a revised process of

assigning APC and status indicators for new and revised Category I and III CPT codes that will be effective January 1. Specifically, we stated that we would include the proposed APC and status indicator assignments for the vast majority of new and revised CPT codes before they are used for payment purposes under the OPPS if the AMA provides CMS with the codes in time for the OPPS/ASC proposed rule. For the CY 2016 OPPS update, we received the CY 2016 CPT codes from AMA for inclusion in the CY 2016 OPPS/ASC proposed rule. We received public comments on the proposed OPPS status indicators for the new CY 2016 CPT codes, which we address in this final rule with comment period.

• *Ambulatory Surgical Center Payment Update:* For CY 2016, we are increasing payment rates under the ASC payment system by 0.3 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a projected CPI–U update of 0.8 percent minus a multifactor productivity adjustment required by the Affordable Care Act of 0.5 percentage point. Based on this update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2016 will be approximately $4.221 billion, an increase of approximately $128 million compared to estimated CY 2015 Medicare payments. In addition, we are establishing a revised process of assigning ASC payment indicators for new and revised Category I and III CPT codes that would be effective January 1, similar to the OPPS process we finalized in the CY 2015 OPPS/ASC final rule with comment period. Specifically, we are including the proposed ASC payment indicator assignments in the OPPS/ASC proposed rule for the vast majority of new and revised CPT codes before they are used for payment purposes under the ASC payment system if the American Medical Association (AMA) provides CMS with the codes in time for the OPPS/ASC proposed rule. We received public comments on the proposed ASC payment indicators for the new CY 2016 CPT codes, which we address in this final rule with comment period.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are establishing requirements for the CY 2017 payment determination and subsequent years and the CY 2018 payment determination and subsequent years. For CY 2017 and subsequent years, we are: (1) Removing the OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache measure, effective January 1, 2016 (no data for this measure will be used for any payment determination); (2) changing the deadline for withdrawing from the Hospital OQR Program from November 1 to August 31 and revising the related regulations to reflect this change; (3) transitioning to a new payment determination timeframe that will use only three quarters of data for the CY 2017 payment determination; (4) making conforming changes to our validation scoring process to reflect changes in the APU determination timeframe; (5) changing the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet Web site) to January 1 through May 15; (6) fixing a typographical error to correct the name of our extension and exception policy to extension and exemption policy; (7) changing the deadline for submitting a reconsideration request to the first business day on or after March 17 of the affected payment year; and (8) amending 42 CFR 419.46(f)(1) and 42 CFR 419.46(e)(2) to replace the term ''fiscal year'' with the term ''calendar year.''

For CY 2018 and subsequent years, we are (1) adding a new measure: OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) with a modification to the proposed manner of data submission, and (2) shifting the quarters on which we base payment determinations to again include four quarters of data.

In addition, we are exploring use of electronic clinical quality measures (eCQMs) and whether, in future rulemaking, we will propose that hospitals have the option to voluntarily submit data for the OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients measure electronically possibly beginning with the CY 2019 payment determination.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are aligning our policies regarding paid claims to be included in the calculation for all claims-based measures, modifying the submission date for reconsideration requests, modifying our policy for the facility identifier for public reporting of ASCQR Program data, and finalizing our policy to not consider IHS hospital outpatient departments that bill as ASCs to be ASCs for purposes of the ASCQR Program. In addition, we are continuing to use the existing submission deadlines for data submitted via an online data submission tool. We also are codifying a number of existing and new policies. We also address public comments that we solicited in the proposed rule on the possible inclusion of two measures in the ASCQR Program measure set in the future.

3. Summary of Costs and Benefits

In sections XXI. and XXII. of this final rule with comment period, we set forth a detailed analysis of the regulatory and Federalism impacts that the changes will have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of the OPPS Update

(1) Impacts of All OPPS Changes

Table 70 in section XXI. of this final rule with comment period displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2016 compared to all estimated OPPS payments in CY 2015. We estimate that the policies finalized in this final rule with comment period will result in a 0.4 percent overall decrease in OPPS payments to providers. We estimate that total OPPS payments for CY 2016, including beneficiary cost-sharing, to the approximate 4,000 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will decrease by approximately $133 million compared to CY 2015 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure that we adopted beginning in CY 2011 and basing payment fully on the type of provider furnishing the service, we estimate a 23.1 percent increase in CY 2016 payments to CMHCs relative to their CY 2015 payments.

(2) Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the FY 2016 IPPS final wage indexes results in no change for urban hospitals and a 0.4 percent decrease for rural hospitals under the OPPS. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data.

(3) Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2016 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not making any change in policies for determining the rural and cancer hospital payment adjustments, and the adjustment amounts do not significantly impact the budget neutrality adjustments for these policies.

(4) Impacts of the OPD Fee Schedule Increase Factor

As a result of the OPD fee schedule increase factor, the 2.0 percent reduction to the conversion factor to redress the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests that are excepted from our final CY 2014 laboratory packaging policy, and other budget neutrality adjustments, we estimate that urban and rural hospitals will experience decreases of approximately 0.4 percent for urban hospitals and 0.6 percent for rural hospitals. Classifying hospitals by teaching status or type of ownership suggests that these hospitals will receive similar decreases.

b. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2016 payment rates compared to estimated CY 2015 payment rates ranges between 5 percent for auditory system services and −5 percent for hematologic and lymphatic system procedures.

c. Impacts of the Hospital OQR Program

We do not expect our CY 2016 policies to significantly affect the number of hospitals that do not receive a full annual payment update.

d. Impacts of the ASCQR Program

We do not expect our CY 2016 policies to significantly affect the number of ASCs that do not receive a full annual payment update.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Social Security Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; and the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015.

Under the OPPS, we pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this final rule with comment period. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow

us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals include: critical access hospitals (CAHs); hospitals located in Maryland and paid under the Maryland All-Payer Model; hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Pub. L. 106–113, and redesignated by section 202(a)(2) of Pub. L. 106–113, requires that we consult with an external advisory panel of experts to annually review the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act and section 222 of the Public Health Service (PHS) Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the PHS Act which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel, or the Panel). The Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the HOP Panel, and at that time named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise), reviews clinical data, and advises CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that: The Panel continues to be technical in nature; is governed by the provisions of the FACA; may convene up to three meetings per year; has a Designated Federal Official (DFO); and is chaired by a Federal Official designated by the Secretary. The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add Critical Access Hospital (CAH) representation to its membership. The current charter was renewed on November 6, 2014 (80 FR 23009) and the number of panel members was revised from up to 19 to up to 15 members.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*.

3. Panel Meetings and Organizational Structure

The Panel has held multiple meetings, with the last meeting taking place on August 24, 2015. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for Panel membership and to announce new members.

The Panel has established an operational structure that, in part, currently includes the use of three subcommittees to facilitate its required review process. The three current subcommittees are the Data Subcommittee, the Visits and Observation Subcommittee, and the Subcommittee for APC Groups and Status Indicator (SI) Assignments.

The Data Subcommittee is responsible for studying the data issues confronting the Panel and for recommending options for resolving them. The Visits and Observation Subcommittee reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital

outpatient visits paid under the OPPS (for example, APC configurations and APC relative payment weights). The Subcommittee for APC Groups and SI Assignments advises the Panel on the following issues: The appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid; and the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made.

Each of these subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 24, 2015 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the August 24, 2015 Panel meeting are included in the sections of this final rule with comment period that are specific to each recommendation. For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS Web site mentioned earlier in this section, and the FACA database at: *http://facadatabase.gov/.*

F. Public Comments Received on the CY 2015 OPPS/ASC Final Rule With Comment Period

We received approximately 38 timely pieces of correspondence on the CY 2015 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 10, 2014 (79 FR 66770), as well as in the correction notice that was published on February 24, 2015 (80 FR 9629), some of which contained comments on the interim APC assignments and/or status indicators of new or replacement HCPCS codes (identified with comment indicator ''NI'' in Addenda B, AA, and BB to that final rule). Summaries of the public comments on new or replacement codes are set forth in this CY 2016 OPPS/ASC final rule with comment period under the appropriate subject-matter headings.

G. Public Comments Received on the CY 2016 OPPS/ASC Proposed Rule

We received approximately 670 timely pieces of correspondence on the CY 2016 OPPS/ASC proposed rule that appeared in the **Federal Register** on July 8, 2015 (80 FR 39200). We note that we received some public comments that were outside the scope of the proposed rule. Out-of-scope public comments are not addressed in this CY 2016 OPPS/ASC final rule with comment period. Summaries of the public comments that are within the scope of the proposed rule and our responses are set forth in the various sections of this final rule with comment period under the appropriate headings.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39210), for the CY 2016 OPPS, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2016, and before January 1, 2017 (CY 2016), using the same basic methodology that we described in the CY 2015 OPPS/ASC final rule with comment period. That is, we proposed to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights. Therefore, for the purpose of recalibrating the proposed APC relative payment weights for CY 2016, we used approximately 151 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2014, and before January 1, 2015. For this final rule with comment period, for the purpose of recalibrating the final APC relative payment weights for CY 2016, we used approximately 163 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2014, and before January 1, 2015. For exact numbers of claims used, we refer readers to the claims accounting narrative under supporting documentation for the CY 2016 OPPS/ASC proposed rule and this final rule with comment period on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

Of the approximately 163 million final action claims for services provided in hospital outpatient settings used to calculate the CY 2016 OPPS payment rates for this final rule with comment period, approximately 125 million claims were the type of bill potentially appropriate for use in setting rates for OPPS services (but did not necessarily contain services payable under the OPPS). Of the approximately 125 million claims, approximately 3 million claims were not for services paid under the OPPS or were excluded as not appropriate for use (for example, erroneous cost-to-charge ratios (CCRs) or no HCPCS codes reported on the claim). From the remaining approximately 122 million claims, we created approximately 95 million single records, of which approximately 43 million were ''pseudo'' single or ''single session'' claims (created from approximately 52 million multiple procedure claims using the process we discuss later in this section). Approximately 3 million claims were trimmed out on cost or units in excess of +/−3 standard deviations from the geometric mean or other trims, yielding approximately 92 million single claims for ratesetting. As described in section II.A.2. of this final rule with comment period, our data development process is designed with the goal of using appropriate cost information in setting the APC relative payment weights. The bypass process is described in section II.A.1.b. of this final rule with comment period. This section discusses how we develop ''pseudo'' single procedure claims (as defined below), with the intention of using more appropriate data from the available claims. In some cases, the bypass process allows us to use some portion of the submitted claim for cost estimation purposes, while the remaining information on the claim continues to be unusable. Consistent with the goal of using appropriate information in our data development process, we only use claims (or portions of each claim) that are appropriate for ratesetting purposes.

The final APC relative weights and payments for CY 2016 in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site) were calculated using claims from CY 2014 that were processed through June 30, 2015. While prior to CY 2013 we historically based the payments on median hospital costs for services in the APC groups, beginning with the CY 2013 OPPS, we established the cost-based relative payment weights for the OPPS using geometric mean costs, as

discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271). For the CY 2016 OPPS, as we proposed, we used this same methodology, basing payments on geometric mean costs. Under this methodology, we select claims for services paid under the OPPS and match these claims to the most recent cost report filed by the individual hospitals represented in our claims data. We continue to believe that it is appropriate to use the most current full calendar year claims data and the most recently submitted cost reports to calculate the relative costs underpinning the APC relative payment weights and the CY 2016 payment rates.

b. Use of Single and Multiple Procedure Claims

For CY 2016, in general, we proposed to continue to use single procedure claims to set the costs on which the APC relative payment weights are based. We generally use single procedure claims to set the estimated costs for APCs because we believe that the OPPS relative weights on which payment rates are based should be derived from the costs of furnishing one unit of one procedure and because, in many circumstances, we are unable to ensure that packaged costs can be appropriately allocated across multiple procedures performed on the same date of service.

It is generally desirable to use the data from as many claims as possible to recalibrate the APC relative payment weights, including those claims for multiple procedures. As we have for several years, we proposed to use date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims. Through bypassing specified codes that we believe do not have significant packaged costs, we are able to use more data from multiple procedure claims. In many cases, this enabled us to create multiple ''pseudo'' single procedure claims from claims that were submitted as multiple procedure claims spanning multiple dates of service, or claims that contained numerous separately paid procedures reported on the same date on one claim. We refer to these newly created single procedure claims as ''pseudo'' single procedure claims. The history of our use of a bypass list to generate ''pseudo'' single procedure claims is well-documented, most recently in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66780 through 66783). In addition, for CY 2008 (72 FR 66614 through 66664), we increased packaging and created the first composite APCs, and continued those policies through CY 2015. Increased packaging and creation of composite APCs also increased the number of bills that we were able to use for ratesetting by enabling us to use claims that contained multiple major procedures that previously would not have been usable. Further, for CY 2009, we expanded the composite APC model to one additional clinical area, multiple imaging services (73 FR 68559 through 68569), which also increased the number of bills we were able to use in developing the OPPS relative weights on which payments are based. We have continued the composite APCs for multiple imaging services through CY 2015, and we proposed to continue this policy for CY 2016. We refer readers to section II.A.2.f. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66810 through 66816) for a discussion of the use of claims in modeling the costs for composite APCs and to section II.A.3. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817 through 66823) for a discussion of our packaging policies for CY 2015. In addition, we proposed to establish additional packaging policies for the CY 2016 OPPS, as discussed in section II.A.3. of this final rule with comment period.

In the proposed rule, we proposed to continue to apply these processes to enable us to use as much claims data as possible for ratesetting for the CY 2016 OPPS. This methodology enabled us to create, for the proposed rule, approximately 38 million ''pseudo'' single procedure claims, including multiple imaging composite ''single session'' bills (we refer readers to section II.A.2.f.(4) of the proposed rule for further discussion), to add to the approximately 49 million ''natural'' single procedure claims.

In addition, we proposed to continue our broader initiative to review, revise, and reorganize APCs across the OPPS to collectively group services that are clinically similar and have similar resource costs within the same APC. The restructuring of APCs are discussed in the applicable sections of this final rule with comment period. In conjunction with this initiative, we proposed to renumber the APCs (except for the composite APCs) primarily to achieve consecutive numbering of APCs within each clinical family of APCs, as discussed in section III.D. of this final rule with comment period. For the proposed rule, we provided a crosswalk from the existing APC numbers to the proposed new APC renumber in Addendum Q to the proposed rule (which is available via the Internet on the CMS Web site).

For CY 2016, in the proposed rule, we proposed to bypass 197 HCPCS codes that were identified in Addendum N to the proposed rule (which is available via the Internet on the CMS Web site). Since the inception of the bypass list, which is the list of codes to be bypassed to convert multiple procedure claims to ''pseudo'' single procedure claims, we have calculated the percent of ''natural'' single claims that contained packaging for each HCPCS code and the amount of packaging on each ''natural'' single claim for each code. Each year, we generally retain the codes on the previous year's bypass list and use the updated year's data (for CY 2016, data available for the proposed rule from CY 2014 claims processed through December 31, 2014) to determine whether it would be appropriate to add additional codes to the previous year's bypass list. For CY 2016, we proposed to continue to bypass all of the HCPCS codes on the CY 2015 OPPS bypass list, with the exception of HCPCS codes that we proposed to delete for CY 2016, which were listed in Table 1 of the proposed rule. (We refer readers to Addendum N to the CY 2015 OPPS/ASC final rule with comment period for the CY 2015 OPPS bypass list. Addendum N is available via the Internet on the CMS Web site.) We also proposed to remove HCPCS codes that are not separately paid under the OPPS because the purpose of the bypass list is to obtain more data for those codes relevant to ratesetting. Some of the codes we proposed to remove from the CY 2016 bypass list were affected by the CY 2016 proposed packaging policy, discussed in section II.A.3. of this final rule with comment period. Some of the codes we proposed to remove have packaged cost patterns associated with their natural single major claims that would no longer meet the bypass list criterion of 5 percent or fewer of the single major claims having packaged costs on the claim. In addition, we proposed to add to the bypass list for CY 2016 HCPCS codes that are not on the CY 2015 bypass list that, using the proposed rule data (CY 2014 claims), met the empirical criteria for the bypass list that are summarized below. Finally, to remain consistent with the CY 2016 proposal to continue to develop OPPS relative payment weights based on geometric mean costs, we also proposed to establish that the packaged cost criterion would continue to be based on the geometric mean cost. The entire list proposed for CY 2016 (including the codes that remain on the bypass list from prior years) was open to public comment in the CY 2016 OPPS/ASC

proposed rule. Because we must make some assumptions about packaging in the multiple procedure claims in order to assess a HCPCS code for addition to the bypass list, we assumed that the representation of packaging on ''natural'' single procedure claims for any given code is comparable to packaging for that code in the multiple procedure claims. The proposed criteria for the bypass list were:

- There are 100 or more ''natural'' single procedure claims for the code. This number of single procedure claims ensures that observed outcomes are sufficiently representative of packaging that might occur in the multiple claims.
- Five percent or fewer of the ''natural'' single procedure claims for the code have packaged costs on that single procedure claim for the code. This criterion results in limiting the amount of packaging being redistributed to the separately payable procedures remaining on the claim after the bypass code is removed and ensures that the costs associated with the bypass code represent the cost of the bypassed service.
- The geometric mean cost of packaging observed in the ''natural'' single procedure claims is equal to or less than $55. This criterion also limits the amount of error in redistributed costs. During the assessment of claims against the bypass criteria, we do not know the dollar value of the packaged cost that should be appropriately attributed to the other procedures on the claim. Therefore, ensuring that redistributed costs associated with a bypass code are small in amount and volume protects the validity of cost estimates for low cost services billed with the bypassed service.

We note that, as we did for CY 2015, we proposed to continue to establish the CY 2016 OPPS relative payment weights based on geometric mean costs. To remain consistent in the metric used for identifying cost patterns, we proposed to use the geometric mean cost of packaging to identify potential codes to add to the bypass list.

In response to public comments on the CY 2010 OPPS/ASC proposed rule requesting that the packaged cost threshold be updated, we considered whether it would be appropriate to update the $50 packaged cost threshold for inflation when examining potential bypass list additions. As discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60328), the real value of this packaged cost threshold criterion has declined due to inflation, making the packaged cost threshold more restrictive over time when considering additions to the bypass list. Therefore, adjusting the threshold by the market basket increase would prevent continuing decline in the threshold's real value. Based on the same rationale described for the CY 2015 OPPS/ASC final rule with comment period (79 FR 66781), we proposed for CY 2016 to continue to update the packaged cost threshold by the market basket increase. By applying the final CY 2015 market basket increase of 2.2 percent (79 FR 66825) to the prior nonrounded dollar threshold of $55.66 (79 FR 66781), we determined that the proposed threshold would remain for CY 2016 at $55 ($56.88 rounded to $55, the nearest $5 increment). Therefore, we proposed to set the geometric mean packaged cost threshold based on the CY 2014 claims data at $55 for a code to be considered for addition to the CY 2016 OPPS bypass list.

For inclusion on the bypass list, a code cannot be a code for an unlisted service. Unlisted codes do not describe a specific service and, therefore, their costs would not be appropriate for bypass list purposes.

In addition, we proposed to continue to include on the bypass list HCPCS codes that we believe have minimal associated packaging, based on our clinical assessment of the complete CY 2016 OPPS proposal. Some of these codes were identified by CMS, and some were identified in prior years by commenters with specialized knowledge of the packaging associated with specific services. We also proposed to continue to include certain HCPCS codes on the bypass list in order to purposefully direct the assignment of packaged costs to a companion code where services always appear together and where there would otherwise be few single procedure claims available for ratesetting. For example, we have previously discussed our reasoning for adding HCPCS code G0390 (Trauma response team associated with hospital critical care service) to the bypass list (73 FR 68513).

As a result of the multiple imaging composite APCs that we established in CY 2009, the program logic for creating ''pseudo'' single procedure claims from bypassed codes that are also members of multiple imaging composite APCs changed. When creating the set of ''pseudo'' single procedure claims, claims that contain ''overlap bypass codes'' (those HCPCS codes that are both on the bypass list and are members of the multiple imaging composite APCs) were identified first. These HCPCS codes were then processed to create multiple imaging composite ''single session'' claims, that is, claims containing HCPCS codes from only one imaging family, thus suppressing the initial use of these codes as bypass codes. However, these ''overlap bypass codes'' were retained on the bypass list because, at the end of the ''pseudo'' single processing logic, we reassessed the claims without suppression of the ''overlap bypass codes'' under our longstanding ''pseudo'' single process to determine whether we could convert additional claims to ''pseudo'' single procedure claims. (We refer readers to section II.A.2.b. of the proposed rule and this final rule with comment period for further discussion of the treatment of ''overlap bypass codes.'') This process also created multiple imaging composite ''single session'' claims that could be used for calculating composite APC costs. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs were identified by asterisks (*) in Addendum N to the proposed rule (which is available via the Internet on the CMS Web site).

Addendum N to the proposed rule included the proposed list of bypass codes for CY 2016. The proposed list of bypass codes contains codes that were reported on claims for services in CY 2014 and, therefore, includes codes that were in effect in CY 2014 and used for billing but were deleted for CY 2015. We retained these deleted bypass codes on the proposed CY 2016 bypass list because these codes existed in CY 2014 and were covered OPD services in that period, and CY 2014 claims data are used to calculate CY 2016 payment rates. Keeping these deleted bypass codes on the bypass list potentially allowed us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that were members of the proposed multiple imaging composite APCs were identified by asterisks (*) in the third column of Addendum N to the proposed rule. HCPCS codes that we proposed to add for CY 2016 were identified by asterisks (*) in the fourth column of Addendum N.

We did not receive any public comments on our proposals for use of single and multiple procedure code claims for ratesetting. Therefore, we are adopting as final the proposed ''pseudo'' single claims process and the final CY 2016 bypass list of 197 HCPCS codes, as displayed in Addendum N to this final rule with comment period (which is available via the Internet on the CMS Web site). Table 1 below contains the list of codes that we are removing from the CY 2016 bypass list.

TABLE 1—HCPCS CODES REMOVED FROM THE CY 2016 BYPASS LIST

HCPCS code	HCPCS short descriptor
11057	Trim skin lesions over 4.
57454	Bx/curett of cervix w/ scope.
88348	Electron microscopy.
92240	Icg angiography.
92546	Sinusoidal rotational test.

c. Calculation and Use of Cost-to-Charge Ratios (CCRs)

In the CY 2016 OPPS/ASC proposed rule (80 FR 39213), we proposed to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2016 APC payment rates were based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2014 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, were from CY 2013. For the CY 2016 OPPS proposed rates, we used the set of claims processed during CY 2014. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. That crosswalk is available for review and continuous comment on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2014 (the year of claims data we used to calculate the proposed CY 2016 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2014 Data Specifications Manual.

In accordance with our longstanding policy, we calculated CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculated CCRs was the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.d.(1) of the proposed rule and this final rule with comment period.

For the CCR calculation process, we used the same general approach that we used in developing the final APC rates for CY 2007 and thereafter, using the revised CCR calculation that excluded the costs of paramedical education programs and weighted the outpatient charges by the volume of outpatient services furnished by the hospital. We refer readers to the CY 2007 OPPS/ASC final rule with comment period for more information (71 FR 67983 through 67985). We first limited the population of cost reports to only those hospitals that filed outpatient claims in CY 2014 before determining whether the CCRs for such hospitals were valid.

We then calculated the CCRs for each cost center and the overall ancillary CCR for each hospital for which we had claims data. We did this using hospital-specific data from the Hospital Cost Report Information System (HCRIS). We used the most recent available cost report data, which, in most cases, were from cost reports with cost reporting periods beginning in CY 2013. For the proposed rule, we used the most recently submitted cost reports to calculate the CCRs to be used to calculate costs for the proposed CY 2016 OPPS payment rates. If the most recently available cost report was submitted but not settled, we looked at the last settled cost report to determine the ratio of submitted to settled cost using the overall ancillary CCR, and we then adjusted the most recent available submitted, but not settled, cost report using that ratio. We then calculated both an overall ancillary CCR and cost center-specific CCRs for each hospital. We used the overall ancillary CCR referenced above for all purposes that require use of an overall ancillary CCR. We proposed to continue this longstanding methodology for the calculation of costs for CY 2016.

Since the implementation of the OPPS, some commenters have raised concerns about potential bias in the OPPS cost-based weights due to ''charge compression,'' which is the practice of applying a lower charge markup to higher cost services and a higher charge markup to lower cost services. As a result, the cost-based weights may reflect some aggregation bias, undervaluing high-cost items and overvaluing low-cost items when an estimate of average markup, embodied in a single CCR, is applied to items of widely varying costs in the same cost center. This issue was evaluated in a report by the Research Triangle Institute, International (RTI). The RTI final report can be found on RTI's Web site at: *http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_ratios_200807_Final.pdf*. For a complete discussion of the RTI recommendations, public comments, and our responses, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527).

We addressed the RTI finding that there was aggregation bias in both the IPPS and the OPPS cost estimation of expensive and inexpensive medical supplies in the FY 2009 IPPS final rule (73 FR 48458 through 45467). Specifically, we created one cost center for ''Medical Supplies Charged to Patients'' and one cost center for ''Implantable Devices Charged to Patients,'' essentially splitting the then current cost center for ''Medical Supplies Charged to Patients'' into one cost center for low-cost medical supplies and another cost center for high-cost implantable devices in order to mitigate some of the effects of charge compression. In determining the items that should be reported in these respective cost centers, we adopted commenters' recommendations that hospitals should use revenue codes established by the AHA's NUBC to determine the items that should be reported in the ''Medical Supplies Charged to Patients'' and the ''Implantable Devices Charged to Patients'' cost centers. For a complete discussion of the rationale for the creation of the new cost center for ''Implantable Devices Charged to Patients,'' a summary of public comments received, and our responses to those public comments, we refer readers to the FY 2009 IPPS final rule.

The cost center for ''Implantable Devices Charged to Patients'' has been available for use for cost reporting periods beginning on or after May 1, 2009. In the CY 2013 OPPS/ASC final rule with comment period, we determined that a significant volume of hospitals were utilizing the ''Implantable Devices Charged to Patients'' cost center. Because a sufficient amount of data from which to generate a meaningful analysis was available, we established in the CY 2013 OPPS/ASC final rule with comment period a policy to create a distinct CCR using the ''Implantable Devices Charged to Patients'' cost center (77 FR 68225). We retained this policy through CY

2015, and we proposed to continue this practice for the CY 2016 OPPS.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create new standard cost centers for ''Computed Tomography (CT),'' ''Magnetic Resonance Imaging (MRI),'' and ''Cardiac Catheterization,'' and to require that hospitals report the costs and charges for these services under these new cost centers on the revised Medicare cost report Form CMS 2552–10. As we discussed in the FY 2009 IPPS and CY 2009 OPPS/ASC proposed and final rules, RTI also found that the costs and charges of CT scans, MRIs, and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI concluded that both the IPPS and the OPPS relative payment weights would better estimate the costs of those services if CMS were to add standard costs centers for CT scans, MRIs, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the cost from charges on claims data. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a more detailed discussion on the reasons for the creation of standard cost centers for CT scans, MRIs, and cardiac catheterization. The new standard cost centers for CT scans, MRIs, and cardiac catheterization were effective for cost report periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10.

Using the June 2015 HCRIS update to estimate costs in the final CY 2016 OPPS ratesetting process, of the 3,830 impact providers, we were able to calculate a valid implantable device CCR for 2,969 hospitals (78 percent), a valid MRI CCR for 2,080 hospitals (54 percent), a valid CT scan CCR for 2,166 hospitals (57 percent), and a valid Cardiac Catheterization CCR for 1,434 hospitals (37 percent).

In our CY 2014 OPPS/ASC proposed rule discussion (78 FR 43549), we noted that, for CY 2014, the estimated changes in geometric mean estimated APC cost of using data from the new standard cost centers for CT scans and MRIs appeared consistent with RTI's analysis of cost report and claims data in the July 2008 final report (pages 5 and 6). RTI concluded that ''in hospitals that aggregate data for CT scanning, MRI, or nuclear medicine services with the standard line for Diagnostic Radiology, costs for these services all appear substantially overstated, while the costs for plain films, ultrasound and other imaging procedures are correspondingly understated.'' We also noted that there were limited additional impacts in the implantable device-related APCs from adopting the new cost report Form CMS 2552–10 because we had used data from the standard cost center for implantable medical devices beginning in CY 2013 OPPS ratesetting, as discussed above.

As we indicated in prior rulemaking (77 FR 68223 through 68225), once we determined that cost report data for the new standard cost centers were sufficiently available, we would analyze that data and, if appropriate, we would propose to use the distinct CCRs for new standard cost centers described above in the calculation of the OPPS relative payment weights. As stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74847), we conducted our analysis and concluded that we should develop distinct CCRs for each of the new cost centers and use them in ratesetting. Therefore, we began in the CY 2014 OPPS, continued in the CY 2015 OPPS, and we proposed to retain this practice for the CY 2016 OPPS, to calculate the OPPS relative payment weights using distinct CCRs for cardiac catheterization, CT scan, MRI, and implantable medical devices. Section XIX. of the proposed rule and section XXI. of this final rule with comment period include the impacts of calculating the CY 2016 OPPS relative payment weights using these standard cost centers that were adopted in CY 2014.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74847), we finalized a policy to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs associated with the CT and MRI APCs. This change allows hospitals additional time to use one of the more accurate cost allocation methods, and thereby improve the accuracy of the CCRs on which the OPPS relative payment weights are developed. In Table 2 below, we display CCR values for providers based on various cost allocation methods.

TABLE 2—CCR STATISCAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost allocation method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0436	0.0582	0.0874	0.1111
Square Feet Only	0.0361	0.0507	0.0780	0.1026
Direct Assign	0.0638	0.0716	0.1076	0.1273
Dollar Value	0.0508	0.0667	0.0972	0.1204
Direct Assign and Dollar Value	0.0508	0.0668	0.0976	0.1203

As part of this transitional policy to estimate the CT and MRI APC relative payment weights using only cost data from providers that do not use ''square feet'' as the cost allocation statistic, we adopted a policy in the CY 2014 OPPS/ASC final rule with comment period that we will sunset this policy in 4 years once the updated cost report data become available for ratesetting purposes. We stated that we believe 4 years is sufficient time for hospitals that have not done so to transition to a more accurate cost allocation method and for the related data to be available for ratesetting purposes. Therefore, in CY 2018, we will estimate the CT and MRI APC relative payment weights using cost data from all providers, regardless of the cost allocation statistic employed. In Table 3 below, we display the impact of excluding claims based on the ''square feet'' cost allocation method from estimates of CT and MRI costs in CY 2016.

TABLE 3—PERCENT CHANGE IN ESTIMATED COST FOR CT AND MRI APCS WHEN EXCLUDING CLAIMS FROM PROVIDERS USING ''SQUARE FEET'' AS THE COST ALLOCATION METHOD

CY 2016 APC	CY 2016 APC descriptor	Percent change
5570*	Computed Tomography without Contrast	15.4
5571*	Level 1 Computed Tomography with Contrast and Computed Tomography Angiography	10.2
5572*	Level 2 Computed Tomography with Contrast and Computed Tomography Angiography	10.5
5581*	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	8.1
5582*	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	6.2
8005	CT & CTA without Contrast Composite	13.7
8006	CT & CTA with Contrast Composite	9.8
8007	MRI & MRA without Contrast Composite	6.9
8008	MRI & MRA with Contrast Composite	6.8

* Renumbered APC for CY 2016.

In summary, we proposed to continue to use data from the ''Implantable Devices Charged to Patients'' and ''Cardiac Catheterization'' cost centers to create distinct CCRs for use in calculating the OPPS relative payment weights for the CY 2016 OPPS. For the ''Magnetic Resonance Imaging (MRI)'' and ''Computed Tomography (CT) Scan'' APCs identified in Table 3 of the proposed rule, we proposed to continue our policy of removing claims from cost modeling for those providers using ''square feet'' as the cost allocation statistic for CY 2016.

Comment: Several commenters supported CMS' proposal to continue removing claims submitted by providers that use the ''square feet'' cost allocation methodology from cost modeling for the CT and MRI APCs. A few commenters suggested that CMS continue its policy of removing claims from providers that use this method for the CY 2018 OPPS update and subsequent calendar years.

Response: We appreciate the commenters' support. As described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74847), the current policy of calculating CT and MRI APC relative payment weights using only data from providers that do not use the ''square feet'' cost allocation method was part of a transitional policy to allow providers to adopt cost allocation methods that improve data and payment accuracy. In the CY 2014 OPPS/ASC final rule with comment period, we noted that we would sunset that policy in 4 years and estimate the CY 2018 CT and MRI APC relative payment weights using cost data from all providers, regardless of which cost allocation method the provider employed. While some commenters believe that we should continue this transition policy of excluding ''square feet'' data from OPPS ratesetting for the CY 2018 OPPS update and subsequent calendar years, we believe that we have given providers sufficient time to adopt one of the more precise cost allocation methodologies.

After consideration of the public comments we received, we are finalizing our proposal to continue to use data from the ''Implantable Devices Charged to Patients'' and ''Cardiac Catheterization'' cost centers to create distinct CCRs for use in calculating the OPPS relative payment weights for the CY 2016 OPPS. For the ''Magnetic Resonance Imaging (MRI)'' and ''Computed Tomography (CT) Scan'' APCs identified in Table 3 above, we are continuing our policy of removing claims from providers that use the ''square feet'' cost allocation methodology for CY 2016 CT and MRI APC cost modeling.

2. Data Development Process and Calculation of Costs Used for Ratesetting

In this section of this final rule with comment period, we discuss the use of claims to calculate the OPPS payment rates for CY 2016. The Hospital OPPS page on the CMS Web site on which this final rule with comment period is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available for purchase under a CMS data use agreement. The CMS Web site, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, includes information about purchasing the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–9–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2014 claims that were used to calculate the proposed and final payment rates for the CY 2016 OPPS.

In the history of the OPPS, we have traditionally established the scaled relative weights on which payments are based using APC median costs, which is a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. For CY 2016, we proposed to continue to use geometric mean costs to calculate the relative weights on which the CY 2016 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.f. of this final rule with comment period to calculate the costs we used to establish the relative payment weights used in calculating the OPPS payment rates for CY 2016 shown in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of the proposed rule and this final rule with comment period for a discussion of the conversion of APC costs to scaled payment weights.

Comment: A few commenters suggested that CMS increase the transparency of its cost estimation process and provide additional detail on how various types of HCPCS code are treated within CMS' claims processing.

Response: We thank the commenters for these suggestions. We have updated the claims accounting narrative for this

final rule with comment period to include additional information on the requested various types of HCPCS code where feasible. This updated claims accounting narrative is available on the 2016 OPPS Final Rule page of the CMS Web site (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html).*

Comment: One commenter suggested that CMS present proposals for significant payment changes, such as expanded packaging, APC configurations, or new comprehensive APCs, at least 1 year before issuance of a proposed rule. The commenter believed that this would increase the transparency of policy changes and facilitate stakeholder review and analysis of the proposed changes.

Response: We thank the commenter for this suggestion. We believe that, for each proposed policy change, we assess the appropriate timeframe for implementation and will continue to do so in the future. We understand that modeling the OPPS is time-consuming and technically complex, and we strive to aid these efforts by providing numerous data files, public use files, and narrative descriptions of the claims accounting process for each rule.

a. Claims Preparation

For the proposed rule, we used the CY 2014 hospital outpatient claims processed through December 31, 2014, to calculate the geometric mean costs of APCs that underpin the proposed relative payment weights for CY 2016. For this final rule with comment period, we used the CY 2014 hospital outpatient claims processed through June 30, 2015, to calculate the geometric mean costs of APCs that underpin the final relative payment weights for CY 2016. To begin the calculation of the relative payment weights for CY 2016, we selected all claims for outpatient services furnished in CY 2014 from the national claims history file. This is not the population of claims paid under the OPPS, but all outpatient claims (including, for example, critical access hospital (CAH) claims and hospital claims for clinical laboratory tests for persons who are neither inpatients nor outpatients of the hospital).

We then excluded claims with condition codes 04, 20, 21, and 77 because these claims are submitted by providers to Medicare with the knowledge that no payment would be made. For example, providers submit claims with a condition code 21 to elicit an official denial notice from Medicare to document that a service is not covered under the OPPS. We then excluded claims for services furnished in Maryland, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands because hospitals in those geographic areas are not paid under the OPPS, and, therefore, we do not use claims for services furnished in these areas in ratesetting.

We divided the remaining claims into the three groups shown below. Groups 2 and 3 comprise the 125 million claims that contain hospital bill types paid under the OPPS.

1. Claims that were not bill types 12X (Hospital Inpatient (Medicare Part B only)), 13X (Hospital Outpatient), 14X (Hospital—Laboratory Services Provided to Nonpatients), or 76X (Clinic—Community Mental Health Center). Other bill types are not paid under the OPPS; therefore, these claims were not used to set OPPS payment rates.

2. Claims that were bill types 12X, 13X or 14X. Claims with bill types 12X and 13X are hospital outpatient claims. Claims with bill type 14X are laboratory specimen claims.

3. Claims that were bill type 76X (CMHC).

To convert charges on the claims to estimated cost, we multiplied the charges on each claim by the appropriate hospital-specific CCR associated with the revenue code for the charge as discussed in section II.A.1.c. of this final rule with comment period. We then flagged and excluded CAH claims (which are not paid under the OPPS) and claims from hospitals with invalid CCRs. The latter included claims from hospitals without a CCR; those from hospitals paid an all-inclusive rate; those from hospitals with obviously erroneous CCRs (greater than 90 or less than 0.0001); and those from hospitals with overall ancillary CCRs that were identified as outliers (that exceeded ±3 standard deviations from the geometric mean after removing error CCRs). In addition, we trimmed the CCRs at the cost center (that is, departmental) level by removing the CCRs for each cost center as outliers if they exceeded ±3 standard deviations from the geometric mean. We used a four-tiered hierarchy of cost center CCRs, which is the revenue code-to-cost center crosswalk, to match a cost center to every possible revenue code appearing in the outpatient claims that is relevant to OPPS services, with the top tier being the most common cost center and the last tier being the default CCR. If a hospital's cost center CCR was deleted by trimming, we set the CCR for that cost center to ''missing'' so that another cost center CCR in the revenue center hierarchy could apply. If no other cost center CCR could apply to the revenue code on the claim, we used the hospital's overall ancillary CCR for the revenue code in question as the default CCR. For example, if a visit was reported under the clinic revenue code but the hospital did not have a clinic cost center, we mapped the hospital-specific overall ancillary CCR to the clinic revenue code. The revenue code-to-cost center crosswalk is available for inspection on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* Revenue codes that we do not use in establishing relative costs or to model impacts are identified with an ''N'' in the revenue code-to-cost center crosswalk.

We applied the CCRs as described above to claims with bill type 12X, 13X, or 14X, excluding all claims from CAHs and hospitals in Maryland, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands and excluding all claims from hospitals for which CCRs were flagged as invalid.

We identified claims with condition code 41 as partial hospitalization services of hospitals and moved them to another file. We note that the separate file containing partial hospitalization claims is included in the files that are available for purchase as discussed above.

We then excluded claims without a HCPCS code. We moved to another file claims that contained only influenza and pneumococcal pneumonia (PPV) vaccines. Influenza and PPV vaccines are paid at reasonable cost; therefore, these claims are not used to set OPPS rates.

We next copied line-item costs for drugs, blood, and brachytherapy sources to a separate file (the lines stay on the claim, but are copied onto another file). No claims were deleted when we copied these lines onto another file. These line-items are used to calculate a per unit arithmetic and geometric mean and median cost and a per day arithmetic and geometric mean and median cost for drugs and nonimplantable biologicals, therapeutic radiopharmaceutical agents, and brachytherapy sources, as well as other information used to set payment rates, such as a unit-to-day ratio for drugs.

Prior to CY 2013, our payment policy for nonpass-through separately paid drugs and biologicals was based on a redistribution methodology that accounted for pharmacy overhead by allocating cost from packaged drugs to separately paid drugs. This methodology typically would have required us to reduce the cost associated

with packaged coded and uncoded drugs in order to allocate that cost. However, for CY 2013, we paid for separately payable drugs and biologicals under the OPPS at ASP+6 percent, based upon the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. Under that policy, we did not redistribute the pharmacy overhead costs from packaged drugs to separately paid drugs. We retained the CY 2013 payment policy for separately payable drugs and biologicals through CY 2015, and as we proposed, we are continuing this payment policy for CY 2016. We refer readers to section V.B.3. of this final rule with comment period for a complete discussion of our CY 2016 payment policy for separately paid drugs and biologicals.

We then removed line-items that were not paid during claims processing, presumably for a line-item rejection or denial. The number of edits for valid OPPS payment in the Integrated Outpatient Code Editor (I/OCE) and elsewhere has grown significantly in the past few years, especially with the implementation of the full spectrum of National Correct Coding Initiative (NCCI) edits. To ensure that we are using valid claims that represent the cost of payable services to set payment rates, we removed line-items with an OPPS status indicator that were not paid during claims processing in the claim year, but have a status indicator of ''S,'' ''T,'' and ''V'' in the prospective year's payment system. This logic preserves charges for services that would not have been paid in the claim year but for which some estimate of cost is needed for the prospective year, such as services newly removed from the inpatient list for CY 2015 that were assigned status indicator ''C'' in the claim year. It also preserves charges for packaged services so that the costs can be included in the cost of the services with which they are reported, even if the CPT codes for the packaged services were not paid because the service is part of another service that was reported on the same claim or the code otherwise violates claims processing edits.

For CY 2016, we proposed to continue the policy we implemented for CY 2013 and retained in subsequent years to exclude line-item data for pass-through drugs and biologicals (status indicator ''G'' for CY 2013) and nonpass-through drugs and biologicals (status indicator ''K'' for CY 2013) where the charges reported on the claim for the line were either denied or rejected during claims processing. Removing lines that were eligible for payment but were not paid ensures that we are using appropriate data. The trim avoids using cost data on lines that we believe were defective or invalid because those rejected or denied lines did not meet the Medicare requirements for payment. For example, edits may reject a line for a separately paid drug because the number of units billed exceeded the number of units that would be reasonable and, therefore, is likely a billing error (for example, a line reporting 55 units of a drug for which 5 units is known to be a fatal dose). As with our trimming in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66788) of line-items with a status indicator of ''S,'' ''T,'' or ''V,'' we believe that unpaid line-items represent services that are invalidly reported and, therefore, should not be used for ratesetting (we note that the deletion of status indicator ''X'' was finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66821)). We believe that removing lines with valid status indicators that were edited and not paid during claims processing increases the accuracy of the data used for ratesetting purposes.

For the CY 2016 OPPS, as part of our proposal and adoption of our proposal to continue packaging payment for clinical diagnostic laboratory tests, as we proposed, we also are applying the line item trim to these services if they did not receive payment in the claims year. Removing these lines ensures that, in establishing the CY 2016 OPPS relative payment weights, we appropriately allocate the costs associated with packaging these services. Additional details and a summary of public comments received and our responses regarding packaging payment for clinical laboratory tests can be found in section II.A.3.b.(3) of this final rule with comment period.

b. Splitting Claims and Creation of ''Pseudo'' Single Procedure Claims

(1) Splitting Claims

In the CY 2016 OPPS/ASC proposed rule (80 FR 39217), for the CY 2016 OPPS, we proposed to then split the remaining claims into five groups: Single majors; multiple majors; single minors; multiple minors; and other claims. (Specific definitions of these groups are presented below.) We note that, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66819 through 66821), we deleted status indicator ''X'' and revised the title and description of status indicator ''Q1'' to reflect that deletion. We also finalized the creation of status indicator ''J1'' in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66800 through 66809) to reflect the comprehensive APCs (C–APCs). For CY 2016, we proposed to define major procedures as any procedure described by a HCPCS code that is assigned a status indicator of ''J1,'' ''J2,'' ''S,'' ''T,'' or ''V,'' to define minor procedures as any procedure described by a HCPCS code that is assigned a status indicator of ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N,'' and to classify ''other'' procedures as any procedure described by a HCPCS code that is assigned a status indicator other than one that we have classified as major or minor. For CY 2016, we proposed to continue to assign status indicator ''R'' to HCPCS codes for blood and blood products; status indicator ''U'' to HCPCS codes for brachytherapy sources; status indicator ''Q1'' to all HCPCS ''STV-packaged codes''; status indicator ''Q2'' to all HCPCS ''T-packaged codes''; status indicator ''Q3'' to all HCPCS codes that may be paid through a composite APC based on composite-specific criteria or paid separately through single code APCs when the criteria are not met; and new status indicator ''Q4'' to HCPCS codes for laboratory tests that will be conditionally packaged on a claim with a service that is assigned status indicator ''S,'' ''T,'' or ''V'' unless an exception applies or the laboratory test is ''unrelated'' to the other HOPD service or services on the claim. For more information on status indicator ''Q4,'' we refer readers to section II.A.3.b.(3) of this final rule with comment period.

As discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68709), we established status indicators ''Q1,'' ''Q2,'' and ''Q3'' to facilitate identification of the different categories of codes. We proposed to treat these codes in the same manner for data purposes for CY 2016 as we have treated them since CY 2008. Specifically, for CY 2016, we are continuing to evaluate whether the criteria for separate payment of codes with a status indicator of ''Q1'' or ''Q2'' are met in determining whether they are treated as major or minor codes. Claims containing codes with a status indicator of ''Q1'' or ''Q2'' are processed through the data system either with status indicator ''N'' to indicate that the services are packaged for payment or, if they meet the criteria for separate payment, they are assigned the status indicator of the APC to which they are assigned and are considered as ''pseudo'' single procedure claims for major codes. Claims containing codes that are assigned status indicator ''Q3'' are paid under individual APCs unless they occur in the combinations that qualify for payment as composite APCs

and, therefore, they are assigned the status indicator of the individual APC to which they are assigned through the data process and are treated as major codes during both the split and ''pseudo'' single creation process. The calculation of the geometric mean costs for composite APCs from multiple procedure major claims is discussed in section II.A.2.f. of this final rule with comment period. HCPCS codes with status indicator ''Q4'' only appear in the OPPS model if they are packaged on a claim with a service that is assigned status indicator ''S,'' ''T,'' or ''V.''

Specifically, we proposed to divide the remaining claims into the following five groups:

1. *Single Procedure Major Claims:* Claims with a single separately payable procedure (that is, status indicator ''S,'' ''T,'' or ''V'' which includes codes with status indicator ''Q3''); claims with status indicator ''J1'' or ''J2,'' which receive special processing for C–APCs, as discussed in section II.A.2.e. of this final rule with comment period; claims with one unit of a status indicator ''Q1'' code (''STV-packaged'') where there was no code with status indicator ''S,'' ''T,'' or ''V'' on the same claim on the same date; or claims with one unit of a status indicator ''Q2'' code (''T-packaged'') where there was no code with a status indicator ''T'' on the same claim on the same date.

2. *Multiple Procedure Major Claims:* Claims with more than one separately payable procedure (that is, status indicator ''S,'' ''T,'' or ''V'' which includes codes with status indicator ''Q3''), or multiple units of one payable procedure. These claims include those codes with a status indicator ''Q2'' code (''T-packaged'') where there was no procedure with a status indicator ''T'' on the same claim on the same date of service but where there was another separately paid procedure on the same claim with the same date of service (that is, another code with status indicator ''S'' or ''V''). We also include in this set claims that contained one unit of one code when the bilateral modifier was appended to the code and the code was conditionally or independently bilateral. In these cases, the claims represented more than one unit of the service described by the code, notwithstanding that only one unit was billed.

3. *Single Procedure Minor Claims:* Claims with a single HCPCS code that was assigned status indicator ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N'' and not status indicator ''Q1'' (''STV-packaged'') or status indicator ''Q2'' (''T-packaged'') code.

4. *Multiple Procedure Minor Claims:* Claims with multiple HCPCS codes that are assigned status indicator ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N;'' claims that contain more than one code with status indicator ''Q1'' (''STV-packaged'') or more than one unit of a code with status indicator ''Q1'' but no codes with status indicator ''S,'' ''T,'' or ''V'' on the same date of service; or claims that contain more than one code with status indicator ''Q2'' (T-packaged), or ''Q2'' and ''Q1,'' or more than one unit of a code with status indicator ''Q2'' but no code with status indicator ''T'' on the same date of service.

5. *Non-OPPS Claims:* Claims that contain no services payable under the OPPS (that is, all status indicators other than those listed for major or minor status). These claims were excluded from the files used for the OPPS. Non-OPPS claims have codes paid under other fee schedules, for example, durable medical equipment, and do not contain a code for a separately payable or packaged OPPS service. Non-OPPS claims include claims for therapy services paid sometimes under the OPPS but billed, in these non-OPPS cases, with revenue codes indicating that the therapy services would be paid under the Medicare Physician Fee Schedule (MPFS).

The claims listed in numbers 1, 2, 3, and 4 above are included in the data file that can be purchased as described above. Claims that contain codes to which we have assigned status indicators ''Q1'' (''STV-packaged'') and ''Q2'' (''T-packaged'') appear in the data for the single major file, the multiple major file, and the multiple minor file used for ratesetting. Claims that contain codes to which we have assigned status indicator ''Q3'' (composite APC members) appear in both the data of the single and multiple major files used in this final rule with comment period, depending on the specific composite calculation.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39217), we proposed to adjust the claims sorting process to determine whether a claim has a bilateral procedure modifier (Modifier 50) before claims are assigned to one of the five claims categories. This proposed adjustment shifts some claims that might otherwise be considered a single major procedure claim to the multiple major procedure claim category due to the presence of the bilateral modifier. We stated that we believe that this proposed adjustment more accurately sorts claims that have a bilateral modifier.

We did not receive any public comments on the proposed process to categorize claims used in CY 2016 OPPS cost modeling. Therefore, we are finalizing our policy as proposed.

(2) Creation of ''Pseudo'' Single Procedure Claims

To develop ''pseudo'' single procedure claims for the proposed rule, we examined both the multiple procedure major claims and the multiple procedure minor claims. We first examined the multiple major procedure claims for dates of service to determine if we could break them into ''pseudo'' single procedure claims using the dates of service for all lines on the claim. If we could create claims with single major procedures by using dates of service, we created a single procedure claim record for each separately payable procedure on a different date of service (that is, a ''pseudo'' single procedure claim).

We also proposed to use the bypass codes listed in Addendum N to the proposed rule (which is available via the Internet on the CMS Web site) and discussed in section II.A.1.b. of the proposed rule and this final rule with comment period to remove separately payable procedures which we determined contained limited or no packaged costs or that were otherwise suitable for inclusion on the bypass list from a multiple procedure bill. As discussed above, we ignored the ''overlap bypass codes,'' that is, those HCPCS codes that were both on the bypass list and are members of the multiple imaging composite APCs, in this initial assessment for ''pseudo'' single procedure claims. The proposed CY 2016 ''overlap bypass codes'' were listed in Addendum N to the proposed rule (which is available via the Internet on the CMS Web site). When one of the two separately payable procedures on a multiple procedure claim was on the bypass list, we split the claim into two ''pseudo'' single procedure claim records. The single procedure claim record that contained the bypass code did not retain packaged services. The single procedure claim record that contained the other separately payable procedure (but no bypass code) retained the packaged revenue code charges and the packaged HCPCS code charges. We also removed lines that contained multiple units of codes on the bypass list and treated them as ''pseudo'' single procedure claims by dividing the cost for the multiple units by the number of units on the line. If one unit of a single, separately payable procedure code remained on the claim after removal of the multiple units of the bypass code, we created a ''pseudo'' single procedure claim from that residual claim record,

which retained the costs of packaged revenue codes and packaged HCPCS codes. This enabled us to use claims that would otherwise be multiple procedure claims and could not be used.

We then assessed the claims to determine if the criteria for the multiple imaging composite APCs, discussed in section II.A.2.f.(3) of the proposed rule and this final rule with comment period, were met. If the criteria for the imaging composite APCs were met, we created a ''single session'' claim for the applicable imaging composite service and determined whether we could use the claim in ratesetting. For HCPCS codes that are both conditionally packaged and are members of a multiple imaging composite APC, we first assessed whether the code would be packaged and, if so, the code ceased to be available for further assessment as part of the composite APC. Because the packaged code will not be a separately payable procedure, we considered it to be unavailable for use in setting the composite APC costs on which the CY 2016 OPPS relative payment weights are based. Having identified ''single session'' claims for the imaging composite APCs, we reassessed the claim to determine if, after removal of all lines for bypass codes, including the ''overlap bypass codes,'' a single unit of a single separately payable code remained on the claim. If so, we attributed the packaged costs on the claim to the single unit of the single remaining separately payable code other than the bypass code to create a ''pseudo'' single procedure claim. We also identified line-items of overlap bypass codes as a ''pseudo'' single procedure claim. This allowed us to use more claims data for ratesetting purposes.

We also examined the multiple procedure minor claims to determine whether we could create ''pseudo'' single procedure claims. Specifically, where the claim contained multiple codes with status indicator ''Q1'' (''STV-packaged'') on the same date of service or contained multiple units of a single code with status indicator ''Q1,'' we selected the status indicator ''Q1'' HCPCS code that had the highest CY 2015 relative payment weight, and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q1.'' We then packaged all costs for the following into a single cost for the ''Q1'' HCPCS code that had the highest CY 2015 relative payment weight to create a ''pseudo'' single procedure claim for that code: additional units of the status indicator ''Q1'' HCPCS code with the highest CY 2015 relative payment weight; other codes with status indicator ''Q1''; and all other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from the data status indicator of ''N'' to the status indicator of the APC to which the selected procedure was assigned for further data processing and considered this claim as a major procedure claim. We used this claim in the calculation of the APC geometric mean cost for the status indicator ''Q1'' HCPCS code.

Similarly, we proposed that if a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') or multiple units of a single code with status indicator ''Q2,'' we selected the status indicator ''Q2'' HCPCS code that had the highest CY 2015 relative payment weight and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the ''Q2'' HCPCS code that had the highest CY 2015 relative payment weight to create a ''pseudo'' single procedure claim for that code: Additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2015 relative payment weight; other codes with status indicator ''Q2''; and other packaged HCPCS codes and packaged revenue code costs. We changed the status indicator for the selected code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned, and we considered this claim as a major procedure claim.

If a multiple procedure minor claim contained multiple codes with status indicator ''Q2'' (''T-packaged'') and status indicator ''Q1'' (''STV-packaged''), we selected the T-packaged status indicator ''Q2'' HCPCS code that had the highest relative payment weight for CY 2015 and set the units to one on that HCPCS code to reflect our policy of paying only one unit of a code with a status indicator of ''Q2.'' We then packaged all costs for the following into a single cost for the selected (''T-packaged'') HCPCS code to create a ''pseudo'' single procedure claim for that code: Additional units of the status indicator ''Q2'' HCPCS code with the highest CY 2015 relative payment weight; other codes with status indicator ''Q2''; codes with status indicator ''Q1'' (''STV-packaged''); and other packaged HCPCS codes and packaged revenue code costs. We selected status indicator ''Q2'' HCPCS codes instead of ''Q1'' HCPCS codes because ''Q2'' HCPCS codes have higher CY 2015 relative payment weights. If a status indicator ''Q1'' HCPCS code had a higher CY 2015 relative payment weight, it became the primary code for the simulated single bill process. We changed the status indicator for the selected status indicator ''Q2'' (''T-packaged'') code from a data status indicator of ''N'' to the status indicator of the APC to which the selected code was assigned and we considered this claim as a major procedure claim.

We then applied our revised process for creating ''pseudo'' single procedure claims to the conditionally packaged codes that do not meet the criteria for packaging, which enabled us to create single procedure claims from them, if they met the criteria for single procedure claims. Conditionally packaged codes are identified using status indicators ''Q1'' and ''Q2,'' and are described in section XI.A. of this final rule with comment period.

Lastly, we excluded those claims that we were not able to convert to single procedure claims even after applying all of the techniques for creation of ''pseudo'' single procedure claims to multiple procedure major claims and to multiple procedure minor claims. As has been our practice in recent years, we also excluded claims that contained codes that were viewed as independently or conditionally bilateral and that contained the bilateral procedure modifier (Modifier 50) because the line-item cost for the code represented the cost of two units of the procedure, notwithstanding that hospitals billed the code with a unit of one.

We did not receive any public comments on our proposed methodology for creating ''pseudo'' single procedure claims. Therefore, we are finalizing our proposal to continue to apply the methodology described above for the purpose of creating ''pseudo'' single procedure claims for the CY 2016 OPPS. The final CY 2016 bypass codes and ''overlap bypass codes'' are listed in Addendum N to this final rule with comment period (which is available via the Internet on the CMS Web site).

c. Completion of Claim Records and Geometric Mean Cost Calculations

(1) General Process

We proposed to then package the costs of packaged HCPCS codes (codes with status indicator ''N'' listed in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) and the costs of those lines for codes with status indicator ''Q1'' or ''Q2'' when they are not separately paid), and the costs of the

services reported under packaged revenue codes in Table 4 of the proposed rule (Table 4 below in this final rule with comment period) that appeared on the claim without a HCPCS code into the cost of the single major procedure remaining on the claim. For a more complete discussion of our CY 2016 OPPS packaging policy, we refer readers to section II.A.3. of this final rule with comment period.

As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66606), for the CY 2008 OPPS, we adopted an APC Panel recommendation that CMS should review the final list of packaged revenue codes for consistency with OPPS policy and ensure that future versions of the I/OCE edit accordingly. As we have in the past, we are continuing to compare the final list of packaged revenue codes that we adopt for CY 2016 to the revenue codes that the I/OCE will package for CY 2016 to ensure consistency.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68531), we replaced the NUBC standard abbreviations for the revenue codes listed in Table 2 of the CY 2009 OPPS/ASC proposed rule with the most current NUBC descriptions of the revenue code categories and subcategories to better articulate the meanings of the revenue codes without changing the list of revenue codes. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60362 through 60363), we finalized changes to the packaged revenue code list based on our examination of the updated NUBC codes and public comment on the CY 2010 proposed list of packaged revenue codes.

For CY 2016, as we did for CY 2015, we reviewed the changes to revenue codes that were effective during CY 2014 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we proposed to package for CY 2016. We stated in the proposed rule that we believe that the charges reported under the revenue codes listed in Table 4 of the proposed rule continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2016, we proposed to continue to package the costs that we derive from the charges reported without HCPCS codes under the revenue codes displayed in Table 4 of the proposed rule for purposes of calculating the geometric mean costs on which the CY 2016 OPPS/ASC payment rates are based.

Comment: One commenter suggested that CMS revisit its ratesetting methodology to prevent items or services that are more costly than a primary service from being packaged into the payment for the primary service. The commenter also suggested that only items or services that are clinically relevant to a primary service be packaged for payment with a primary service.

Response: We thank the commenter for these suggestions. Since the beginning of the OPPS and throughout its development, we have striven to find ways to improve our methodologies for estimating the costs associated with providing services, including our methodology for packaging services. We will continue to look at ways to improve our ratesetting process, including improving our packaging logic, in future payment years. We only assign packaged status indicators to services that we determine are ancillary, supportive, dependent, or adjunctive to a primary service. We disagree with the commenter that only payment for less costly services should be packaged into payment for a primary service, as the cost of a packaged service relative to a primary service is not necessarily determinative of packaged status.

For the reasons set forth in the proposed rule, we are finalizing the proposed packaged revenue codes for CY 2016, without modification, which are identified in Table 4 below.

TABLE 4—CY 2016 PACKAGED REVENUE CODES

Revenue code	Description
250	Pharmacy; General Classification.
251	Pharmacy; Generic Drugs.
252	Pharmacy; Non-Generic Drugs.
254	Pharmacy; Drugs Incident to Other Diagnostic Services.
255	Pharmacy; Drugs Incident to Radiology.
257	Pharmacy; Non-Prescription.
258	Pharmacy; IV Solutions.
259	Pharmacy; Other Pharmacy.
260	IV Therapy; General Classification.
261	IV Therapy; Infusion Pump.
262	IV Therapy; IV Therapy/Pharmacy Svcs.
263	IV Therapy; IV Therapy/Drug/Supply Delivery.
264	IV Therapy; IV Therapy/Supplies.
269	IV Therapy; Other IV Therapy.
270	Medical/Surgical Supplies and Devices; General Classification.
271	Medical/Surgical Supplies and Devices; Non-sterile Supply.
272	Medical/Surgical Supplies and Devices; Sterile Supply.
275	Medical/Surgical Supplies and Devices; Pacemaker.
276	Medical/Surgical Supplies and Devices; Intraocular Lens.
278	Medical/Surgical Supplies and Devices; Other Implants.
279	Medical/Surgical Supplies and Devices; Other Supplies/Devices.
280	Oncology; General Classification.
289	Oncology; Other Oncology.
331	Radiology—Therapeutic and/or Chemotherapy Administration; Chemotherapy Admin—Injected.
332	Radiology—Therapeutic and/or Chemotherapy Administration; Chemotherapy Admin—Oral.
335	Radiology—Therapeutic and/or Chemotherapy Administration; Chemotherapy Admin—IV.
343	Nuclear Medicine; Diagnostic Radiopharmaceuticals.
344	Nuclear Medicine; Therapeutic Radiopharmaceuticals.
360	Operating Room Services; General Classification.
361	Operating Room Services; Minor Surgery.
362	Operating Room Services; Organ Transplant—Other than Kidney.
369	Operating Room Services; Other OR Services.

TABLE 4—CY 2016 PACKAGED REVENUE CODES—Continued

Revenue code	Description
370	Anesthesia; General Classification.
371	Anesthesia; Anesthesia Incident to Radiology.
372	Anesthesia; Anesthesia Incident to Other DX Services.
379	Anesthesia; Other Anesthesia.
390	Administration, Processing and Storage for Blood and Blood Components; General Classification.
392	Administration, Processing and Storage for Blood and Blood Components; Processing and Storage.
399	Administration, Processing and Storage for Blood and Blood Components; Other Blood Handling.
410	Respiratory Services; General Classification.
412	Respiratory Services; Inhalation Services.
413	Respiratory Services; Hyperbaric Oxygen Therapy.
419	Respiratory Services; Other Respiratory Services.
621	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Radiology.
622	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Other DX Services.
623	Medical Supplies—Extension of 027X, Surgical Dressings.
624	Medical Surgical Supplies—Extension of 027X; FDA Investigational Devices.
630	Pharmacy—Extension of 025X; Reserved.
631	Pharmacy—Extension of 025X; Single Source Drug.
632	Pharmacy—Extension of 025X; Multiple Source Drug.
633	Pharmacy—Extension of 025X; Restrictive Prescription.
681	Trauma Response; Level I Trauma.
682	Trauma Response; Level II Trauma.
683	Trauma Response; Level III Trauma.
684	Trauma Response; Level IV Trauma.
689	Trauma Response; Other.
700	Cast Room; General Classification.
710	Recovery Room; General Classification.
720	Labor Room/Delivery; General Classification.
721	Labor Room/Delivery; Labor.
722	Labor Room/Delivery; Delivery Room.
724	Labor Room/Delivery; Birthing Center.
729	Labor Room/Delivery; Other Labor Room/Delivery.
732	EKG/ECG (Electrocardiogram); Telemetry.
760	Specialty Services; General Classification.
761	Specialty Services; Treatment Room.
762	Specialty services; Observation Hours.
769	Specialty Services; Other Specialty Services.
770	Preventive Care Services; General Classification.
801	Inpatient Renal Dialysis; Inpatient Hemodialysis.
802	Inpatient Renal Dialysis; Inpatient Peritoneal Dialysis (Non-CAPD).
803	Inpatient Renal Dialysis; Inpatient Continuous Ambulatory Peritoneal Dialysis (CAPD).
804	Inpatient Renal Dialysis; Inpatient Continuous Cycling Peritoneal Dialysis (CCPD).
809	Inpatient Renal Dialysis; Other Inpatient Dialysis.
810	Acquisition of Body Components; General Classification.
819	Acquisition of Body Components; Other Donor.
821	Hemodialysis—Outpatient or Home; Hemodialysis Composite or Other Rate.
824	Hemodialysis—Outpatient or Home; Maintenance—100%.
825	Hemodialysis—Outpatient or Home; Support Services.
829	Hemodialysis—Outpatient or Home; Other OP Hemodialysis.
942	Other Therapeutic Services (also see 095X, an extension of 094x); Education/Training.
943	Other Therapeutic Services (also see 095X, an extension of 094X), Cardiac Rehabilitation.
948	Other Therapeutic Services (also see 095X, an extension of 094X), Pulmonary Rehabilitation.

In accordance with our longstanding policy, we proposed to continue to exclude: (1) Claims that had zero costs after summing all costs on the claim; and (2) claims containing packaging flag number 3. Effective for services furnished after July 1, 2014, the I/OCE assigned packaging flag number 3 to claims on which hospitals submitted token charges less than $1.01 for a service with status indicator ''S'' or ''T'' (a major separately payable service under the OPPS) for which the Medicare Administrative Contractor (MAC) was required to allocate the sum of charges for services with a status indicator equaling ''S'' or ''T'' based on the relative payment weight of the APC to which each code was assigned. We do not believe that these charges, which were token charges as submitted by the hospital, are valid reflections of hospital resources. Therefore, we deleted these claims. We also deleted claims for which the charges equaled the revenue center payment (that is, the Medicare payment) on the assumption that, where the charge equaled the payment, to apply a CCR to the charge would not yield a valid estimate of relative provider cost. We are continuing these processes for the CY 2016 OPPS.

For the remaining claims, we then standardized 60 percent of the costs of the claim (which we have previously determined to be the labor-related portion) for geographic differences in labor input costs. We made this adjustment by determining the wage index that applied to the hospital that furnished the service and dividing the cost for the separately paid HCPCS code furnished by the hospital by that wage index. The claims accounting that we provide for the proposed rule and final rule with comment period contains the formula we use to standardize the total cost for the effects of the wage index. As

has been our policy since the inception of the OPPS, we used the pre-reclassified wage indices for standardization because we believe that they better reflect the true costs of items and services in the area in which the hospital is located than the post-reclassification wage indices and, therefore, would result in the most accurate unadjusted geometric mean costs. We used these pre-reclassified wage indices for standardization using the new OMB labor market area delineations described in section II.C. of this final rule with comment period.

In accordance with our longstanding practice, we also excluded single and ''pseudo'' single procedure claims for which the total cost on the claim was outside 3 standard deviations from the geometric mean of units for each HCPCS code on the bypass list (because, as discussed above, we used claims that contain multiple units of the bypass codes).

After removing claims for hospitals with error CCRs, claims without HCPCS codes, claims for immunizations not covered under the OPPS, and claims for services not paid under the OPPS, approximately 122 million claims remained. Using these approximately 122 million claims, we created approximately 95 million single and ''pseudo'' single procedure claims, of which we used approximately 92 million single claims (after trimming out approximately 3 million claims as discussed in section II.A.1.a. of this final rule with comment period) in the CY 2016 geometric mean cost development and ratesetting.

As discussed above, the OPPS has historically developed the relative weights on which APC payments are based using APC median costs. For the CYs 2013, 2014, and 2015 OPPS, we calculated the APC relative payment weights using geometric mean costs, and we are continuing this practice for CY 2016. Therefore, the following discussion of the 2 times rule violation and the development of the relative payment weight refers to geometric means. For more detail about the CY 2016 OPPS/ASC policy to calculate relative payment weights based on geometric means, we refer readers to section II.A.2.c. of this final rule with comment period.

We used these claims to calculate the CY 2016 geometric mean costs for each separately payable procedure described by the HCPCS code and each APC. The comparison of HCPCS code-specific and APC geometric mean costs determines the applicability of the 2 times rule. Section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group shall not be treated as comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the same group (the 2 times rule). While we have historically applied the 2 times rule based on median costs, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68270), as part of the CY 2013 policy to develop the OPPS relative payment weights based on geometric mean costs, we also applied the 2 times rule based on geometric mean costs. For the CY 2016 OPPS, as we proposed, we are continuing to develop the APC relative payment weights based on geometric mean costs.

We note that, for purposes of identifying significant HCPCS codes for examination in the 2 times rule, we consider codes that have more than 1,000 single major claims or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC geometric mean cost to be significant. This longstanding definition of when a HCPCS code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims is negligible within the set of approximately 92 million single procedure or single session claims we use for establishing geometric mean costs. Similarly, a HCPCS code for which there are fewer than 99 single claims and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC geometric mean. We note that this method of identifying significant HCPCS codes within an APC for purposes of the 2 times rule was used in prior years under the median-based cost methodology. Under our CY 2016 policy to continue to base the relative payment weights on geometric mean costs, we believe that this same consideration for identifying significant HCPCS codes should apply because the principles are consistent with their use in the median-based cost methodology. Unlisted codes are not used in establishing the percent of claims contributing to the APC, nor are their costs used in the calculation of the APC geometric mean. Finally, we reviewed the geometric mean costs for the services for which we will pay separately under this final rule with comment period, and we reassigned HCPCS codes to different APCs where it was necessary to ensure clinical and resource homogeneity within the APCs. The APC geometric means were recalculated after we reassigned the affected HCPCS codes. Both the HCPCS code-specific geometric means and the APC geometric means were weighted to account for the inclusion of multiple units of the bypass codes in the creation of ''pseudo'' single procedure claims.

As we discuss in sections II.A.2.d., II.A.2.f., and VIII.B. of this final rule with comment period, in some cases, APC geometric mean costs were calculated using variations of the process outlined above. Specifically, section II.A.2.d. of this final rule with comment period addresses the calculation of single APC criteria-based geometric mean costs. Section II.A.2.f. of this final rule with comment period discusses the calculation of composite APC criteria-based geometric mean costs. Section VIII.B. of this final rule with comment period addresses the methodology for calculating the geometric mean costs for partial hospitalization services.

We did not receive any public comments on our proposal for completion of claims records and calculation of geometric means cost. Therefore, we are adopting the geometric means calculation process that we proposed as final. We are finalizing our proposed methodology for calculating geometric means costs for purposes of creating relative payment weights and subsequent APC payment rates for the CY 2016 OPPS.

(2) Recommendations of the Advisory Panel on Hospital Outpatient Payment (the Panel) Regarding Data Development

At the August 24, 2015 meeting of the Panel, we discussed our standard analysis of APCs, specifically those APCs for which geometric mean costs in the proposed rule run of CY 2014 claims data varied significantly from the CY 2013 claims data used for the CY 2015 OPPS/ASC final rule with comment period. We also discussed the ''pseudo'' single development process for the CY 2015 OPPS/ASC final rule with comment period.

At the August 24, 2015 Panel meeting, the Panel made two recommendations related to the data process. The Panel's data-related recommendations and our responses follow.

Recommendation: The Panel recommends that the work of the Data Subcommittee continue.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that CMS provide the Panel with a list of APCs fluctuating

significantly in costs at the next Panel meeting.

CMS Response: We are accepting this recommendation.

Recommendation: The Panel recommends that Michael Schroyer serve as Chair of the Data Subcommittee.

CMS Response: We are accepting this recommendation.

d. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

(a) Methodology

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39222), for CY 2016, we proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, in order to address the differences in CCRs and to better reflect hospitals' costs, we proposed to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We also proposed to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We proposed to calculate the costs upon which the CY 2016 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We stated in the proposed rule that we continue to believe that the hospital-specific simulated blood-specific CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that this methodology in CY 2016 will result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We invited public comments on this proposal to continue this longstanding methodology.

Comment: Commenters supported the proposal to continue to separately pay for blood and blood products using a blood-specific CCR methodology.

Response: We appreciate the commenters' support.

Comment: Numerous commenters (various hospitals, blood centers, associations, and other stakeholders) expressed concern regarding the proposed CY 2016 payment rates for blood and blood products. The commenters believed that the proposed payment rates do not accurately reflect the cost of collecting, processing, and distributing blood products to patients. The commenters noted that the payment rates did not align with the costs statistics data provided with the proposed rule, and therefore the commenters believed that the CY 2016 proposed payment rates for blood and blood products were produced in error.

Response: We acknowledge that an error occurred in the calculation of the proposed CY 2016 payment rates for blood and blood products included in the proposed rule. The payment rates included in the proposed rule erroneously were not calculated using the hospital-specific simulated blood-specific CCR methodology described in the proposed rule (which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs). As a result of correcting this error, payment rates for blood and blood products increased approximately 10 percent to 60 percent from the proposed CY 2016 payment rates. We have corrected this error in this final rule with comment period and the final CY 2016 payment rates reflect this correction.

After consideration of the public comments we received, we are finalizing, without modification, our CY 2016 proposal to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology. The final CY 2016 payment rates for blood and blood products (which are identified with status indicator ''R'') are reflective of the use of the hospital-specific simulated blood-specific CCR methodology and can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

(b) New HCPCS Codes for Pathogen-Reduced Blood Products

For CY 2016, the HCPCS Workgroup established three new HCPCS P-codes for new pathogen-reduced blood products, effective January 1, 2016, as follows:

- P9070 (Plasma, pooled multiple donor, pathogen reduced, frozen, each unit);
- P9071 (Plasma (single donor), pathogen reduced, frozen, each unit); and
- P9072 (Platelets, pheresis, pathogen reduced, each unit).

The term ''pathogen reduction'' describes various techniques (including treatment with Amotosalen and UVA light) used on blood products to eliminate certain pathogens and reduce the risk of transfusion-associated infections. As discussed above, we calculate payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. Because these three HCPCS P-codes are new for CY 2016, there are currently no claims data on the charges and costs for these blood products upon which to apply our blood-specific CCR methodology. Therefore, we are establishing interim payment rates for these three HCPCS P-codes based on a crosswalk to existing blood product HCPCS codes that we believe provide the best proxy for the costs of the three new blood products described by the above listed new HCPCS P-codes. Table 5 below list the new pathogen-reduced blood products

HCPCS P-codes and their payment crosswalks.

TABLE 5—NEW PATHOGEN-REDUCED BLOOD PRODUCTS HCPCS P-CODES AND INTERIM PAYMENT RATES AND CROSSWALKS FOR CY 2016

New CY 2016 HCPCS P-code	New HCPCS P-code long descriptor	Crosswalked HCPCS P-code	Crosswalked HCPCS P-code long descriptor	Final CY 2016 OPPS payment amount
P9070	Plasma, pooled multiple donor, pathogen reduced, frozen, each unit.	P9059	Fresh frozen plasma between 8–24 hours of collection, each unit.	$73.08
P9071	Plasma (single donor), pathogen reduced, frozen, each unit.	P9017	Fresh frozen plasma (single donor), frozen within 8 hours of collection, each unit.	72.56
P9072	Platelets, pheresis, pathogen reduced, each unit.	P9037	Platelets, pheresis, leukocytes reduced, irradiated, each unit.	641.85

These interim payment rates are open for public comment in this CY 2016 final rule with comment period. Specifically, the new HCPCS P-codes are flagged with comment indicator ''NI'' in Addendum B to this final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2016 and are seeking public comments on the APC and status indicator assignments. Once we have claims data for these new HCPCS P-codes, we will calculate payment rates using the claims data that should be available for these new codes beginning in CY 2018, which is our practice for other blood products for which claims data have been available for 2 years.

During the process of creating these new HCPCS P-codes for the three pathogen-reduced blood products, we examined the current set of HCPCS P-codes, which became effective many years ago. We believe that the HCPCS P-codes for these products could benefit from a careful examination and review with possible revision and updating to make the HCPCS P-codes describing blood products reflect current product descriptions and utilization while minimizing redundancy and potentially outdated descriptors. Therefore, we intend in future rulemaking to evaluate the set of HCPCS P-codes and propose revisions that may be necessary to create a current and robust code set for blood products.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66796 through 66798) for further discussion of the history of OPPS payment for brachytherapy sources.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39222), for CY 2016, we proposed to use the costs derived from CY 2014 claims data to set the proposed CY 2016 payment rates for brachytherapy sources, as we proposed to use to set the proposed payment rates for most other items and services that would be paid under the CY 2016 OPPS. We based the proposed payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology proposed for other items and services paid under the OPPS, as discussed in section II.A.2. of the proposed rule and this final rule with comment period. We also proposed to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We proposed to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per source basis (as opposed to, for example, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). For CY 2016 and subsequent years, we also proposed to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010 by section 142 of Pub. L. 110–275). That policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

The proposed CY 2016 payment rates for brachytherapy sources were included in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) and were identified with status indicator ''U.''

We invited public comments on this proposed policy. We also requested recommendations for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources.

Comment: One commenter expressed concern regarding the outpatient

hospital claims data that CMS used to set the prospective payment rates for brachytherapy sources. The commenter stated that high dose rate (HDR) brachytherapy devices are renewable because the devices have a 90-day use span and are used in the treatment of multiple patients during this 90-day span. According to the commenter, the true cost of treatment involving brachytherapy sources depends on the number of patients treated by a hospital within a 90-day period, as well as the number of treatments required and the intensity of the treatments. For this reason, the commenter believed that it is difficult to establish fair and adequate prospective payment rates for brachytherapy sources. The commenter also noted that the brachytherapy source payment data continue to show huge variation in per unit cost across hospitals.

In addition, the commenter believed that CMS' claims data contain rank order anomalies, causing the usual cost relationship between the high activity palladium-103 source (HCPCS code C2635, Brachytherapy source, non-stranded, high activity, palladium-103, greater than 2.2 mci (NIST) per source) and the low activity palladium-103 sources (HCPCS code C2640, Brachytherapy source, stranded, palladium-103, per source and HCPCS code C2641, Brachytherapy source, non-stranded, palladium-103, per source) to be reversed. The commenter noted that the proposed geometric mean costs of the brachytherapy source HCPCS codes are approximately $35, $72, and $72, respectively. The commenters stated that, based on its experience, stranded palladium-103 sources (HCPCS code C2640) always cost more than non-stranded palladium-103 sources (HCPCS code C2641), which is not reflected in the proposed rule claims data that CMS used. The commenter expressed concern that payment for brachytherapy sources are unstable and fluctuate significantly since CMS implemented the prospective payment methodology based on source-specific median cost in CY 2010 and geometric mean unit cost in CY 2013.

Response: As stated above, we believe that geometric mean costs based on hospital claims data for brachytherapy sources have produced reasonably consistent per-source cost estimates over the past several years, comparable to the patterns we have observed for many other OPPS services whose payments are set based upon relative payment weights from claims data. We believe that our per-source payment methodology specific to each source's radioisotope, radioactive intensity, and stranded or non-stranded configuration, supplemented by payment based on the number of sources used in a specific clinical case, adequately accounts for the major expected sources of variability across treatments. (We refer readers to 72 FR 66782; 74 FR 60534; 75 FR 71979; 76 FR 74161; 77 FR 68241; 78 FR 74861; and 79 FR 66796.) We believe that the CY 2014 brachytherapy source claims data used for CY 2016 ratesetting produce adequate payment rates for brachytherapy sources. In addition, as we have explained previously, a prospective payment system relies upon the concept of averaging, where the payment may be more or less than the estimated cost of providing a service for a particular patient. With the exception of outlier cases, the payment for services is adequate to ensure access to appropriate care. In the case of brachytherapy sources for which the law requires separate payment groups, without packaging, the costs of these individual items could be expected to show greater variation than some other APCs under the OPPS because higher variability in costs for some component items and services is not balanced with lower variability in costs for others, and because relative payment weights are typically estimated using a smaller set of claims. Nevertheless, we believe that prospective payment rates for brachytherapy sources based on geometric mean costs of the services reported on claims calculated according to the standard OPPS methodology are appropriate and provide hospitals with the greatest incentives for efficiency in furnishing brachytherapy treatment.

Under the OPPS, it is the relativity of costs, not the absolute costs, that is important, and we believe that brachytherapy sources are appropriately paid according to the standard OPPS approach. Furthermore, some sources may have geometric mean costs and payment rates based on 50 or fewer providers because it is not uncommon for OPPS rates to be based on claims from a relatively small number of hospitals that furnished the service in the year of claims data available for the OPPS update year. Fifty hospitals may report hundreds of brachytherapy sources on claims for many cases and comprise the universe of providers using particular low volume sources, for which we are required to pay separately by statute. Further, our methodology for estimating geometric mean costs for brachytherapy sources utilizes all line-item charges for those sources, which allows us to use all hospital reported charge and estimated cost information to set payment rates for these items. Therefore, no brachytherapy source claims are excluded from the calculation of geometric means costs. We have no reason to believe that prospective payment rates based on claims data from those providers furnishing a particular source do not appropriately reflect the cost of that source to hospitals. As with most other OPPS services, we note that the geometric mean costs for brachytherapy sources are based upon the costs of those providers' sources in CY 2014. Hospitals individually determine their charge for an item or service, and one of Medicare's primary requirements for setting a charge is that it be reasonably and consistently related to the cost of the item or service for that facility. (We refer readers to the Medicare Provider Reimbursement Manual, Part I, Section 2203, which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.html?DLPage=1&DLSort=0&DLSortDir=ascending.*) We then estimate a cost from that charge using the hospital's most recent Medicare hospital cost report data in our standard OPPS ratesetting process.

We acknowledge that HDR brachytherapy sources such as HDR iridium-192 have a fixed active life and must be replaced every 90 days. As a result, a hospital's per treatment cost for the source would be dependent on the number of treatments furnished per source. The cost of the brachytherapy source must be amortized over the life of the source. Therefore, when establishing charges for HDR iridium-192, we expect hospitals to project the number of treatments that would be provided over the life of the source and establish charges for the source accordingly (72 FR 66783; 74 FR 60535; 75 FR 71980; 76 FR 74162; 77 FR 68242; and 78 FR 74861). For most payable services under the OPPS, our practice is to establish prospective payment rates based on the geometric mean costs determined from hospitals' claims data to provide incentives for efficient and cost effective delivery of these services.

With regard to the commenter's stated concerns relating to the differences in costs for high-activity and low-activity palladium-103 sources, our claims data consistently have shown higher average costs for low-activity palladium-103 sources. For the high-activity palladium-103 sources described by HCPCS code C2635, our claims data showed that 9 hospitals submitted claims for this source in CY 2014, compared to 91 and 145 hospitals that submitted claims for the low-activity palladium-103 sources described by

HCPCS codes C2640 and C2641, respectively. It is clear from these claims data that fewer hospitals furnished the high-activity palladium-103 source than the low-activity palladium-103 sources, and we expect that the hospital cost distribution for those hospitals could be different than the cost distribution of the large numbers of hospitals reporting the low-activity palladium-103 sources, as previously stated (74 FR 60535; 75 FR 71979; 76 FR 74162; 77 FR 68242; and 78 FR 74861). These varied cost distributions clearly contribute to the observed relationship in geometric mean cost between the different types of sources. However, we see no reason why our standard ratesetting methodology for brachytherapy sources that relies on all claims data from all hospitals furnishing brachytherapy sources would not yield valid geometric mean costs for those hospitals furnishing the different brachytherapy sources upon which CY 2016 prospective payments are based.

Comment: A number of commenters noted that the proposed CY 2016 payment rate for brachytherapy sources described by HCPCS code C2616 (Brachytx, non-str, yttrium-90) would not adequately cover a hospital's true cost for purchasing the device. The commenters expressed concern that the claims data used to calculate the CY 2016 proposed payment rate does not accurately represent charges for the Y–90 brachytherapy devices and the CY 2015 purchase price incurred by hospitals. In addition, the commenters believed that inconsistent or incorrect reporting (or both) of revenue codes for the use of Y–90 brachytherapy devices adversely affected the proposed CY 2016 payment rate for HCPCS code C2616.

Response: As illustrated in Table 6 below, the CY 2016 geometric mean cost of brachytherapy sources described by HCPCS code C2616 for this final rule with comment period is approximately $16,760, compared with approximately $16,160 for CY 2015, and $16,890 for CY 2014. Furthermore, we note that the CY 2016 geometric mean cost is based on a greater number of providers, days, and units in comparison to CY 2014 and CY 2015.

TABLE 6—COST STATISTICS FOR BRACHYTHERAOPY SOURCES DESCRIBED BY HCPCS CODE C2616 FOR CY 2014 THROUGH CY 2016

Calendar year	HCPCS code	Number of providers	Days	Units	Geometric mean unit cost
2014	C2616	246	2,237	2,237	$16,888.06
2015	C2616	299	2,464	2,464	16,164.79
2016	C2616	352	3,153	3,153	16,764.72

We believe that some variation in relative cost from year to year is to be expected in a prospective payment system, particularly for low-volume items.

For all APCs whose payment rates are based upon relative payment weights, we note that the quality and accuracy of reported units and charges significantly influence the final geometric mean costs that are the basis for our payments. Beyond our standard OPPS trimming methodology (described in section II.A.2. for this final rule with comment period) that we apply to those claims that have passed various types of claims processing edits, it is not our policy to critique the accuracy of hospital coding and charging for the purpose of ratesetting. Moreover, we do not believe it is necessary to incorporate external cost data from manufacturers of Y–90 brachytherapy sources (or any other brachytherapy sources) because, in a relative weight system like the OPPS, it is the relativity of the costs of services to one another, rather than absolute cost, that is important in setting payment rates. External data lack relativity to the estimated costs derived from the claims and cost report data and generally are not appropriate for determining relative weights that result in payment rates when costs derives from hospital claims and cost report data for services are available.

After consideration of the public comments we received, we are finalizing our proposal to continue to set the payment rates for brachytherapy sources using our established prospective payment methodology, which is based on geometric mean costs. The CY 2016 final payment rates for brachytherapy sources are found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

As stated in the proposed rule, we continue to invite hospitals and other parties to submit recommendations to us for new codes to describe new brachytherapy sources. Such recommendations should be directed to the Division of Outpatient Care, Mail Stop C4–03–27, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

e. Comprehensive APCs (C–APCs) for CY 2016

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66810).

Under this policy, we designated a HCPCS code assigned to a C–APC as the primary service (identified by a new OPPS status indicator ''J1''). When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a complete

comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C–APC policy include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute that must be separately paid. This includes certain mammography and ambulance services that are not ever covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act, and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801).

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period for the C–APCs and modified and implemented in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C–APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1,'' excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator ''J1'' are assigned to C–APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service, provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service, except the excluded services that are described below (78 FR 74865 and 79 FR 66800).

In addition, payment for outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and not therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are outpatient department services and not therapy services. Therefore, the requirement for functional reporting under the regulations at 42 CFR 410.59(a)(4) and 42 CFR 410.60(a)(4) does not apply.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and those drugs that are usually self-administered (SADs), unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

Items and services excluded from the C–APC payment policy include: SADs that are not considered supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; services excluded from the OPPS according to section 1833(t)(1)(B) of the Act, including recurring therapy services, which we considered unrelated to the comprehensive service (defined as therapy services reported on a separate facility claim for recurring services), ambulance services, diagnostic and screening mammography, the annual wellness visit providing personalized prevention plan services, and pass-through drugs and devices that are paid according to section 1833(t)(6) of the Act.

We also excluded preventive services. For a description of the preventive services that are excluded from the C–APC payment policy, we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66800 through 66801) and the list below in Table 7, which also includes any new preventive services added for CY 2016.

Other exclusions include brachytherapy services and pass-through drugs, biologicals, and devices that are required by statute to be separately payable (78 FR 74868 and 74909 and 79 FR 66801). In addition, we also excluded services assigned to OPPS status indicator ''F,'' which are services not paid under the OPPS and are instead paid on a reasonable cost basis (that is, certain certified registered nurse assistant (CRNA) services, Hepatitis B vaccines, and corneal tissue acquisition, which is not part of a comprehensive service for CY 2015). In Table 7 below, we list the services that are excluded from the C–APC payment policy.

TABLE 7—COMPREHENSIVE APC PAYMENT POLICY EXCLUSIONS FOR CY 2016

Ambulance services;
Brachytherapy;

TABLE 7—COMPREHENSIVE APC PAYMENT POLICY EXCLUSIONS FOR CY 2016—Continued

Diagnostic and mammography screenings;
Physical therapy, speech-language pathology and occupational therapy services—Therapy services reported on a separate facility claim for recurring services;
Pass-through drugs, biologicals, and devices;
Preventive services defined in 42 CFR 410.2: • Annual wellness visits providing personalized prevention plan services • Initial preventive physical examinations • Pneumococcal, influenza, and hepatitis B vaccines and administrations • Mammography Screenings • Pap smear screenings and pelvic examination screenings • Low Dose Computed Tomography • Prostate cancer screening tests • Colorectal cancer screening tests • Diabetes outpatient self-management training services • Bone mass measurements • Glaucoma screenings • Medical nutrition therapy services • Cardiovascular screening blood tests • Diabetes screening tests • Ultrasound screenings for abdominal aortic aneurysm • Additional preventive services (as defined in section 1861(ddd)(1) of the Act);
Self-administered drugs (SADs)—Drugs that are usually self-administered and do not function as supplies in the provision of the comprehensive service;
Services assigned to OPPS status indicator ''F'' (certain CRNA services, Hepatitis B vaccines and corneal tissue acquisition);
Services assigned to OPPS status indicator ''L'' (influenza and pneumococcal pneumonia vaccines); and
Certain Part B inpatient services—Ancillary Part B inpatient services payable under Part B when the primary ''J1'' service for the claim is not a payable Medicare Part B inpatient service (for example, exhausted Medicare Part A benefits, beneficiaries with Part B only).

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator ''J1'' as a single ''J1'' unit procedure claim (78 FR 74871 and 79 FR 66801). We sum all line item charges for services included on the C–APC claim, convert the charges to costs, and calculate the ''comprehensive'' geometric mean cost of one unit of each service assigned to status indicator ''J1.'' (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a C–APC, inclusive of all of the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, excluding claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator ''J1'' according to their comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof (approximately 20 percent of CY 2014 claims), we identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported ''J1'' services reported on a claim map to different C–APCs, we designate the ''J1'' service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator ''J1'' to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying ''J1'' service code combinations or code combinations of ''J1'' services and certain add-on codes (as described further below) from the originating C–APC (the C–APC to which the designated primary service is first assigned) to a higher paying C–APC in the same clinical family of C–APCs, if reassignment is clinically appropriate and the reassignment would not create a violation of the 2 times rule in the receiving APC (the higher paying C–APC in the same clinical family of C–APCs). We implement this type of complexity adjustment when the code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule (cost threshold).

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if they meet the complexity adjustment

criteria. For new HCPCS codes, we determine initial C–APC assignments and complexity adjustments using the best data available, crosswalking the new HCPCS codes to predecessor codes wherever possible.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family, unless the APC reassignment is not clinically appropriate, the reassignment would create a violation of the 2 times rule in the receiving APC, or the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service-add-on combinations may qualify for a complexity adjustment. First, the add-on code must be an eligible add-on code. The list of add-on codes that are eligible for complexity adjustment evaluation was included in Table 8 of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66810), and also was identified as Addendum J to the proposed rule (which is available via the Internet on the CMS Web site). In the CY 2016 OPPS/ASC proposed rule (80 FR 39225), for CY 2016, we did not propose to add any add-on codes to the list of add-on codes that are evaluated for a complexity adjustment when performed in conjunction with a primary C–APC procedure.

To determine which combinations of primary service codes reported in conjunction with an eligible add-on code may qualify for a complexity adjustment for CY 2016, we apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code. If the frequency and cost criteria thresholds for a complexity adjustment are met, and reassignment to the next higher cost APC in the clinical family is appropriate, we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the eligible add-on code combination to a higher cost C–APC within the same clinical family of C–APCs. If any add-on code combination reported in conjunction with the primary service code does not qualify for a complexity adjustment, payment for these services is packaged within the payment for the complete comprehensive service. We list the complexity adjustments proposed for add-on code combinations for CY 2016, along with all of the other complexity adjustments, in Addendum J to this final rule with comment period (which is available via the Internet on the CMS Web site).

We are providing in Addendum J to this final rule with comment period a breakdown of cost statistics for each code combination that will qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this final rule with comment period also contains summary cost statistics for each of the code combinations that describe a complex code combination that will qualify for a complexity adjustment and will be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all reassigned complex code combinations are represented by an alphanumeric code with the last 4 digits of the designated primary service followed by ''A'' (indicating ''adjustment''). For example, the geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3208A, which is assigned to renumbered C–APC 5223 (Level 3 Pacemaker and Similar Procedures) (previously APC 0089), includes all code combinations that are reassigned to renumbered C–APC 5223 when CPT code 33208 is the primary code. Providing the information contained in Addendum J in this final rule with comment period allows stakeholders the opportunity to better assess the impact associated with the reassignment of each of the code combinations eligible for a complexity adjustment.

(2) C–APCs To Be Paid Under the C–APC Payment Policy for CY 2016

(a) CY 2016 C–APCs

In the CY 2016 OPPS/ASC proposed rule (80 FR 39225), for CY 2016, we proposed to continue to apply the C–APC payment policy methodology made effective in CY 2015, as described in detail below. We proposed to continue to define the services assigned to C–APCs as primary services, and to define a C–APC as a classification for the provision of a primary service and all adjunctive services and supplies provided to support the delivery of the primary service. We also proposed to follow the C–APC payment policy methodology of including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1,'' excluding services that are not covered OPD services or that cannot by statute be paid under the OPPS.

As indicated in the CY 2016 OPPS/ASC proposed rule (80 FR 39225), after our annual review of the OPPS, we proposed to establish nine additional C–APCs to be paid under the existing C–APC payment policy beginning in CY 2016. All C–APCs, including those effective in CY 2016 and those being proposed for CY 2016, were displayed in Table 6 of the proposed rule with the proposed new C–APCs denoted with an asterisk. Addendum J to the proposed rule (which is available via the Internet on the CMS Web site) contained all of the data related to the C–APC payment policy methodology, including the list of proposed complexity adjustments.

Comment: Several commenters generally supported the concept of creating larger payment bundles under the OPPS. The commenters endorsed the C–APC payment policy and the proposal to establish nine additional C–APCs for CY 2016 to be paid under the existing policy.

Response: We appreciate the commenters' support.

Comment: Some commenters expressed concerns that the C–APC payment rates do not accurately reflect all of the costs associated with the primary service and all adjunctive services. Many of these commenters opposed the expansion of the C–APC policy and requested a delay in the implementation of the proposed CY 2016 C–APCs until the effect of the existing C–APCs can be assessed. Other commenters stated that the C–APC payment rates may not appropriately account for the cost of recurring services such as radiation oncology and dialysis that are unrelated to the primary service, but may be included in a C–

APC claim. Some commenters also requested CMS to provide for transparency in the development of C–APC payment rates and data inputs.

Response: We do not believe that we should delay implementation of the proposed CY 2016 C–APCs to allow time for assessment of the effect of the existing C–APCs. It is unclear what specific analyses the commenters are requesting we perform before establishing additional C–APCs. In addition, we believe we have provided adequate information to enable stakeholders sufficient time to perform independent analysis of the proposed C–APC payment rates and their effects.

We believe that the additional nine C–APCs that we proposed for CY 2016 and the existing 25 C–APCs meet the established C–APC criteria. In addition, the commenters did not present any data or evidence that would suggest that the C–APC payment methodology used to calculate the CY 2016 payment rates is inappropriate. We calculate payment rates for C–APCs with the same basic methodology used to calculate payment rates for other APCs. We calculated the final relative payment weights for C–APCs by using relative costs derived from our standard process as described earlier in section II.A. of this final rule with comment period. Specifically, after converting charges to costs on the claims, we identified all claims reporting a single procedure described by a HCPCS code assigned to status indicator ''J1'' as constituting a comprehensive service. These claims were, by definition, classified as single major procedure claims. Any claims that contained more than one of these procedures were identified but were included in calculating the cost of the procedure that had the greatest cost when traditional HCPCS level accounting was applied. All other costs were summed to calculate the total cost of the comprehensive service, and statistics for those services were calculated in the usual manner. Claims with extreme costs were excluded in accordance with our usual process. We used the final relative payment weights of these comprehensive services to calculate final payments following our standard methodology. We believe that the C–APC payment methodology is consistent with our goal of making the OPPS more like a prospective payment system and less like a fee schedule. As is our current practice, we intend to continue to review and monitor all of our payment rates to ensure that they are accurate and reflect the average resource costs of furnishing a service or set of services. In the event that we discover inaccuracies in the development of payment rates, CMS will take appropriate action and make adjustments as necessary.

With respect to the public comments regarding the inclusion of unrelated services on a C–APC claim, we note that we have responded to similar comments in a prior rulemaking. We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74865) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66804 and 66806) for a complete discussion of this issue. We believe that the central attribute of the C–APC payment policy is the packaging of all the services related to the primary service, with the exception of those services described above that, according to the statute, cannot be packaged or the list of preventive services that generally would not be provided at the time of a major procedure assigned to a C–APC. We believe that other services performed at the time of major procedures included in C–APCs can reasonably be considered to be related to the primary service or procedure. Therefore, we consider all services reported on the claim to be related to the primary service and include these services in establishing the payment rate for the C–APC. We do not believe that a significant amount of unrelated services would be billed on the claim for the primary service.

Further, we note that the comments received regarding this issue were primarily concerned with unrelated services reported on claims spanning 30 days. We have previously issued manual guidance in the Internet Only Manual, Pub. 100–4, Chapter 1, Section 50.2.2, that states that only recurring services should be billed monthly. We also have specified that, in the event that a recurring service occurs on the same day as an acute service that falls within the span of the recurring service claim, hospitals should bill separately for recurring services on a monthly claim (repetitive billing) and submit a separate claim for the acute service (79 FR 66804). In addition, we have instructed hospitals that laboratory tests ordered by unrelated providers for unrelated medical conditions may be billed on a 14X bill-type (78 FR 74926).

Lastly, we do not believe that it would be an undue hardship for some hospitals to alter their processes in order to submit separate claims for services that are unrelated both clinically and in regard to time to the comprehensive service.

In response to comments requesting additional transparency of the development of C–APCs and their proposed cost, we believe that the data made available to the public as part of the proposed rule was appropriate, clear, and sufficient. For further information on our data process, we refer readers to section II.A.1.b. of this final rule with comment period.

Comment: A few commenters requested that CMS provide more clarity regarding the definition of adjunctive services.

Response: A description of services that are considered to be adjunctive to the primary comprehensive service is provided in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74865) as well as the CY 2015 OPPS/ASC final rule with comment period (79 FR 66800). As previously stated, adjunctive services include services that are integral, ancillary, supportive, or dependent that are provided during the delivery of the comprehensive service. This includes the diagnostic procedures, laboratory tests and other diagnostic tests, and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that are provided during the comprehensive service, except for mammography services and ambulance services, which are never payable as OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act.

Comment: One commenter expressed concerns regarding payment for durable medical equipment that is included on the claim with a primary service and packaged into the C–APC payment for the service. The commenter stated that, with the implementation of the C–APC payment policy, these items and services are no longer paid under separate fee schedules and their costs are included in determining the relative weights for the C–APCs. Further, the commenter stated that CMS did not provide any evidence that funds were added to the OPPS for these packaged groups and that not adding these funds could potentially add costs to the payment system without increasing payment rates. In addition, the commenter expressed concerns that the relative weights of the new C–APCs will increase, in turn causing the relative weights of other APCs to decrease, which would unfairly decrease payment rates for those other separately paid procedures.

Response: The costs of durable medical equipment, prosthetics, and orthotics have been accounted for in the OPPS. Funds were transferred from the DMEPOS Fee Schedule to the OPPS to account for costs of durable medical equipment. We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66823) for a discussion of the redistribution from the DMEPOS Fee Schedule to the OPPS of approximately $1 million.

Also, with regard to the effect of the increase in the relative weights for the C–APCs, we disagree with the commenters that payment rates for other separately paid procedures are unfairly reduced. Because funds were transferred from the DMEPOS Fee Schedule to account for the costs of durable medical equipment, the relativity of the OPPS payment weights has not been distorted. This accounting for additional DME costs would make the relative payment weights of OPPS services (both comprehensive and noncomprehensive) reflective of their estimated costs. Further, in a budget neutral system, changes to any OPPS relative payment weights have redistributional effects throughout the system and any policy changes or data updates have the potential to cause these effects.

Comment: One commenter opposed CMS' proposal to assign the procedure described by new CPT code 0392T (Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (*i.e.,* magnetic band)) to C–APC 5362 (Level 2 Laparoscopy). Although the commenter did not suggest a specific APC or C–APC to which the procedure should be assigned, the commenter stated that the proposed C–APC assignment for the procedure described by CPT code 0392T results in a significant payment reduction for the procedure and creates a situation where the cost of the device represents approximately 51 percent of the payment rate for C–APC 5362. Therefore, the commenter requested that CMS consider an alternative APC assignment for this procedure. Another commenter suggested that CMS create a third level to the C–APC structure for the Laparoscopic Procedures clinical family that includes laparoscopic procedures with a mean geometric cost that is greater than $8,000.

Response: We disagree with the commenter's request. As a part of our broader efforts to thoroughly review, revise, and consolidate APCs to improve both resource and clinical homogeneity, we proposed a two-level APC structure for laparoscopy procedures for CY 2016. This proposal reduced the levels in the Laparoscopic Procedures clinical family from four levels in CY 2015 to two levels proposed for CY 2016. The procedure described by CPT code 0392T is similar in terms of clinical characteristics to the other procedures assigned to C–APC 5362 (Level 2 Laparoscopy), which has the highest payment rate in this clinical family. In addition, CPT code 0392T replaced HCPCS code C9737 (Laparoscopy, surgical, esophageal sphincter augmentation with device (*e.g.,* magnetic band)), beginning July 1, 2015. In CY 2015, the procedure described by HCPCS code C9737 was assigned to APC 0174 (Level 4 Laparoscopy). Because CPT code 0392T describes the same procedure as HCPCS code C9737, we proposed to assign the new CPT code to the same APC and status indicator as its predecessor HCPCS C-code. In addition, because CPT code 0392T is new for CY 2015 and we do not have claims data for ratesetting purposes for this code, we used the geometric mean cost of the predecessor HCPCS code (C9737) as a proxy for the APC assignment. The geometric mean cost of the procedure described by HCPCS code C9737 is approximately $9,779 and the geometric mean cost of C–APC 5362 is approximately $7,179, which comprises significant services ranging in cost from approximately $6,139 to approximately $9,551. Therefore, the assignment of CPT code 0392T to C–APC 5362 is based on similar resource use and does not result in a violation of the 2 times rule. In addition, CPT code 0392T is a laparoscopic procedure that is similar in clinical characteristics to other procedures assigned to C–APC 5362. Once we have available claims data for the procedure described by CPT code 0392T, we intend to reevaluate this APC assignment under the yearly review of APC assignments.

We believe that the procedures assigned to C–APC 5362 have similar resource utilization and do not create a violation of the 2 times rule within the C–APC. Therefore, we do not believe that creating another level in the structure of this clinical family is warranted.

Comment: One commenter recommended that the Neurostimulators C–APC clinical family be restructured to: (1) Assign all of the single and multiple lead combination procedures to C–APC 5462 (Level 2 Neurostimulators); (2) assign all of the single generators (without placement of a lead) and low cost combination full system implants (one generator and one or more leads) to C–APC 5463 (Level 3 Neurostimulator); and (3) assign all of the multiple generators for bilateral procedures and high cost full system implants (one generator and one or more leads) to C–APC 5464 (Level 4 Neurostimulators). The commenter noted that it appears that the procedures assigned to the Neurostimulators C–APC clinical family were based on the comparable cost of the procedures alone rather than also factoring in clinical similarity. The commenter believed that the recommended restructuring would improve the clinical coherence of the procedures assigned to the neurostimulators C–APC family and increase the stability of the C–APC.

Response: We do not believe that we should restructure the Neurostimulators C–APC clinical family as recommended by the commenter. We note that APC groupings are based on two factors, clinical similarity and resource similarity. The highest level in this APC series includes various combinations of neurostimulator generator implantation procedures with or without leads (and no other types of procedures) within the specified cost range. The commenter suggested that we define clinical similarity very narrowly with strict adherence to the CPT code descriptors. If the OPPS were a fee schedule that did not assign procedures to groups, this could be an acceptable approach. However, the OPPS is a prospective payment system that uses APC groupings of clinically similar services. We believe that the proposed structure of this C–APC clinical family best meets the objective of both clinical and resource homogeneity within the context of a prospective payment system.

Comment: A few commenters requested that CMS make modifications to the C–APC complexity adjustment policy. Some commenters requested that CMS revise the criteria for a claim to qualify for a complexity adjustment beyond the current frequency and cost thresholds to account for the patient acuity experienced at institutions such as academic medical centers, cancer hospitals, and trauma centers. Other commenters requested that CMS consider the inclusion of three or more primary ''J1'' codes in the evaluation of complexity adjustments instead of the current code pair comparison policy. The commenter believed that the reliance on code combinations based on cost ranking of codes would lead to instability in the complexity adjustments from year to year, and would not take into consideration a large number of comprehensive claims with multiple ''J1'' services.

Response: While we acknowledge the challenges involved with treating

complex patients, as discussed in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66805), OPPS payments are not currently based on patient severity or diagnosis like payments under the IPPS. Therefore, we are unable to make adjustments based on these factors.

With regard to considering the inclusion of three or more primary ''J1'' services in evaluation of complexity adjustments, we reiterate our statement in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66806) in which we disagreed that assigning complexity adjustments based on cost ranking of primary and secondary codes is either insufficient or would result in instability of the complexity adjustments in future years. Ranking ''J1'' services based on comprehensive geometric mean costs to determine the primary ''J1'' service on a claim does not result in instability in the evaluation of complexity adjustments because, by definition, the complexity adjustment is for costly cases relative to the primary (most costly) ''J1'' service. We proposed complexity adjustments for certain code pairs to provide a higher payment by promoting the claim for high cost procedure pairs consisting of a primary comprehensive procedure and a secondary comprehensive procedure that represent sufficiently frequent and sufficiently costly comprehensive procedure pairs to the next higher paying APC within a clinical family, such that these claims are separated from and provided a higher payment than all of the services that are accounted for in the APC assignment of the primary service. We do not believe that providing a complexity adjustment to any claim that has three or more ''J1'' services or to all claims reporting code pairs of ''J1'' services that meet the cost and frequency criteria would adequately serve the stated purpose of the policy. The intent of the complexity adjustment policy is to identify a limited number of costly procedure pairs that would qualify for a higher payment at the next higher paying C–APC within the clinical family, not to unpackage and separately pay for all of the high cost services that are associated with the primary ''J1'' procedure.

Comment: One commenter requested that CMS allow any add-on codes describing status indicator ''J1'' procedures to be eligible for complexity adjustments when the codes appear on the claim in combination with a primary ''J1''service. The commenter noted that the current list of add-on codes eligible for complexity adjustments includes only add-on codes formerly assigned to device-dependent APCs. The commenter further reasoned that, because CMS has extended the concept of C–APCs beyond the original policy of applying the comprehensive APC methodology to device-dependent APCs, the list of eligible add-on procedures should be expanded as well.

Response: We agree with the commenters. The current policy allows add-on codes that were (prior to CY 2015) assigned to device-dependent APCs to be evaluated for a complexity adjustment when provided in combination with a primary ''J1'' service. This policy was adopted because the original group of C–APCs was primarily the former device-dependent APCs; therefore, the add-on codes that were evaluated for a complexity adjustment were consistent with the codes assigned as primary ''J1''services under the original C–APCs. As we expand the number of C–APCs, we believe that we must also expand the number of add-on codes that can be evaluated for a complexity adjustment beyond only those add-on codes that were once assigned to device-dependent APCs. Therefore, we are revising the list of add-on codes that are evaluated for a complexity adjustment to include all add-on codes that can be appropriately reported in combination with a base code that describes a primary ''J1''service.

In order to qualify for a complexity adjustment, the primary service add-on combination must meet the frequency (25 or more claims reporting the code combination) and cost (no violation of the 2 times rule) thresholds discussed above. Table 8 of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66810) (now also Table 8 in this final rule with comment period) has been updated to include the additional add-on codes that can be evaluated for a complexity adjustment.

TABLE 8—FINAL CY 2016 PACKAGED CPT ADD-ON CODES THAT ARE EVALUATED FOR A COMPLEXITY ADJUSTMENT

CY 2016 CPT/HCPCS add-on code	CY 2016 short descriptor
C9601	Perc drug-el cor stent bran.
C9603	Perc d-e cor stent ather br.
C9605	Perc d-e cor revasc t cabg b.
C9608	Perc d-e cor revasc chro add.
G0289	Arthro, loose body + chondro.
0172T	Lumbar spine process addl.
0205T	Inirs each vessel add-on.

TABLE 8—FINAL CY 2016 PACKAGED CPT ADD-ON CODES THAT ARE EVALUATED FOR A COMPLEXITY ADJUSTMENT—Continued

CY 2016 CPT/HCPCS add-on code	CY 2016 short descriptor
0289T	Laser inc for pkp/lkp donor.
0290T	Laser inc for pkp/lkp recip.
0291T	Iv oct for proc init vessel.
0294T	Ins lt atrl mont pres lead.
0376T	Insert ant segment drain int.
0396T	Intraop kinetic balnce sensr.
0397T	Ercp w/optical endomicroscpy.
20930	Sp bone algrft morsel add-on.
20931	Sp bone algrft struct add-o.
20936	Sp bone agrft local add-on.
20937	Sp bone agrft morsel add-on.
20938	Sp bone agrft struct add-on.
22515	Perq vertebral augmentation.
22552	Addl neck spine fusion.
22585	Additional spinal fusion.
22614	Spine fusion extra segment.
22632	Spine fusion extra segment.
22840	Insert spine fixation device.
22841	Insert spine fixation device.
22842	Insert spine fixation device.
22843	Insert spine fixation device.
22844	Insert spine fixation device.
22845	Insert spine fixation device.
22846	Insert spine fixation device.
22847	Insert spine fixation device.
22848	Insert spine fixation device.
22851	Apply spine prosth device.
22858	Second level cer diskectomy.
27358	Remove femur lesion/fixation.
29826	Shoulder arthroscopy/surgery.
33225	L ventric pacing lead add-on.
37222	Iliac revasc add-on.
37223	Iliac revasc w/stent add-on.
37232	Tib/per revasc add-on.
37233	Tibper revasc w/ather add-on.
37234	Revsc opn/prq tib/pero stent.
37235	Tib/per revasc stnt & ather.
37237	Open/perq place stent ea add.
37239	Open/perq place stent ea add.
38900	Io map of sent lymph node.
43273	Endoscopic pancreatoscopy.
43283	Lap esoph lengthening.
43338	Esoph lengthening.
49326	Lap w/omentopexy add-on.
49327	Lap ins device for rt.
49435	Insert subq exten to ip cath.

TABLE 8—FINAL CY 2016 PACKAGED CPT ADD-ON CODES THAT ARE EVALUATED FOR A COMPLEXITY ADJUSTMENT—Continued

CY 2016 CPT/HCPCS add-on code	CY 2016 short descriptor
57267	Insert mesh/pelvic flr addon.
60512	Autotransplant parathyroid.
63035	Spinal disk surgery add-on.
63043	Laminotomy addl cervical.
63044	Laminotomy addl lumbar.
63048	Remove spinal lamina add-on.
63057	Decompress spine cord add-on.
63066	Decompress spine cord add-on.
63076	Neck spine disk surgery.
65757	Prep corneal endo allograft.
66990	Ophthalmic endoscope add-on.
92921	Prq cardiac angio addl art.
92925	Prq card angio/athrect addl.
92929	Prq card stent w/angio addl.
92934	Prq card stent/ath/angio.
92938	Prq revasc byp graft addl.

TABLE 8—FINAL CY 2016 PACKAGED CPT ADD-ON CODES THAT ARE EVALUATED FOR A COMPLEXITY ADJUSTMENT—Continued

CY 2016 CPT/HCPCS add-on code	CY 2016 short descriptor
92944	Prq card revasc chronic addl.
92973	Prq coronary mech thrombect.
92974	Cath place cardio brachytx.
92978	Intravasc us heart add-on.
92998	Pul art balloon repr precut.
93462	L hrt cath trnsptl puncture.
93463	Drug admin & hemodynmic meas.
93571	Heart flow reserve measure.
93609	Map tachycardia add-on.
93613	Electrophys map 3d add-on.
93621	Electrophysiology evaluation.
93622	Electrophysiology evaluation.
93623	Stimulation pacing heart.
93655	Ablate arrhythmia add on.
93657	Tx l/r atrial fib addl.
93662	Intracardiac ecg (ice).

After consideration of the public comments we received, we are finalizing our proposal with a slight modification to establish 10 additional C–APCs to be paid under the existing C–APC payment policy beginning in CY 2016. Because an additional level 5 was added to the musculoskeletal procedures APC series (we refer readers to section III.D.9. of this final rule with comment period), the final number of additional C–APCs for CY 2016 is 10. In addition, we are adopting a final policy to include all add-on codes that are paired with a primary service assigned status indicator ''J1'' to be evaluated to qualify for a complexity adjustment as shown in Table 8 above. All C–APCs, including those newly added for CY 2016, are displayed in Table 9 of this final rule with comment period with the new C–APCs denoted with an asterisk. Addendum J to this final rule with comment period (which is available via the Internet on the CMS Web site) contains all of the data related to the C–APC payment policy methodology, including the list of complexity adjustments.

TABLE 9—FINAL CY 2016 C–APCS

CY 2016 C–APC +	CY 2016 APC Group title	Clinical family	New C–APC
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5165	Level 5 ENT Procedures	ENTXX	*
5166	Level 6 ENT Procedures	ENTXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5492	Level 2 Intraocular Procedures	EYEXX	*
5493	Level 3 Intraocular Procedures	EYEXX	
5494	Level 4 Intraocular Procedures	EYEXX	
5331	Complex GI Procedures	GIXXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	*
5361	Level 1 Laparoscopy	LAPXX	*
5362	Level 2 Laparoscopy	LAPXX	*
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5123	Level 3 Musculoskeletal Procedures	ORTHO	*
5124	Level 4 Musculoskeletal Procedures	ORTHO	
5125	Level 5 Musculoskeletal Procedures	ORTHO	*
5471	Implantation of Drug Infusion Device	PUMPS	
5627	Level 7 Radiation Therapy	RADTX	
5375	Level 5 Urology and Related Services	UROXX	*
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5191	Level 1 Endovascular Procedures	VASCX	
5192	Level 2 Endovascular Procedures	VASCX	
5193	Level 3 Endovascular Procedures	VASCX	
5881	Ancillary Outpatient Services When Patient Expires	N/A	*
8011	Comprehensive Observation Services	N/A	*

+ We refer readers to section III.D. of this final rule with comment period for a discussion of the overall restructuring and renumbering of APCs.

* New C–APC for CY 2016.
Clinical Family Descriptor Key:
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery.
ENTXX = ENT Procedures.
EPHYS = Cardiac Electrophysiology.
EYEXX = Ophthalmic Surgery.
GIXXX = Gastrointestinal Procedures.
GYNXX = Gynecologic Procedures.
LAPXX = Laparoscopic Procedures.
NSTIM = Neurostimulators.
ORTHO = Orthopedic Surgery.
PUMPS = Implantable Drug Delivery Systems.
RADTX = Radiation Oncology.
UROXX = Urologic Procedures.
VASCX = Vascular Procedures.

(b) Observation Comprehensive APC (C–APC 8011)

As part of our expansion of the C–APC payment policy methodology, we have identified an instance where we believe that comprehensive payments are appropriate, that is, when a claim contains a specific combination of services performed in combination with each other, as opposed to the presence of a single primary service identified by status indicator ''J1.'' To recognize such instances, in the CY 2016 OPPS/ASC proposed rule (80 FR 39226), for CY 2016, we proposed to create a new status indicator ''J2'' to designate specific combinations of services that, when performed in combination with each other and reported on a hospital Medicare Part B outpatient claim, would allow for all other OPPS payable services and items reported on the claim (excluding all preventive services and certain Medicare Part B inpatient services) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim. Additional information about the proposed new status indicator ''J2'' and its proposed C–APC assignment is provided below.

It has been our longstanding policy to provide payment to hospitals in certain circumstances when extended assessment and management of a patient occur (79 FR 66811 through 66812). Currently, payment for all qualifying extended assessment and management encounters is provided through APC 8009 (Extended Assessment and Management (EAM) Composite) (79 FR 66811 through 66812). Under this policy, we allow services identified by the following to qualify for payment through EAM composite APC 8009: A clinic visit (described by HCPCS code G0463); a Level 4 or 5 Type A ED visit (described by CPT codes 99284 or 99285); a Level 5 Type B ED visit (described by HCPCS code G0384); and a direct referral for observation (described by HCPCS code G0379), or critical care services (described by CPT code 99291) provided by a hospital in conjunction with observation services of substantial duration (8 or more hours) (provided the observation was not furnished on the same day as surgery or postoperatively) (79 FR 66811 through 66812).

For CY 2016, we proposed to pay for all qualifying extended assessment and management encounters through a newly created ''Comprehensive Observation Services'' C–APC (C–APC 8011) and to assign the services within this APC to proposed new status indicator ''J2,'' as described earlier in this section. Specifically, we proposed to make a C–APC payment through the proposed new C–APC 8011 for claims that meet the following criteria:

- The claims do not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service on the same day or 1 day earlier than the date of service associated with services described by HCPCS code G0378;
- The claims contain 8 or more units of services described by HCPCS code G0378 (Observation services, per hour);
- The claims contain services described by one of the following codes: HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as services described by HCPCS code G0378; CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) provided on the same date of service or 1 day before the date of service for services described by HCPCS code G0378; and
- The claims do not contain services described by a HCPCS code to which we have assigned status indicator ''J1.''

We proposed to utilize all of the claims that meet the above criteria in ratesetting for the proposed new C–APC 8011, and to develop the geometric mean costs of the comprehensive service based on the costs of all reported OPPS payable services reported on the claim (excluding all preventive services and certain Medicare Part B inpatient services). The proposed CY 2016 geometric mean cost resulting from this methodology was approximately $2,111, based on 1,191,120 claims used for ratesetting.

With the proposal to establish a new C–APC 8011 to capture qualifying extended assessment and management encounters that currently are paid using composite APC 8009, in the CY 2016 OPPS/ASC proposed rule, we correspondingly proposed to delete APC 8009, as it would be replaced with proposed new C–APC 8011.

As stated earlier, we proposed to assign certain combinations of procedures within proposed new C–APC 8011 to the proposed new status indicator ''J2,'' to distinguish the new C–APC 8011 from the other C–APCs. Comprehensive payment would be made through the new C–APC 8011 when a claim contains a specific combination of services performed in combination with each other, as opposed to the presence of a single primary service identified by status indicator ''J1.'' We believe that a distinction in the status indicator is necessary to distinguish between the logic required to identify when a claim qualifies for payment through a C–APC because of the presence of a status indicator ''J1'' procedure on the claim versus when a claim qualifies for payment through a C–APC because of the presence of a specific combination of services on the claim. Specifically, for proposed new C–APC 8011, we believe the assignment of certain combinations

of services that qualify under proposed new C–APC 8011 to the new proposed status indicator ''J2'' is necessary because claims containing procedures assigned status indicator ''T'' that are performed on the same day or day before observation care is provided would not be payable through the proposed new C–APC 8011, and the initial ''J1'' logic would not exclude claims containing procedures assigned status indicator ''T'' from qualifying for payment through another appropriately assigned C–APC based on the primary ''J1'' procedure.

For claims reporting services assigned to status indicator ''J1'' that qualify for payment through a C–APC and services assigned to status indicator ''J2'' that qualify for payment through a C–APC, we proposed that payment for services would be made through the C–APC to which the primary ''J1'' procedure is assigned or through the C–APC to which the primary ''J2'' procedures is assigned, and all of the OPPS payable services performed would be deemed adjunctive services to the primary status indicator ''J1'' service, including the specific combination of services performed in combination with each other that would otherwise qualify for payment through a C–APC based on the primary procedure being assigned to status indicator ''J2.'' We proposed that the presence of the specific combination of services performed in combination with each other that would otherwise qualify the service for payment through a C–APC because it is assigned to status indicator ''J2'' on a hospital outpatient claim would not result in a complexity adjustment for the service qualifying for payment through a C–APC because the primary procedure is assigned to status indicator ''J1.''

Under the C–APC payment policy, we note that, instead of paying copayments for a number of separate services that are generally, individually subject to the copayment liability cap at section 1833(t)(8)(C)(i) of the Act, beneficiaries can expect to pay a single copayment for the comprehensive service that would be subject to the copayment liability cap. As a result, we expect that this policy likely reduces the possibility that the overall beneficiary liability exceeds the cap for most of these types of claims.

Comment: Many commenters, including MedPAC, supported the proposal to create new C–APC 8011. The majority of those commenters who supported the proposal requested that CMS not allow any claims reporting a surgical procedure (assigned status indicator ''T'') to qualify for payment through C–APC 8011, regardless of whether the procedure assigned status indicator ''T'' was furnished before or after observation services (described by HCPCS code G0378) were provided. A few other commenters who supported the proposal requested that CMS make separate payment for services assigned to the proposed new C–APC 8011 and the procedure assigned status indicator ''T,'' when a procedure assigned status indicator ''T'' was furnished after observation services were provided as part of an encounter that would otherwise qualify for payment through the proposed new C–APC 8011. One commenter requested that CMS package payment for all procedures assigned status indicator ''T'' into the payment for the services through the proposed new C–APC 8011, regardless of whether the procedure assigned status indicator ''T'' was provided prior to or after the furnishing the services described by HCPCS code G0378 when both services are present on a claim that would otherwise qualify for payment through the proposed new C–APC 8011. Other commenters recommended that CMS make modifications to the proposal, including creating a cost threshold to exclude relative high-cost but low frequency services from being packaged into the payment for services assigned to C–APC 8011; excluding the payment for specified covered outpatient drugs (SCODs) from being packaged into the payment for proposed new C–APC 8011; establishing multiple observation C–APCs; and creating a complexity adjustment factor for services assigned to proposed new C–APC 8011 similar to the complexity adjustment used for services assigned status indicator ''J1'' and paid through other C–APCs.

Response: We appreciate the commenters' support of our proposal to create new C–APC 8011. In response to comments pertaining to packaging the payment for procedures assigned status indicator ''T'' into the payment for proposed new C–APC 8011, we are sensitive to commenters' concerns regarding packaging payment for potentially high-cost surgical procedures into the payment for an observation C–APC and agree that claims reporting procedures assigned status indicator ''T'' should not qualify for payment through C–APC 8011, regardless of whether the procedure assigned status indicator ''T'' was furnished before or after observation services (described by HCPCS code G0378) were provided. We believe that excluding all claims reporting procedures assigned status indicator ''T'' from qualifying for payment through the new C–APC 8011 will eliminate any need to create a cost threshold to exclude payment for relative high-cost but low frequency services from being packaged into the payment for C–APC 8011, as well as eliminate any need to create a complexity adjustment factor for services assigned to C–APC 8011 or to create multiple observation C–APCs.

While we believe that payment for surgical procedures should not be packaged into the payment for services assigned to C–APC 8011, we do not believe that separate payment should be made for both C–APC 8011 and the procedure assigned status indicator ''T'' when the procedure assigned status indicator ''T'' was provided as part of an encounter that would otherwise qualify for payment through the proposed new C–APC 8011.

Accordingly, we are adopting a policy that payment for observation services will always be packaged when furnished with a procedure assigned status indicator ''T.'' For CY 2016, consistent with our modified final policy discussed in this final rule with comment period, payment for observation services will be packaged into the surgical procedure when comprehensive observation services are furnished with a procedure assigned status indicator ''T,'' while eligible separately payable services will receive separate payment.

In addition, we do not believe that payment for SCODs should be excluded from packaging into the payment made through C–APC 8011 because the services are considered supportive and ancillary when furnished during an outpatient observation encounter and, therefore, are appropriate for inclusion in the comprehensive payment through C–APC 8011.

Comment: A number of commenters who supported the proposal suggested that CMS include all emergency department (ED) visits as eligible services paid through C–APC 8011, as opposed to limiting the eligible services to only high-level ED visits.

Response: We agree with the commenters' suggestion that CMS assign all ED visits to C–APC 8011, rather than only the high-level ED visits, because we believe that all ED visits should be eligible to trigger C–APC payment in the same fashion that all clinic visits are eligible to trigger C–APC payment to C–APC 8011. We believe that including all ED visits in C–APC 8011 is more consistent with our comprehensive payment policy. Allowing all ED visits to be eligible to trigger C–APC payment through C–APC 8011 means that we will make C–APC payment for the full spectrum of ED and clinic visits when furnished in conjunction with 8 or more

hours of observation and without a surgical procedure.

Comment: One commenter requested that CMS withdraw its requirement to ''carve out,'' or not include under the reported observation hours, the number of hours associated with active monitoring.

Response: We disagree with the commenter. Consistent with Section 290.2.2 of Chapter 4 of the Medicare Claims Processing Manual, observation services should not be billed concurrently with diagnostic or therapeutic services for which active monitoring is a part of the procedure.

Comment: Some commenters expressed concern that the proposed payment rate for C–APC 8011 does not adequately cover the costs of the services involved, and may result in a disincentive for hospitals to establish policies that result in premature discharge of these patients.

Response: The proposed geometric mean cost of C–APC 8011 upon which the CY 2016 proposed payment rate is based, represents the geometric mean cost of all services reported on claims that qualified for payment through the former EAM composite APC. Based on the approximately 1.2 million claims used for ratesetting for C–APC 8011, we believe that the CY 2016 geometric mean cost and associated CY 2016 payment rate appropriately reflect the appropriate comprehensive payment for encounters qualifying for payment through C–APC 8011. Accordingly, we do not believe the proposed payment rate for C–APC 8011 would incentivize hospitals to prematurely discharge patients.

Comment: A few commenters expressed concern that, because the breadth of services that may be included in these observation stays varies widely based on the specific diagnoses associated with the stay, critical care hospitals and those hospitals in areas with low socio-demographic status may be disproportionately penalized by receiving payment for services through C–APC 8011. Another commenter expressed concern that the proposed creation of C–APC 8011 would incentivize use of the least expensive test for complex Medicare patients with serious life-threatening symptoms, regardless of what may be the best test for a patient at a given time based on the physician's clinical judgment.

Response: We do not agree with the commenters' assertion that the creation of new C–APC 8011 would incentivize hospitals to furnish the cheapest test to complex Medicare patients at the expense of what may be the most appropriate course of treatment because we believe that hospitals provide appropriate reasonable and necessary care that is in the best interest of the patient, and if furnishing a more costly test represents the most appropriate course of treatment, hospitals would provide such a service. As noted earlier in this section, the payment rate for C–APC 8011 was based on all services reported on claims that previously qualified for the EAM composite APC. Therefore, we believe the payment rate appropriately reflects the average resources expended in furnishing comprehensive observation services. In addition, we have no reason or evidence to support the commenters' assertion that critical care hospitals and those in areas with low socio-demographic status may be disproportionately penalized by receiving payment for services through C–APC 8011, as the commenter did not explain the basis for this assertion. We believe that hospitals will continue to provide appropriate care that is reasonable and necessary. We note that, as part of our annual rulemaking cycle, we will continue to examine the claims data and monitor any changes in the provision of care associated with furnishing observation services and payment through C–APC 8011.

Comment: A number of commenters requested that CMS provide additional transparency on the development of C–APC 8011 and its proposed cost, as well as assess the risk of care fragmentation and analyze the impact of the C–APC payment methodology on a variety of factors such as length of stay, patient diagnosis, and patient age. One commenter asked CMS to remind providers of the critical importance of reporting all services provided to patients, regardless of whether they are separately paid or not.

Response: In response to comments requesting additional transparency on the development of C–APC 8011 and its proposed cost, we believe that the data made available to the public as part of the addenda to the proposed rule was appropriate, clear, and sufficient. For further information on our data process, we refer readers to section II.A.1.b. of this final rule with comment period. Furthermore, as indicated earlier in this section, as part of our annual rulemaking cycle, we will continue to examine the claims data and monitor any changes in the provision of care, including care fragmentation and other factors such as length of stay associated with furnishing observation services and payment through C–APC 8011. We also remind providers to report all services provided to patients, regardless of whether they are separately paid or not.

A number of comments presented specific issues pertaining to self-administered drugs, long observation stays, outpatient observation notice, and the 3-day inpatient stay requirement for Medicare paid skilled nursing facility (SNF) coverage. We did not propose or discuss policies in the proposed rule that implicated any of the specific issues raised by the commenters. Therefore, we believe these comments are outside the scope of the proposed rule, and we are not responding to them in this final with comment period.

After consideration of the public comments we received, effective beginning CY 2016, we are finalizing our proposals to delete APC 8009, to establish new C–APC 8011, and to develop the geometric mean costs of the C–APCs based on the costs of all reported OPPS payable services reported on the claim (excluding all preventive services and certain Medicare Part B inpatient services). We also are finalizing our proposal to pay for all qualifying extended assessment and management encounters through C–APC 8011 and to assign the services within this APC to proposed new status indicator ''J2.'' In addition, we are modifying our proposed criteria for services to qualify for comprehensive payment through C–APC 8011 and how we identify all claims used in ratesetting for the new C–APC 8011. Specifically, we are adopting the following two modifications to our proposal: (1) The criteria for services to qualify for payment through C–APC 8011 and the claims identified for purposes of ratesetting for C–APC 8011 will exclude all claims containing a status indicator ''T'' procedure from qualification; and (2) any level ED visit is an eligible service that could trigger qualification and payment through C–APC 8011, as opposed to only high-level emergency department visits. The finalized criteria for services to qualify for payment through C–APC 8011 are listed below. All claims meeting these criteria will be utilized in ratesetting purposes for C–APC 8011 for CY 2016.

- The claims do not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T'';
- The claims contain 8 or more units of services described by HCPCS code G0378 (Observation services, per hour);
- The claims contain services provided on the same date of service or 1 day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct referral of patient for hospital observation care) on the same date of service as HCPCS code G0378;

CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and

- The claims do not contain a service that is described by a HCPCS code to which we have assigned status indicator ''J1.''

The final CY 2016 geometric mean cost for C–APC 8011 resulting from this methodology is approximately $2,275, based on 1,338,889 claims used for ratesetting.

(3) CY 2016 Policies for Specific C–APCs

(a) Stereotactic Radiosurgery (SRS)

With the advent of C–APCs, the OPPS consists of a wide array of payment methodologies, ranging from separate payment for a single service to a C–APC payment for an entire outpatient encounter with multiple services. As described above, our C–APC payment policy generally provides payment for a primary service and all adjunctive services provided to support the delivery of the primary service, with certain exceptions, reported on the same claim, regardless of the date of service. Since implementation of the C–APC policy and subsequent claims data analyses, we have observed circumstances in which necessary services that are appropriately included in an entire outpatient encounter payment are furnished prior to a primary ''J1'' service and billed separately. That is, our analysis of billing patterns associated with certain procedures assigned status indicator ''J1'' indicates that providers are reporting planning services, imaging tests, and other ''planning and preparation'' services that are integrally associated with the direct provision of the primary ''J1'' service on a separate claim. The physician practice patterns associated with reporting the provision of various stereotactic radiosurgery (SRS) treatments presents an example of this issue.

Section 634 of the American Taxpayer Relief Act (ATRA) of 2012 (Pub. L. 112–240) amended section 1833(t)(16) of the Act by adding a new subparagraph (D) to require that OPPS payments for Cobalt-60 based SRS (also referred to as gamma knife) be reduced to equal that of payments for robotic linear accelerator-based (LINAC) SRS, for covered OPD services furnished on or after April 1, 2013. This payment reduction does not apply to hospitals in rural areas, rural referral centers, or SCHs. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66809), we created C–APC 0067 (which was proposed to be renumbered to C–APC 5631 for CY 2016) for procedures involving single-session cranial SRS services. Because section 1833(t)(16)(D) of the Act requires equal payment for SRS delivered by Cobalt-60 based or LINAC based technology, proposed renumbered C–APC 5631 includes two types of services involving SRS delivery instruments, which are described by HCPCS code 77371 (Radiation treatment delivery, stereotactic radiosurgery [SRS], complete course of treatment cranial lesion(s) consisting of 1 session; multi-source Cobalt 60-based) and HCPCS code 77372 (Linear accelerator based) (79 FR 66862).

As discussed in the CY 2016 OPPS/ASC proposed rule (80 FR 39228), based on our analysis of CY 2014 claims data (the data used to develop the proposed CY 2016 payment rates), we identified differences in the billing patterns for SRS procedures delivered using Cobalt-60 based and LINAC based technologies. In particular, our claims data analysis results revealed that services involving SRS delivered by Cobalt-60 based technologies (as described by HCPCS code 77371) typically included SRS treatment planning services (for example, imaging studies, radiation treatment aids, and treatment planning) and the actual deliveries of SRS treatment on the same date of service and reported on the same claim. In contrast, claims data analysis results revealed that services involving SRS delivered by LINAC-based technologies (as described by HCPCS code 77372) frequently included services related to SRS treatment (for example, imaging studies, radiation treatment aids, and treatment planning) that were provided on different dates of services and reported on claims separate from the actual delivery of SRS treatment. Because services involving Cobalt-60 based and LINAC-based technologies are proposed to be assigned to proposed renumbered C–APC 5631, the costs of both technologies are reflected in the C–APC payment rate.

The policy intent of C–APCs is to bundle payment for all services related and adjunctive to the primary ''J1'' procedure. In light of this, we believe that all essential planning and preparation services also should be paid through the C–APC. For accuracy of payment, we make a single payment through the C–APC that includes payment for these essential planning and preparation services, and we do not pay separately for C–APC services when they are furnished prior to delivery of the primary ''J1'' procedure and reported on separate claims. Procedures involving SRS services are just one example of where this may be occurring under our C–APC payment policy.

As a result of our SRS claims data findings, in the CY 2016 OPPS/ASC proposed rule (80 FR 39228), for CY 2016, we proposed to change payment for SRS treatment under proposed renumbered C–APC 5631 by identifying any services that are differentially reported using HCPCS codes 77371 and 77372 on the same claim and on claims one month prior to the delivery of SRS services in proposed renumbered C–APC 5631, including planning and preparation services, and removing these claims from our C–APC geometric mean cost calculations for CY 2016 and CY 2017, while we collect data using a modifier, which is discussed in greater detail below. For any of the services that we remove from the C–APC payment bundle, we proposed that those services would receive separate payment even when appearing in combination with a primary ''J1'' procedure (described either by HCPCS code 77371 or 77372) on the same claim for both CY 2016 and CY 2017. Specifically, we proposed to apply this treatment for the following codes for planning and preparation services:

- CT localization (HCPCS codes 77011 and 77014);
- MRI imaging (HCPCS codes 70551, 70552, and 70553);
- Clinical treatment planning (HCPCS codes 77280, 77285, 77290, and 77295); and
- Physics consultation (HCPCS code 77336).

We invited public comments on our proposal to remove claims reporting planning and preparation service for SRS treatment from our geometric mean

cost calculation for the CY 2016 and CY 2017 payment rate for proposed renumbered C–APC 5631 and to allow for separate payment of these same services during CY 2016 and CY 2017 using either modality. As discussed in detail below, our long-term goal is to create a single prospective payment for the entire outpatient encounter by packaging payment for all C–APC services, including all planning and preparation services that occur prior to the primary ''J1'' procedure.

Comment: Several commenters supported our policy proposal to remove claims reporting planning and preparation services from the geometric mean cost calculations for proposed renumbered C–APC 5631. The commenters believed that because of the coding changes implemented over the past few years to describe SRS delivery by LINAC-based and Cobalt-60 based technologies, hospitals have incorrectly coded claims reporting SRS services. To remedy perceived payment inaccuracies for C–APC 5631, the commenters urged CMS to adopt the policy as proposed.

Response: We appreciate the commenters' support of our proposal.

Comment: In contrast, many commenters opposed the policy proposal regarding payment for SRS services and recommended that CMS leave the four identified categories of services within the C–APC payment methodology for CY 2016 and work with stakeholders to improve the coding guidance for SRS services.

Response: As we stated in the proposed rule, the policy intent of the C–APCs is to bundle payment for all services related and adjunctive to the primary ''J1'' procedure. In light of this, we believe that all services that are adjunctive to the primary service should be paid through the C–APC. However, our claims analysis has shown that the services described by HCPCS codes that we proposed to exclude from the C–APC payment were frequently reported on a separate claim than the primary ''J1'' SRS service and, therefore, received separate payment in addition to the full C–APC payment. Therefore, to collect claims data on the adjunctive services for the SRS ''J1'' procedures and to ensure appropriate ratesetting for the SRS C–APC in the future, we believe it is necessary to unbundle payment for the adjunctive services for CY 2016 and CY 2017. Because the intent of a C–APC is to bundle payment for all services related and adjunctive to the primary ''J1'' procedure, we agree that coding and billing guidance and instructions for SRS services should reflect the inclusion of the comprehensive services that were furnished in conjunction with the primary ''J1'' service and we proposed the use of a modifier to better identify when related comprehensive services were being billed separately.

Comment: One commenter requested clarification on how CMS will pay for planning and preparation services performed prior to the actual delivery of the SRS service, such as basic dosimetry (CPT code 77300), since CMS did not specifically propose to remove these costs from the calculation of C–APC 5631.

Response: Only the above-identified 10 planning and preparation CPT codes that we proposed to remove from the C–APC bundle payment for SRS delivery services will be paid for separately in CY 2016 when furnished to a beneficiary within one month of the SRS treatment. For CY 2016 and CY 2017, these codes will not be included in the C–APC payment for SRS even if they are furnished on the same date of service. The services that we did not propose to remove from the geometric mean cost calculations will continue to be paid through C–APC 5631 (for CY 2016, this will be C–APC 5627). However, we remind hospitals that procedure codes related to the primary SRS service should either be reported on the same claim, or, if furnished on a different date than the primary service, must include modifier ''CP'' that we are adopting in this final rule with comment period (as discussed in detail below).

Comment: Commenters requested that CMS provide additional guidance on the specific items and services, apart from the four identified categories, that are to be reported with the proposed modifier as integral, ancillary, supportive, dependent, and adjunctive to either HCPCS code 77371 or 77372. Commenters also asked for clarification on the time period in which CMS will consider the delivery of a service to be adjunctive to the primary ''J1'' SRS treatment.

Response: As we stated in the proposed rule, any service that is integral, ancillary, supportive, dependent and adjunctive to the primary ''J1'' service identified by either HCPCS code 77371 or 77372 that is reported on a different claim than the primary ''J1'' service must be billed with the HCPCS modifier. We believe that hospitals, physicians, and other clinical staff that furnish comprehensive services are in a position to identify these types of related services. We do not believe that it is feasible or practicable for us to identify all of the services that could potentially be related to a primary ''J1'' service given differences in medical practice. We expect providers to identify any adjunctive services provided within 30 days prior to SRS treatment.

After consideration of the public comments we received, for CY 2016 and CY 2017, we are finalizing our proposal to remove planning and preparation services (identified by the following 10 specific HCPCS codes: 70551, 70552, 70553, 77011, 77014, 77280, 77285, 77290, 77295, and 77336) from the geometric mean cost calculations for proposed C–APC 5631 which, beginning in CY 2016, will be C–APC 5627 (Level 7 Radiation Therapy). In addition, for CY 2016 and CY 2017, we will separately pay for planning and preparation services adjunctive to the delivery of the SRS treatment through either modality, regardless of whether they are furnished on the same date of service as the primary ''J1'' SRS service.

(b) Data Collection for Nonprimary Services in C–APCs

As mentioned above, provider practice patterns can create a need for hospitals to perform services that are integral, ancillary, supportive, dependent, and adjunctive, hereinafter collectively referred to as ''adjunctive services'', to a comprehensive service prior to the delivery of that service—for example, testing leads for a pacemaker insertion or planning for radiation treatment. As the C–APC policy continues to expand, we need a mechanism to identify these adjunctive services that are furnished prior to the delivery of the associated primary ''J1'' service so that payments under the encounter-based C–APC will be more accurate.

To meet this objective, in the CY 2016 OPPS/ASC proposed rule (80 FR 39228), for CY 2016, we proposed to establish a HCPCS modifier to be reported with every service code that describes an adjunctive service to a comprehensive service, but is reported on a different claim. We proposed that the modifier would be reported on UB–04 form (CMS Form 1450) for hospital outpatient services. Specifically, hospitals would report this modifier for services that are adjunctive to a primary procedure code assigned a status indicator ''J1'' and that are reported on a different claim than the primary ''J1'' service. The collection of this information would allow us to begin to assess the accuracy of the claims data used to set payment rates for C–APC services. This information would be useful in refining our C–APC ratesetting process. Based on the collection of these data, we envision creating a single encounter payment for primary ''J1'' services that reflects the costs of all of the resources used during

the delivery of the primary services. We also would discontinue separate payment for any of these packaged adjunctive services, even when furnished prior to delivery of the primary ''J1''service. As noted above, we proposed to use the modifier to identify planning and preparation services for primary ''J1'' procedures involving SRS services with this goal in mind.

We invited additional public comments on whether to adopt a condition code as early as CY 2017, which would replace this modifier to be used for CY 2016 data collection, for collecting this service-level information.

Comment: Overall, few commenters supported CMS' proposed policy to collect claims data on the costs of adjunctive services furnished prior to a primary ''J1'' procedure and reported on a different claim. Those commenters who supported the policy proposal encouraged CMS to implement this proposal to begin an effort to include the costs of all planning and preparation services in the payment bundles for C–APCs.

Response: We appreciate the commenters' support.

Comment: A significant number of commenters opposed the proposed policy to require hospitals to report a modifier with every HCPCS code that describes services that are adjunctive to a comprehensive service (as described by a ''J1'' status indicator), but reported on a different claim. The commonly cited concerns among the commenters who opposed the proposed policy were as follows:

- Definition of related and adjunctive services. Commenters requested that CMS provide greater clarity on the definition of adjunctive services. Specifically, the commenters recommended that CMS identify and propose adjunctive services by HCPCS code for each primary ''J1'' service, similar to the SRS C–APC proposal, so that hospitals will know which HCPCS codes describing adjunctive services to report with the modifier. Without specific guidance from CMS on the scope of these adjunctive services, some commenters expressed uncertainty about their ability to accurately report services using the modifier.
- Operational challenges and administrative burden. Commenters asserted that operationalizing new reporting requirements for modifiers is challenging because it requires a manual claims review to determine appropriateness of a modifier. In addition, commenters recommended that CMS delay implementation or withdraw the proposed modifier for C–APC adjunctive services data collection so that facilities can successfully implement ICD–10 and accurately use the PO modifier and the new modifier 59 subset X (E,S,P, and U).

Response: We appreciate the thoughtful comments that were submitted and, based on the above-mentioned issues, particularly the desire for CMs to provide additional information pertaining to adjunctive services for each C–APC raised by the commenters, are modifying our proposal to only require that the modifier be used with respect to reporting adjunctive services related to primary ''J1'' SRS services that are reported separately on different claims. We believe that it is appropriate to finalize our proposal to require the use of the modifier for adjunctive SRS services based on our analysis of claims data and information submitted by stakeholders who are familiar with the distinct processes of care for each type of SRS technology. We are not finalizing our proposal to require the use of the modifier for reporting any other C–APC services at this time. We will take these comments into consideration if we propose a modifier for the other C–APCs in future rulemaking.

Comment: Several commenters raised technical questions about the application of the proposed adjunctive services modifier. Specifically, commenters posed the following questions:

- Should facilities report adjunctive planning and preparation services when furnished in a setting outside of the HOPD?
- Are adjunctive services limited to preoperative testing and planning services only?
- Does the modifier apply to services performed by different physicians within a health system?

Response: As noted above, we are finalizing our proposal to require the use of the modifier for reporting adjunctive and related services to a primary ''J1'' SRS procedure at this time. We intend to issue further subregulatory guidance on use of the modifier with respect to SRS services prior to January 1, 2016. The commenters' technical questions will be addressed in that guidance.

Comment: One commenter supported the use of a modifier over a condition code to report adjunctive services. The commenter stated that because CMS proposed to require the use of the modifier for CY 2016, it is less burdensome to continue its use in subsequent years than switch to a condition code. In addition, several commenters asked CMS to delay implementation of the requirement to use the adjunctive services modifier until additional clarifying instruction is provided on how to identify adjunctive services furnished prior to a primary ''J1'' service. Alternatively, commenters recommended that CMS follow a step-wise roll out approach and propose select C–APCs through annual rulemaking for which the use of the adjunctive services modifier will be required.

Response: We appreciate the feedback from the commenter regarding the preference for use of a modifier rather than a condition code. For CY 2016, we are finalizing a policy to only require the use of the HCPCS code modifier for adjunctive services related to primary ''J1'' SRS services (described by HCPCS codes 77371 and 77372) that are reported on a separate claim than the primary ''J1'' service. In response to comments on additional clarification on how to identify adjunctive services, we have identified these services for SRS treatments in this final rule with comment period. Because we are not adopting a policy to require the use of this HCPCS modifier for other C–APCs at this time, we are not providing additional information relating to adjunctive services for other C–APCs in this final rule with comment period.

After consideration of the public comments we received we are finalizing our proposal, with modification. Specifically, for CY 2016 and CY 2017, we are adopting a policy to require the use of a HCPCS code modifier for adjunctive SRS C–APC services that are reported separate from the primary ''J1'' SRS service. Effective January 1, 2016, hospitals must use the HCPCS code modifier ''CP'' (Adjunctive service related to a procedure assigned to a comprehensive ambulatory payment classification (C–APC) procedure, but reported on a different claim) to report adjunctive service(s) related to a primary ''J1'' SRS services that is reported on a separate claim than the primary ''J1'' service. With respect to other C–APCs, we are not adopting a policy to require the use of the HCPCS code modifier to identify adjunctive services that are reported separately at this time, but may consider doing so in the future.

(c) Payment for Claims Reporting Inpatient Only Services Performed on a Patient Who Dies Before Admission

Currently, composite APC 0375 (Ancillary Outpatient Services When Patient Dies) packages payment for all services provided on the same date as an inpatient only procedure that is performed on an emergence basis on an outpatient who dies before admission

when the modifier ''–CA'' appears on the claim. For CY 2016, we proposed to provide payment through proposed renumbered C–APC 5881 for all services reported on the same claim as an inpatient only procedure with the modifier ''–CA.'' We stated in the proposed rule that this proposal provides for all services reported on the same claim as an inpatient only procedure with modifier ''–CA'' would be paid through a single prospective payment for the comprehensive service. In the CY 2016 OPPS/ASC proposed rule (80 FR 39228), we proposed to renumber APC 0375 as APC 5881 (Ancillary Outpatient Services When Patient Dies) for CY 2016.

We did not receive any public comments on this proposal. Therefore, we are finalizing, without modification, our proposal to provide payment through renumbered C–APC 5881 for all services provided on the same date and reported on the same claim as an inpatient only procedure with the modifier ''–CA.''

f. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for extended assessment and management services, low dose rate (LDR) prostate brachytherapy, mental health services, and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for a full discussion of the development of the composite APC methodology (72 FR 66611 through 66614 and 66650 through 66652) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) for more recent background.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39228 through 39232), for CY 2016, we proposed to continue our composite APC payment policies for LDR prostate brachytherapy services, mental health services, and multiple imaging services, as discussed below. For CY 2016, we proposed to discontinue our composite APC payment policies for qualifying extended assessment and management services (APC 8009) and to pay for these services through proposed new C–APC 8011 (Comprehensive Observation Services), as presented in a proposal included under section II.A.2.e. of the proposed rule. As a result, we proposed to delete APC 8009 for CY 2016.

We noted that we finalized a policy to discontinue our composite APC payment policies for cardiac electrophysiologic evaluation and ablation services (APC 8000), and to pay for these services through C–APC 0086 (Level III Electrophysiologic Procedures), as presented in a proposal included under section II.A.2.e. of the CY 2015 OPPS/ASC proposed rule (79 FR 66800 through 66810). As a result, in the CY 2015 OPPS/ASC final rule with comment period, we deleted APC 8000 for CY 2015 (79 FR 66810). For CY 2016, we proposed to continue to pay for cardiac electrophysiologic evaluation and ablation services through existing C–APC 0086 (that was proposed to be renumbered C–APC 5213).

(1) Low Dose Rate (LDR) Prostate Brachytherapy Composite APC

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the composite treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex), which are generally present together on claims for the same date of service in the same operative session. In order to base payment on claims for the most common clinical scenario, and to further our goal of providing payment under the OPPS for a larger bundle of component services provided in a single hospital encounter, beginning in CY 2008, we began providing a single payment for LDR prostate brachytherapy when the composite service, reported as CPT codes 55875 and 77778, is furnished in a single hospital encounter. We base the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the geometric mean cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778 and that do not contain other separately paid codes that are not on the bypass list. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66652 through 66655) for a full history of OPPS payment for LDR prostate brachytherapy services and a detailed description of how we developed the LDR prostate brachytherapy composite APC. (We note that, for CY 2016, we did not propose to renumber composite APC 8001 as part of our overall APC restructuring and renumbering discussed in section III.D. of the proposed rule.)

In the CY 2016 OPPS/ASC proposed rule (80 FR 39229), for CY 2016, we proposed to continue to pay for LDR prostate brachytherapy services using the composite APC payment methodology proposed and implemented for CY 2008 through CY 2015. That is, we proposed to use CY 2014 claims reporting charges for both CPT codes 55875 and 77778 on the same date of service with no other separately paid procedure codes (other than those on the bypass list) to calculate the proposed payment rate for composite APC 8001. Consistent with our CY 2008 through CY 2015 practice, in the proposed rule, we proposed to not use the claims that meet these criteria in the calculation of the geometric mean costs of procedures or services assigned to APC 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures) (which was proposed to be renumbered APC 5375 in the proposed rule) and APC 0651 (Complex Interstitial Radiation Source Application) (which was proposed to be renumbered APC 5641 in the proposed rule), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. We proposed to continue to calculate the proposed geometric mean costs of procedures or services assigned to proposed renumbered APCs 5375 and 5641 using single and ''pseudo'' single procedure claims. We stated that we continue to believe that composite APC 8001 contributes to our goal of creating hospital incentives for efficiency and cost containment, while providing hospitals with the most flexibility to manage their resources. We

also stated that we continue to believe that data from claims reporting both services required for LDR prostate brachytherapy provide the most accurate geometric mean cost upon which to base the proposed composite APC payment rate.

Using a partial year of CY 2014 claims data available for the CY 2016 proposed rule, we were able to use 226 claims that contained both CPT codes 55875 and 77778 to calculate the proposed geometric mean cost of approximately $3,807 for these procedures upon which the proposed CY 2016 payment rate for composite APC 8001 was based.

Comment: One commenter expressed concern that the proposed CY 2016 payment rate for APC 8001 is based only on 226 claims that reported both CPT codes 55875 and 77778 on the same date of service, a significant decrease in the number of claims used from the CY 2015 final rule ratesetting, which was based on 406 available claims.

Response: We were able to identify 240 claims in the CY 2014 claims data available for this CY 2016 final rule, which we used to set the final CY 2016 payment rate for APC 8001 (which has a geometric mean cost of approximately $3,542), compared to the 226 claims that were available and used for ratesetting for the CY 2016 proposed rule (which had a geometric mean cost of approximately $3,807). With regard to the commenters' concern regarding the decrease in the number of claims available for CY 2016 ratesetting relative to the number of claims available for CY 2015 ratesetting, we note that there is typically some fluctuation in costs from year to year. We acknowledge that the number of claims available and used for ratesetting for APC 8001 has continuously decreased over recent years. However, the percentage of single frequency claims compared to total claims that were available and that we were able to use for ratesetting in this final rule with comment period is comparable to prior years.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to continue to use the payment rate for composite APC 8001 to pay for LDR prostate brachytherapy services for CY 2016 and to set the payment rate for this APC using our established methodology.

(2) Mental Health Services Composite APC

In the CY 2016 OPPS/ASC proposed rule (80 FR 39229 through 39230), for CY 2016, we proposed to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

Specifically, we proposed that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on one date of service based on the payment rates associated with the APCs for the individual services exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be assigned to proposed renumbered composite APC 8010 (Mental Health Services Composite) (existing APC 0034). We also proposed to continue to set the payment rate for proposed renumbered composite APC 8010 at the same payment rate that we proposed to establish for proposed renumbered APC 5862 (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs) (existing APC 0176), which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the payment rate for proposed renumbered composite APC 8010. Under this policy, the I/OCE would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for proposed renumbered APC 5862 (existing APC 0176) for all of the specified mental health services furnished by the hospital on that single date of service. We stated that we continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource-intensive of all outpatient mental health services. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

We did not receive any public comments on this proposal. Therefore, we are finalizing our CY 2016 proposal, without modification, that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on one date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be assigned to renumbered composite APC 8010 (Mental Health Services Composite) (existing APC 0034) for CY 2016. For CY 2016, we also will continue to set the payment rate for renumbered composite APC 8010 (existing APC 0034) at the same payment rate that we established for renumbered APC 5862 (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs) (existing APC 0176), which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital will continue to be paid the payment rate for renumbered composite APC 8010.

(3) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, in order to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 12 of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74920 through 74924).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and

• APC 8008 (MRI and MRA with Contrast Composite).

(We note that we did not propose to renumber these composite APCs as part of our overall restructuring and renumbering of APCs as discussed in section III.D. of the proposed rule.)

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

In the CY 2016 OPPS/ASC proposed rule (80 FR 39230), for CY 2016, we proposed to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We stated that we continue to believe that this policy will reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

The proposed CY 2016 payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from a partial year of CY 2014 claims available for the proposed rule that qualified for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we used to calculate the final CY 2014 and CY 2015 geometric mean costs for these composite APCs, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), were identified by asterisks in Addendum N to the proposed rule (which is available via the Internet on the CMS Web site) and are discussed in more detail in section II.A.1.b. of the proposed rule and this final rule with comment period.

For the CY 2016 OPPS/ASC proposed rule, we were able to identify approximately 584,194 ''single session'' claims out of an estimated 1.5 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 39 percent of all eligible claims, to calculate the proposed CY 2016 geometric mean costs for the multiple imaging composite APCs. Table 7 of the proposed rule listed the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2016.

Comment: One commenter supported CMS' decision to not propose any new multiple imaging composite APCs and requested that CMS provide stakeholders with the opportunity to meaningfully comment on any new composite APCs that the agency may propose in the future.

Response: We appreciate the commenter's support.

After consideration of the public comment we received, we are finalizing our proposal to continue the use of multiple imaging composite APCs to pay for services providing more than one imaging procedure from the same family on the same date, without modification. For this CY 2016 final rule with comment period, we were able to identify approximately 616,602 ''single session'' claims out of an estimated 1.6 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 38 percent of all eligible claims, to calculate the final CY 2016 geometric mean costs for the multiple imaging composite APCs. Table 10 below lists the HCPCS codes that are subject to the multiple imaging composite APC policy and their respective families and approximate composite APC geometric mean costs for CY 2016.

TABLE 10—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1—Ultrasound	
CY 2016 APC 8004 (Ultrasound Composite)	CY 2016 Approximate APC Geometric Mean Cost = $296
76604	Us exam, chest.
76700	Us exam, abdom, complete.
76705	Echo exam of abdomen.
76770	Us exam abdo back wall, comp.
76775	Us exam abdo back wall, lim.
76776	Us exam k transpl w/Doppler.
76831	Echo exam, uterus.
76856	Us exam, pelvic, complete.
76870	Us exam, scrotum.
76857	Us exam, pelvic, limited.
Family 2—CT and CTA with and without Contrast	
CY 2016 APC 8005 (CT and CTA without Contrast Composite) *	CY 2016 Approximate APC Geometric Mean Cost = $325
70450	Ct head/brain w/o dye.
70480	Ct orbit/ear/fossa w/o dye.
70486	Ct maxillofacial w/o dye.

TABLE 10—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

70490	Ct soft tissue neck w/o dye.
71250	Ct thorax w/o dye.
72125	Ct neck spine w/o dye.
72128	Ct chest spine w/o dye.
72131	Ct lumbar spine w/o dye.
72192	Ct pelvis w/o dye.
73200	Ct upper extremity w/o dye.
73700	Ct lower extremity w/o dye.
74150	Ct abdomen w/o dye.
74261	Ct colonography, w/o dye.
74176	Ct angio abd & pelvis.
CY 2016 APC 8006 (CT and CTA with Contrast Composite)	CY 2016 Approximate APC Geometric Mean Cost = $548
70487	Ct maxillofacial w/dye.
70460	Ct head/brain w/dye.
70470	Ct head/brain w/o & w/dye.
70481	Ct orbit/ear/fossa w/dye.
70482	Ct orbit/ear/fossa w/o & w/dye.
70488	Ct maxillofacial w/o & w/dye.
70491	Ct soft tissue neck w/dye.
70492	Ct sft tsue nck w/o & w/dye.
70496	Ct angiography, head.
70498	Ct angiography, neck.
71260	Ct thorax w/dye.
71270	Ct thorax w/o & w/dye.
71275	Ct angiography, chest.
72126	Ct neck spine w/dye.
72127	Ct neck spine w/o & w/dye.
72129	Ct chest spine w/dye.
72130	Ct chest spine w/o & w/dye.
72132	Ct lumbar spine w/dye.
72133	Ct lumbar spine w/o & w/dye.
72191	Ct angiograph pelv w/o & w/dye.
72193	Ct pelvis w/dye.
72194	Ct pelvis w/o & w/dye.
73201	Ct upper extremity w/dye.
73202	Ct uppr extremity w/o & w/dye.
73206	Ct angio upr extrm w/o & w/dye.
73701	Ct lower extremity w/dye.
73702	Ct lwr extremity w/o & w/dye.
73706	Ct angio lwr extr w/o & w/dye.
74160	Ct abdomen w/dye.
74170	Ct abdomen w/o & w/dye.
74175	Ct angio abdom w/o & w/dye.
74262	Ct colonography, w/dye.
75635	Ct angio abdominal arteries.
74177	Ct angio abd & pelv w/contrast.
74178	Ct angio abd & pelv 1+ regns.

* If a ''without contrast'' CT or CTA procedure is performed during the same session as a ''with contrast'' CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.

Family 3—MRI and MRA with and without Contrast

CY 2016 APC 8007 (MRI and MRA without Contrast Composite) *	CY 2016 Approximate APC Geometric Mean Cost = $631
70336	Magnetic image, jaw joint.
70540	Mri orbit/face/neck w/o dye.
70544	Mr angiography head w/o dye.
70547	Mr angiography neck w/o dye.
70551	Mri brain w/o dye.
70554	Fmri brain by tech.
71550	Mri chest w/o dye.
72141	Mri neck spine w/o dye.
72146	Mri chest spine w/o dye.
72148	Mri lumbar spine w/o dye.
72195	Mri pelvis w/o dye.
73218	Mri upper extremity w/o dye.
73221	Mri joint upr extrem w/o dye.
73718	Mri lower extremity w/o dye.
73721	Mri jnt of lwr extre w/o dye.
74181	Mri abdomen w/o dye.
75557	Cardiac mri for morph.

TABLE 10—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

75559	Cardiac mri w/stress img.
C8901	MRA w/o cont, abd.
C8904	MRI w/o cont, breast, uni.
C8907	MRI w/o cont, breast, bi.
C8910	MRA w/o cont, chest.
C8913	MRA w/o cont, lwr ext.
C8919	MRA w/o cont, pelvis.
C8932	MRA, w/o dye, spinal canal.
C8935	MRA, w/o dye, upper extr.
CY 2016 APC 8008 (MRI and MRA with Contrast Composite)	CY 2016 Approximate APC Geometric Mean Cost = $945
70549	Mr angiograph neck w/o & w/dye.
70542	Mri orbit/face/neck w/dye.
70543	Mri orbt/fac/nck w/o & w/dye.
70545	Mr angiography head w/dye.
70546	Mr angiograph head w/o & w/dye.
70547	Mr angiography neck w/o dye.
70548	Mr angiography neck w/dye.
70552	Mri brain w/dye.
70553	Mri brain w/o & w/dye.
71551	Mri chest w/dye.
71552	Mri chest w/o & w/dye.
72142	Mri neck spine w/dye.
72147	Mri chest spine w/dye.
72149	Mri lumbar spine w/dye.
72156	Mri neck spine w/o & w/dye.
72157	Mri chest spine w/o & w/dye.
72158	Mri lumbar spine w/o & w/dye.
72196	Mri pelvis w/dye.
72197	Mri pelvis w/o & w/dye.
73219	Mri upper extremity w/dye.
73220	Mri uppr extremity w/o & w/dye.
73222	Mri joint upr extrem w/dye.
73223	Mri joint upr extr w/o & w/dye.
73719	Mri lower extremity w/dye.
73720	Mri lwr extremity w/o & w/dye.
73722	Mri joint of lwr extr w/dye.
73723	Mri joint lwr extr w/o & w/dye.
74182	Mri abdomen w/dye.
74183	Mri abdomen w/o & w/dye.
75561	Cardiac mri for morph w/dye.
75563	Card mri w/stress img & dye.
C8900	MRA w/cont, abd.
C8902	MRA w/o fol w/cont, abd.
C8903	MRI w/cont, breast, uni.
C8905	MRI w/o fol w/cont, brst, un.
C8906	MRI w/cont, breast, bi.
C8908	MRI w/o fol w/cont, breast.
C8909	MRA w/cont, chest.
C8911	MRA w/o fol w/cont, chest.
C8912	MRA w/cont, lwr ext.
C8914	MRA w/o fol w/cont, lwr ext.
C8918	MRA w/cont, pelvis.
C8920	MRA w/o fol w/cont, pelvis.
C8931	MRA, w/dye, spinal canal.
C8933	MRA, w/o&w/dye, spinal canal.
C8934	MRA, w/dye, upper extremity.
C8936	MRA, w/o&w/dye, upper extr.

* If a ''without contrast'' MRI or MRA procedure is performed during the same session as a ''with contrast'' MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.

3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular patient. The OPPS packages payment for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a

variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which often results if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2000 OPPS final rule (65 FR 18434), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817). Over the last 15 years, as we have refined our understanding of the OPPS as a prospective payment system, we have packaged numerous services that were originally paid separately. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

For CY 2016, we have examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment of the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies. In general, in the CY 2016 OPPS/ASC proposed rule (80 FR 39233 through 39236), for CY 2016, we proposed to package the costs of selected newly identified ancillary services into payment with a primary service where we believe that the proposed packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code. Below we discuss the items and services that we proposed to package beginning in CY 2016 and are finalizing in this final rule with comment period.

b. Packaging Policies for CY 2016

(1) Ancillary Services

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66819 through 66822), we conditionally packaged payment for ancillary services assigned to APCs with a geometric mean cost of less than or equal to $100 (prior to application of the conditional packaging status indicator). The ancillary services that we identified are primarily minor diagnostic tests and procedures that are often performed with a primary service, although there are instances where hospitals provide such services alone and without another primary service during the same encounter. Under this policy, we assigned the conditionally packaged services to status indicator ''Q1,'' which indicates that the service is separately payable when not billed on the same date of service as a HCPCS code assigned status indicator ''S,'' ''T,'' or ''V.'' Exclusions to this ancillary service packaging policy include preventive services, certain psychiatric and counseling-related services, and certain low-cost drug administration services. The policy adopted in CY 2015 was proposed in response to public comments on the CY 2014 ancillary packaging proposal, which expressed concern that certain low volume but relatively costly ancillary services would have been packaged into high volume but relatively inexpensive primary services (for example, a visit) (74 FR 74945). We noted in the CY 2015 OPPS/ASC final rule with comment period that the $100 geometric mean cost limit target was a selection criterion for the initial set of services in conditionally packaged ancillary service APCs under this packaging policy. The $100 geometric mean cost target was not intended to be a threshold above which ancillary services will not be packaged, but was a basis for selecting the initial set of APCs under the conditional packaging policy for ancillary services, which would likely be updated and expanded upon in the future. An increase in the geometric mean cost of any of those packaged APCs to above $100 in future years does not change the conditionally packaged status of services assigned to the APCs selected in CY 2015 in a future year. When we finalized this policy, we stated that we would continue to consider services in these APCs to be conditionally packaged and would review the conditionally packaged status of ancillary services annually. The ancillary services packaging policy is codified in the regulations at 42 CFR 419.2(b)(7).

For CY 2016, as we did in CY 2015, we examined categories of ancillary services that are integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment of the primary services that they support. As previously stated, the $100 geometric mean cost target we adopted in CY 2015 was not intended to be a threshold above which ancillary services will not be packaged, but was a basis for selecting the initial set of APCs under the conditional packaging policy for ancillary services, which would likely be updated and expanded upon in the future. Accordingly, in the CY 2016 OPPS/ASC proposed rule (80 FR 39233), for CY 2016, we proposed to not limit our examination to ancillary service APCs with a geometric mean cost of $100 or less. The geometric mean cost limit of $100 only applied in 2015, and it is no longer relevant. We stated in the

proposed rule that we believe there are some ancillary services that are assigned to APCs with a geometric mean cost above $100, but for which conditional packaging is appropriate, given the context in which the service is performed. For CY 2016, we proposed to evaluate categories of ancillary services by considering the clinical similarity of such categories of services to the currently conditionally packaged ancillary services that have already been determined to be integral, ancillary, supportive, dependent, or adjunctive to a primary service. Under this proposal, we identified services in certain APCs that meet these criteria. Specifically, for CY 2016, we proposed to expand the set of conditionally packaged ancillary services to include services in the three APCs listed in Table 8 of the proposed rule (80 FR 39234) (APC 5734 (Level 4 Minor Procedures); APC 5673 (Level 3 Pathology); and APC 5674 (Level 4 Pathology)). Ancillary services in the APCs in Table 8 of the proposed rule are typically furnished with a higher paying, separately payable primary procedure.

However, to avoid packaging a subset of high-cost pathology services into lower cost and possibly nonprimary services (for example, low-cost imaging services) frequently billed with some of the services assigned to Level 3 and Level 4 pathology APCs, we proposed to package Level 3 and 4 pathology services only when they are billed with a surgical service. We believe that pathology services are routine tests that are typically performed ancillary or adjunctive to another primary service, most commonly surgery, to establish or confirm a diagnosis. For the Level 3 and 4 pathology APCs, we proposed that the assigned status indicator would be ''Q2'' (''T packaging''). The HCPCS codes that we proposed to conditionally package as ancillary services for CY 2016 were displayed in Addendum B to the CY 2016 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site). The supporting documents for the proposed rule are available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Comment: Several commenters supported designating as conditionally packaged the services assigned to APCs 5734, 5673, and 5674.

Response: We appreciate the commenters' support.

Comment: Several commenters objected to the conditional packaging proposal. Some commenters objected because they believed that CMS has finalized too many new packaging policies in recent years. Other commenters objected to the proposed conditionally packaging of the services in the Levels 3 and 4 Pathology APCs because they believed that these more expensive pathology tests (as compared to the services assigned to the Levels 1 and 2 Pathology APCs) could be packaged with less costly surgical procedures.

Response: The number of other recent packaging proposals in the CY 2014 and CY 2015 OPPS/ASC final rules with comment periods has no bearing on this CY 2016 packaging proposal. The CY 2016 packaging proposal is based on the payment packaging principles specified earlier. We believe that these three APCs consist of services that are generally integral, ancillary, supportive, dependent, or adjunctive to a primary service. In addition, because this proposal is for conditional packaging, if the services are provided alone, the services would be separately paid. We also have not stated that more costly services cannot be packaged into less costly services.

After consideration of the public comments we received, we are finalizing our proposal to conditionally packaged ancillary services assigned to APCs 5734, 5673, and 5674 for CY 2016. The three APCs and their CY 2016 final status indicators and payment rates are displayed in Table 11 below.

TABLE 11—APCS FOR CONDITIONALLY PACKAGED ANCILLARY SERVICES FOR CY 2016

Renumbered CY 2016 APC	CY 2016 APC title	CY 2016 OPPS status indicator	CY 2016 payment rate
5734	Level 4 Minor Procedures	Q1	$119.58
5673	Level 3 Pathology	Q2	229.13
5674	Level 4 Pathology	Q2	459.96

The HCPCS codes that we are conditionally packaging as ancillary services for CY 2016 are displayed in Addendum B to this CY 2016 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site). The supporting documents for the final rule with comment period are available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

In addition, in the CY 2016 OPPS/ASC proposed rule (80 FR 39234), we proposed to continue to exclude certain services from this ancillary services packaging policy. As established in CY 2015, preventive services, certain psychiatric and counseling-related services, and certain low-cost drug administration services are separately payable under the OPPS (79 FR 66819). Preventable services that would continue to be exempted from the ancillary service packaging policy for CY 2016 were listed in Table 9 of the proposed rule.

Comment: Several commenters supported this proposal.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our policy to continue to exempt preventive services from the ancillary services packaging policy for CY 2016. Preventive services that will continue to be exempted from the ancillary service packaging policy for CY 2016 and subsequent years are listed in Table 12 below.

TABLE 12—PREVENTIVE SERVICES EXEMPTED FROM THE ANCILLARY SERVICES PACKAGING POLICY

HCPCS code	Short descriptor	CY 2016 status indicator	CY 2016 APC
76977	Us bone density measure	S	5732

TABLE 12—PREVENTIVE SERVICES EXEMPTED FROM THE ANCILLARY SERVICES PACKAGING POLICY—Continued

HCPCS code	Short descriptor	CY 2016 status indicator	CY 2016 APC
77078	Ct bone density axial	S	5521
77080	Dxa bone density axial	S	5522
77081	Dxa bone density/peripheral	S	5521
G0117	Glaucoma scrn hgh risk direc	S	5732
G0118	Glaucoma scrn hgh risk direc	S	5732
G0130	Single energy x-ray study	S	5521
G0389	Ultrasound exam aaa screen	S	5531
G0404	Ekg tracing for initial prev	S	5731
Q0091	Obtaining screen pap smear	S	5731

(2) Drugs and Biologicals That Function as Supplies When Used in a Surgical Procedure

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74930 through 74939), we finalized a policy at 42 CFR 419.2(b)(16) to unconditionally package all drugs and biologicals that function as supplies when used in a surgical procedure. As noted in that final rule with comment period, supplies are a large category of items that typically are either for single patient use or have a shorter life span in use than equipment. Supplies can be anything that is not equipment and include not only minor, inexpensive, or commodity-type items but also include a wide range of products used in the hospital outpatient setting, including certain implantable medical devices, drugs, biologicals, or radiopharmaceuticals (78 FR 74390). When evaluating whether a particular drug may meet the criteria for packaging under this policy, we do not consider low drug product utilization and/or drug product cost (as compared to the primary service APC payment) to be factors in our determination (79 FR 66875). We unconditionally package all drugs and biologicals that function as supplies in a surgical procedure (79 FR 74930).

For CY 2016, we conducted a comprehensive review of CY 2015 separately payable OPPS drugs; that is, drugs with either a status indicator of ''G'' or ''K.'' For each separately payable drug, we reviewed the FDA-approved label and conducted a clinical review to determine whether a drug is indicated for use in a surgical procedure. Based on our clinical review, in the CY 2016 OPPS/ASC proposed rule (80 FR 39235), for CY 2016, we proposed to package payment for the four drugs that were listed in Table 10 of the proposed rule (80 FR 39235) based on their primary function as a supply in a surgical procedure, which typically means that the drug or biological is integral to or dependent on or supportive of or adjunctive to a surgical procedure (HCPCS code J0583 (Injection, bivalirudin, 1 mg); HCPCS code J7315 (Mitomycin, ophthalmic, 0.2 mg); HCPCS code C9447 (Injection, phenylephrine and ketorolac, 4 ml vial); and HCPCS code J0130 (Injection abciximab, 10 mg)). We noted in the proposed rule that one drug, described by HCPCS code C9447, whose payment would otherwise be packaged in CY 2016, currently has pass-through payment status. Therefore, we did not propose to package payment for the drug described by HCPCS code C9447 for CY 2016. Instead, we proposed to package payment for this drug for CY 2018, after its drug pass-through payment status has expired.

Comment: A few commenters requested that CMS not package the drug described by HCPCS code J7315 as a surgical supply. One commenter in particular believed that, because the drug mitomycin is not necessarily required in all trabeculectomies, the packaging regulation for drugs and biologicals that function as supplies when used in a surgical procedure specified at § 419.2(b)(16) of the regulations should not apply to HCPCS code J7315.

Response: We addressed a similar comment and explained this packaging policy as it applies to HCPCS code J7315 in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938). We are repeating some of the points made in our response here. First, HCPCS code J7315 describes a drug. Second, indication for the drug described by HCPCS code J7315 is ''for use as an *adjunct to ab externo glaucoma surgery''* (emphasis added). The drugs that function as surgical supplies packaging policy specified at § 419.2(b)(16) applies to all drugs and biologicals that are either integral or ancillary or supportive or dependent or *adjunctive* to a surgical procedure (78 FR 74938). Because the drug described by HCPCS code J7315 is an adjunct to surgery (the drug's only indication), payment for the drug is packaged in CY 2016 in accordance with § 419.2(b)(16). For purposes of packaging payment, it does not matter in what percentage of trabeculectomies the drug described by HCPCS code J7315 is used. Packaging policies apply both to products that are used as a necessary ingredient to a procedure (meaning that the test or procedure cannot be performed without the product) and to products that are optional and only occasionally used with a procedure. The frequency of use relative to overall procedure frequency is not a factor in determining whether a drug or biological is packaged under § 419.2(b)(16). With packaging of a drug or biological payment into the procedure payment, surgeons, hospitals, and ASCs can weigh the clinical utility of the product for a particular case against the cost of the product (because payment is fixed for the overall procedure and includes all supplies). If the clinical utility of a product is high relative to the cost, hospitals and ASCs (on an order by a physician) would be more likely to use the product. If the opposite is true, they would be less likely to use a product. Packaging policies support the medically necessary use of products and should restrain use that may be more a matter of convenience than of medical necessity. Therefore, we are finalizing our proposal to package the drug described by HCPCS code J7315 (and assign it status indicator ''N'') for CY 2016 and subsequent years.

Comment: One commenter expressed concern that mitomycin is overused in trabeculectomies. The commenter believed that target intraocular pressures (IOPs) should be better tailored to the individual patient rather than always aiming for very low IOPs that are achievable with mitomycin. The commenter stated that the current CMS payment policy of separate payment for mitomycin may encourage the use of mitomycin in trabeculectomy.

Response: We appreciate this thoughtful comment. As stated above, we believe that packaging payment for mitomycin will require facilities to focus on the clinical utility of mitomycin in a particular case because using the packaged drug will be a cost that must be covered by the trabeculectomy procedure payment. On the contrary, separate payment for drugs creates a financial incentive for hospitals and ASCs to use drugs because they are paid an additional amount at ASP+6 percent. In addition, if the facility acquires a drug whose payment is at less than ASP, the profit for using the drug is even greater than 6 percent of the drug's ASP.

Comment: One commenter requested that CMS not package the drug described by HCPCS code C9447 (phenylephrine and ketorolac) as a surgical supply beginning in CY 2018. While the commenter did not disagree that the drug would be subject to the packaging regulation at § 419.2(b)(16), the commenter predicted that packaging of this drug will result in the use of lower quality alternative drugs. In addition, the commenter requested that, if CMS packages payment for the drug described by HCPCS code C9447, CMS create a separate APC with higher payment rates for procedures that use packaged drugs.

Response: Because the drug described by HCPCS code C9447 functions as a surgical supply in cataract surgery, payment for the drug will be packaged under § 419.2(b)(16) after its pass-through status expires beginning in CY 2018. Which particular drugs surgeons, hospitals, and ASCs will employ to perform cataract surgery is a matter of choice by the physician and the facility. Through packaging of the payment for supplies into the payment for the procedure, CMS generally leaves decision-making about which packaged services to use during a procedure in the hands of physicians and providers. We believe that pass-through payment status should facilitate the use of the drug described by HCPCS code C9447. With the packaging of the payment for the drug described by HCPCS code C9447 into the cataract surgery procedure payment, we believe surgeons, hospitals, and ASCs can weigh the clinical utility of the product for a particular case against the cost of the product (because payment is fixed for the overall procedure and includes all supplies). If the clinical utility of the drug is high relative to its cost, hospitals and ASCs (on an order by a physician) would be more likely to use the product. If the opposite is true, they would be less likely to use the product. If successful cataract surgery depends upon the use of the drug described by HCPCS code C9447, we expect that hospitals and ASCs will bear the additional cost of the drug. As noted above, packaging policies support the medically necessary use of products and should restrain use that may be more a matter of convenience than of medical necessity.

We are finalizing our proposal to package the drug described by HCPCS code C9447 (and assign it status indicator ''N'') beginning in CY 2018 and subsequent years. We are not creating a separate APC with a higher payment for cataract surgery that uses the drug described by HCPCS code C9447, as the commenter requested. We believe that doing so would be inconsistent with the packaging policy. The payment for cataract surgery is a total payment that includes all necessary equipment and supplies, including drugs and biologicals that are employed before, during, and after a surgery.

Comment: One commenter requested that CMS not package payment for the drug described by HCPCS code J0583. The commenter stated that, because HCPCS code J0583 describes a specified covered outpatient drug (SCOD), the drug cannot be packaged because of the specific statutory payment methodology that applies to SCODs. The commenter also requested that, if CMS finalizes the proposal to package payment for the drug described by HCPCS code J0583 as a surgical supply, CMS should also package payment for the drugs described by HCPCS codes J1327 (Eptifibatide) and J3246 (Tirofiban hydrochloride) to ensure that the packaging policy is not implemented in an arbitrary and capricious manner.

Response: We have previously explained why SCODs can be packaged in the OPPS (72 FR 66766). The drug described by HCPCS code J0583 is indicated for various types of patients undergoing percutaneous coronary intervention (PCI), which we consider to be a surgical procedure for purposes of this packaging policy. The drugs described by HCPCS codes J1327 and J3246 mentioned by the commenter have other indications besides facilitating PCI. The drugs described by HCPCS codes J1327 and J3246 are indicated for the treatment of acute coronary syndrome (ACS). These drugs were not among the drugs proposed to be packaged as surgical supplies because they have nonsurgical indications.

Comment: A few commenters requested that CMS revise its packaging policy to unpackage payment for diagnostic radiopharmaceuticals, stress agents, and Cysview. The commenters believed that packaging payment for these products limits patient access.

Response: We disagree with the commenters that packaging limits patient access to diagnostic radiopharmaceuticals, stress agents, and Cysview. We believe that unconditionally packaging diagnostic radiopharmaceuticals, stress agents, Cysview, and other drugs and biologicals that function as surgical supplies establishes better incentives to ensure clinically appropriate patient care.

As discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925 through 74926), like other prospective payment systems, the OPPS relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a specific service or bundle of specific services for a particular patient. There are many items and services in the OPPS in which use of the item or service may increase the cost per case above that of the average or typical case, and there are cases where no additional items or services are necessary and the cost of a typical case is much less than the average. This is a fundamental aspect of a prospective payment system. Overall, we believe that OPPS payments reflect average estimated costs for both situations and encourage the hospital to assess the appropriate use of those additional items and services in diagnosing bladder cancer and other diseases.

While we continuously examine our claims data to identify data anomalies or inconsistencies in billing patterns, we also welcome and appreciate public comments that support claims data on how our packaging policy may adversely impacts patient access.

After consideration of the public comments we received, we are finalizing our proposal to package payment for the four discussed drugs. We are not modifying our drug packaging policy and will continue to package drugs and biologicals that function as supplies when used in a surgical procedure as codified at 42 CFR 419.2(b)(15) and (b)(16). Table 13 below lists the drugs that we are finalizing as unconditionally packaged surgical supplies beginning in the calendar year indicated in the table.

TABLE 13—DRUGS PACKAGED AS SURGICAL SUPPLIES

HCPCS code	Descriptor	CY 2015 status indicator	Primary use in surgical procedure	First calendar year packaged
J0583	Injection, bivalirudin, 1 mg	K	Percutaneous Coronary Intervention[PCI]/PCTA [percutaneous transluminal coronary angioplasty] procedures.	2016
J7315	Mitomycin, ophthalmic, 0.2 mg	G	Glaucoma surgery	2016
C9447	Injection, phenylephrine and ketorolac, 4 ml vial.	G	Cataract surgery	2018
J0130	Injection abciximab, 10 mg	K	PCI procedure	2016

(3) Clinical Diagnostic Laboratory Tests

(a) Background

In CY 2014, we finalized a policy to package payment for most clinical diagnostic laboratory tests in the OPPS (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17)). Under current policy, certain clinical diagnostic laboratory tests that are listed on the Clinical Laboratory Fee Schedule (CLFS) are packaged in the OPPS as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting on the same date of service as the laboratory test. Specifically, we conditionally package laboratory tests and only pay separately for a laboratory test when (1) it is the only service provided to a beneficiary on a given date of service; or (2) it is conducted on the same date of service as the primary service, but is ordered for a different diagnosis than the other hospital outpatient services and ordered by a practitioner different than the practitioner who ordered the other hospital outpatient services. Also excluded from this conditional packaging policy are molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 (78 FR 74939 through 74942), which are assigned status indicator ''A'' in Addendum B to this final rule with comment period (which is available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*). When laboratory tests are not packaged under the OPPS and are listed on the CLFS, they are paid at the CLFS payment rates outside the OPPS under Medicare Part B.

To implement our packaging policy in CY 2014, we assigned status indicator ''N,'' which describes unconditionally packaged items and services, to all laboratory tests paid at the CLFS rates except molecular pathology tests. We indicated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74939) that hospitals should use the 14X bill type for laboratory tests to bill and receive separate payment for laboratory tests that are the only services provided on a date of service and laboratory tests provided on the same date of service as another hospital outpatient service but ordered for a different diagnosis than the primary service and ordered by a different practitioner than the practitioner who ordered the other hospital outpatient service. Therefore, under our final policy, we relied on hospitals to identify when laboratory tests should be separately paid and bill those laboratory tests on a 14X bill type.

Upon implementation of this final policy in January 2014, the National Uniform Billing Committee (NUBC) expressed concern that the 14X bill type was not an appropriate choice of bill type for billing for laboratory tests other than for laboratory tests on referred specimens and requested that CMS find another mechanism for hospitals to bill for separately payable laboratory tests. (We refer readers to our Medicare Learning Network article on this issue on the CMS Web site at: *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1412.pdf*.) In Transmittal 2971, Change Request 8776, July 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS), which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2971CP.pdf*, we implemented modifier ''L1'' (Separately payable laboratory test) to be used in lieu of the 14X bill type. Specifically, we stated that hospitals should use the ''L1'' modifier to indicate when laboratory tests meet either of the two exceptions for separate payment described above.

(b) CY 2016 Laboratory Test Packaging Proposals and Finalized Policies

In the CY 2016 OPPS/ASC proposed rule (80 FR 39235 through 39236), for CY 2016 and subsequent years, we proposed a few revisions to the laboratory packaging policy. First, with regard to the particular molecular pathology tests in the code range expressly excluded from the previous policy, we proposed to expand this exclusion to exclude all molecular pathology tests from our packaging policy, including any new codes that also describe molecular pathology tests. In our rationale for excluding these laboratory tests from our final packaging policy in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74939), we stated that we did not propose to package molecular pathology laboratory tests because we believed that these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we proposed to package. As stated in the CY 2016 OPPS/ASC proposed rule, we believe that this rationale remains applicable and may be appropriately extended to any new molecular pathology tests. Therefore, for CY 2016, we proposed to assign all laboratory tests that describe molecular pathology tests status indicator ''A'' in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site), which means that they would be separately paid at the CLFS rates outside of the OPPS.

Second, in the CY 2016 OPPS/ASC proposed rule (80 FR 39236), we proposed for CY 2016 to make separate payment for preventive laboratory tests and we assigned them status indicator ''A'' in Addendum B to the proposed rule. Laboratory tests that are considered preventive are listed in Section 1.2, Chapter 18 of the Medicare Claims Processing Manual (Pub. 100–04). We currently make an exception to conditional packaging of ancillary services for ancillary services that are also preventive services (79 FR 66819). We stated in the proposed rule that, for consistency, we believe that such an

exception should also apply to laboratory tests that are classified as preventive services.

Finally, for CY 2016, we proposed in the CY 2016 OPPS/ASC proposed rule (80 FR 39236) to modify our current conditional packaging policy that laboratory tests are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting when those services are provided on the same date of service as the primary service and when they are ordered for the same diagnosis and by the same practitioner as the practitioner who ordered the other hospital outpatient service. Specifically, we proposed to consider laboratory tests provided during the same outpatient stay (rather than specifically provided on a same date of service as the primary service) as integral, ancillary, supportive, dependent, or adjunctive to a primary service or services, except when a laboratory test is ordered for a different diagnosis and by a different practitioner than the practitioner who ordered the other hospital outpatient services. In some cases, outpatient hospital stays span more than a single date. For laboratory tests reported on a claim with a primary service, we stated in the proposed rule that we do not believe that a different date of service for the laboratory test affects whether that test is integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the HOPD. Further, as we discussed in the proposed rule, in reviewing our CY 2014 claims data, we observed hospitals indicating separate payment by reporting the ''L1'' modifier for only a few laboratory tests reported on different days than another hospital outpatient service. We concluded that hospitals generally do not view laboratory tests occurring on a different day than a primary service during an outpatient stay as a reason for separate payment. Therefore, we proposed to package laboratory tests that are reported on the same claim with a primary service, regardless of the date of service.

As stated in the proposed rule (80 FR 39236), this proposal does not affect our existing policy to provide separate payment for laboratory tests: (1) If they are the only services furnished to an outpatient and are the only services on a claim and have a payment rate on the CLFS; or (2) if they are ordered for a different diagnosis than another hospital outpatient service by a practitioner different than the practitioner who ordered the other hospital outpatient service (78 FR 74942). As indicated in the proposed rule, we also plan to continue to have hospitals report the ''L1'' modifier to identify any clinically ''unrelated'' laboratory tests that are furnished on the same claim as OPPS services, but are ordered by a different practitioner and for a different diagnosis than the other hospital outpatient service. However, for ease of administration, we also proposed to implement claims processing edits through a new conditional packaging status indicator ''Q4'' that would identify 13X bill type claims where there are only laboratory HCPCS codes that appear on the CLFS; automatically change their status indicator to ''A''; and pay them separately at the CLFS payment rates. For such claims, the ''L1'' modifier would not be used (80 FR 39236). Status indicator ''Q4'' is defined as ''packaged APC payment if billed on the same claim as a HCPCS code assigned status indicator ''J1,'' ''J2,'' ''S,'' ''T,'' ''V,'' ''Q1,'' ''Q2,'' or ''Q3,'' otherwise separately paid, and would apply to conditionally packaged laboratory tests. In our CY 2014 claims data, we observed some claims reporting laboratory services and no other OPPS services that were not paid because the hospital did not appropriately report the ''L1'' modifier. We further believe that the status indicator ''N'' for unconditional packaging does not accurately reflect the payment status of these laboratory tests. These tests may be eligible to receive separate payment at the CLFS payment rates in several circumstances as discussed above. With the assignment of the proposed ''Q4'' modifier to laboratory tests, we proposed that modifier ''L1'' would only be used to identify ''unrelated'' laboratory tests that are ordered for a different diagnosis and by a different practitioner than the other hospital outpatient services on the claim.

We invited public comments on these proposals.

Comment: Many commenters agreed with expanding the molecular pathology test exception to include new molecular pathology tests, and not only the tests listed in the CY 2014 OPPS/ASC final rule with comment period. In addition, many commenters agreed with the proposal for separate payment for preventive laboratory tests.

Response: We appreciate the commenters' support for these proposals.

Comment: A few commenters disagreed with the assignment of status indicator ''E'' (Not paid by Medicare when submitted on outpatient claims) for the following CPT codes that describe new multianalyte assays with algorithmic analyses (MAAAs):

- CPT code 81490 (Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score);
- CPT code 81535 (Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination);
- CPT code 81536 (Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure)); and
- CPT code 81538 (Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival).

In addition, the commenters agreed with CMS' designation of certain other MAAAs as separately paid molecular pathology tests, but requested that CMS also assign status indicator ''A'' to the four MAAAs codes listed above. The commenters believed that the rationale stated in the proposed rule for not packaging payment for molecular pathology laboratory tests (that is, that ''we believed that these relatively new tests [molecular pathology laboratory tests] may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we . . . package'' (80 FR 39236)) applies equally to the four new nonmolecular pathology MAAAs listed above, and for this reason, payment for these MAAAs should also not be packaged.

Response: We agree in part with the commenters. We agree that the MAAAs codes in question should not be assigned status indicator ''E'' for CY 2016 because there is some local Medicare coverage for these codes. However, the proposal was limited to molecular pathology laboratory tests and not to any laboratory test that could possibly fit into the molecular pathology test exception rationale. While we did not propose to extend the packaging exception that applies to molecular pathology laboratory tests to these nonmolecular pathology MAAAs laboratory tests, we may consider whether additional exceptions to the OPPS laboratory test packaging policy should apply to tests other than

molecular pathology tests in the future. For CY 2016, the four MAAAs codes listed above are assigned status indicator ''Q4.''

Comment: Many commenters supported the proposed ''Q4'' status indicator for conditionally packaged laboratory tests. The commenters expressed their appreciation for the administrative convenience this policy will afford hospitals in receiving separate payment without the use of a modifier for laboratory tests provided without other hospital services. However, some commenters objected to the associated logic of applying laboratory test packaging at the claim level instead of at the date of service level. These commenters believed that laboratory tests performed during an outpatient hospital stay but on a different date of service might not be ancillary to a primary service on a different date of service. Some commenters also believed that payment for laboratory tests should not be packaged into payment for other conditionally packaged services that are assigned status indicator ''Q1'' or ''Q2,'' because they were concerned that the cost of some packaged laboratory tests could exceed the cost of other conditionally packaged services into which the laboratory tests are packaged.

Response: We appreciate the commenters' support for the proposed ''Q4'' status indicator. However, we believe that the ''Q4'' status indicator should apply at the claim level. We believe that it is appropriate to package payment for laboratory tests that are provided on a different date of service than other hospital services. For example, a patient could be seen in the emergency room and receive some laboratory tests prior to midnight and receive the remainder of the services after midnight on a different date of service. This order of services should not affect whether the laboratory tests are packaged. Therefore, we believe that the ''Q4'' status indicator should identify packaging of laboratory tests into procedures on the same claim, regardless of the date of service, unless an exception applies. Regarding the commenters' concern about costly laboratory tests possibly being packaged into less costly services that are assigned status indicator ''Q1'' or ''Q2,'' it is possible that this could happen but, given the low cost of most laboratory tests relative to most other hospital outpatient services, we do not believe that this would be a common occurrence. In addition, packaging in the OPPS is not limited to only ancillary or subordinate services that are lower cost than a primary service. In some cases, the packaged services can have a higher cost than the primary service.

After consideration of the public comments we received, we are finalizing the changes to the laboratory test packaging policy as proposed, with one modification. We are assigning status indicator ''Q4'' (instead of ''E'') to CPT codes 81490, 81535, 81536, and 81538. Status indicator assignments for laboratory tests are included in Addendum B to this final rule with comment period (which is available at the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*). When laboratory tests are not packaged under the OPPS and are listed on the CLFS, they are paid at the CLFS payment rates outside the OPPS under Medicare Part B.

4. Calculation of OPPS Scaled Payment Weights

In the CY 2016 OPPS/ASC proposed rule (80 FR 39236 through 39237), we proposed to calculate the relative payment weights for each APC shown in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site) using the APC costs discussed in sections II.A.1. and II.A.2. of the proposed rule. Prior to CY 2007, we standardized all of the relative payment weights to APC 0601 (Mid-Level Clinic Visit) because mid-level clinic visits were among the most frequently performed services in the hospital outpatient setting. We assigned APC 0601 a relative payment weight of 1.00 and divided the median cost for each APC by the median cost for APC 0601 to derive an initial unscaled relative payment weight for each APC.

Beginning with the CY 2007 OPPS (71 FR 67990), we standardized all of the relative payment weights to the median cost of APC 0606 (Level 3 Clinic Visits) because we deleted APC 0601 as part of the reconfiguration of the clinic visit APCs. We selected APC 0606 as the base APC because it was the mid-level clinic visit APC (that is, Level 3 of 5 levels). We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs rather than median-based APC costs to calculate relative payment weights. In the CY 2016 OPPS/ASC proposed rule (80 FR 39236 through 39237), we proposed to continue this policy for CY 2016 and subsequent years.

As noted earlier for CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a new policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For the CY 2014 and CY 2015 OPPS final rules with comment period, we standardized all of the relative payment weights to the geometric mean cost of APC 0634 as discussed in section VII. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66823). As noted in section VII. of the CY 2016 proposed rule, for CY 2016, we proposed to delete APC 0634 and to move the outpatient clinic visit HCPCS code G0463 to APC 0632 (Level 2 Examinations and Related Services) (80 FR 39237). Accordingly, for CY 2016 and subsequent years, we proposed to standardize all of the relative payment weights to APC 0632. As stated in the proposed rule, we believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2016, we proposed to renumber APC 0632 as APC 5012 (Level 2 Examination and Related Services). For CY 2016, we proposed to assign proposed renumbered APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the proposed geometric mean cost for proposed renumbered APC 5012 to derive the proposed unscaled relative payment weight for each APC. The choice of the APC on which to standardize the proposed relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated

aggregate weight under the OPPS for CY 2016 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, we proposed to compare the estimated aggregate weight using the CY 2015 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2016 unscaled relative payment weights.

We did not receive any public comments on our proposal to use the geometric mean cost of renumbered APC 5012 to standardize relative payment weights. Therefore, we are finalizing the use of the relative payment weight of 1.00 for APC 5012 to derive the unscaled relative payment weight for each APC.

For CY 2015, we multiplied the CY 2015 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2014 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2016, we proposed to apply the same process using the estimated CY 2016 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scaler by dividing the CY 2015 estimated aggregate weight by the unscaled CY 2016 estimated aggregate weight (80 FR 39237).

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* Click on the CY 2016 OPPS final rule link and open the claims accounting document link at the bottom of the page.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39237), we proposed to compare the estimated unscaled relative payment weights in CY 2016 to the estimated total relative payment weights in CY 2015 using CY 2014 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we proposed to adjust the calculated CY 2016 unscaled relative payment weights for purposes of budget neutrality. We proposed to adjust the estimated CY 2016 unscaled relative payment weights by multiplying them by a weight scaler of 1.3823 to ensure that the proposed CY 2016 relative payment weights are scaled to be budget neutral. The proposed CY 2016 relative payment weights listed in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site) were scaled and incorporated the recalibration adjustments discussed in sections II.A.1. and II.A.2. of the proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.3. of this final rule with comment period) is included in the budget neutrality calculations for the CY 2016 OPPS.

We did not receive any public comments on the proposed weight scaler calculation. Therefore, we are finalizing the calculation process described in the proposed rule without modification. Using updating final rule claims data, we are updating the estimated CY 2016 unscaled relative payment weights by multiplying them by a weight scaler of 1.3852 to ensure that the final CY 2016 relative payment weights are scaled to be budget neutral.

B. Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49508), consistent with current law, based on IHS Global Insight, Inc.'s second quarter 2015 forecast of the FY 2016 market basket increase, the FY 2016 IPPS market basket update is 2.4 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(iv) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), provide adjustments to the OPD fee schedule increase factor for CY 2016.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509), we discussed the calculation of the final MFP adjustment for FY 2016, which is a 0.5 percentage point reduction.

In the CY 2016 OPPS/ASC proposed rule, we proposed that if more recent data became subsequently available after the publication of the proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such updated data, if appropriate, to determine the CY 2016 market basket update and the MFP adjustment, components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2016 OPPS/ASC final rule with comment period. Consistent with that proposal, and the FY 2016 IPPS/LTCH PPS final rule, we applied the updated final FY 2016 market basket percentage increase and the MFP adjustment to the OPD fee schedule increase factor for the CY 2016 OPPS.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that, for each of years 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 2016, section 1833(t)(3)(G)(iv) of the Act provides a -0.2 percentage point reduction to the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act. Therefore, in accordance with sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(iv) of the Act, in the CY 2016 OPPS/ASC proposed rule, we proposed to apply a 0.2 percentage point reduction to the OPD fee schedule increase factor for CY 2016.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee

schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we are applying an OPD fee schedule increase factor of 1.7 percent for the CY 2016 OPPS (which is 2.4 percent, the final estimate of the hospital inpatient market basket percentage increase, less the final 0.5 percentage point MFP adjustment, and less the 0.2 percentage point additional adjustment).

Hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIII. of this final rule with comment period.

In the CY 2016 OPPS/ASC proposed rule, we proposed to amend 42 CFR 419.32(b)(1)(iv)(B) by adding new paragraph (*7*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2016, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS, and to reflect the requirement in section 1833(t)(3)(G)(iv) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by an additional 0.2 percentage point for CY 2016.

We did not receive any public comments on our proposed adjustments to the OPD fee schedule increase factor or on the proposed changes to the regulations at 42 CFR 419.32(b)(1)(iv)(B). For the reasons discussed above, we are adjusting the OPD fee schedule increase factor and finalizing the changes to the regulations as proposed.

To set the OPPS conversion factor for the CY 2016 proposed rule, we increased the CY 2015 conversion factor of $74.173 by 1.9 percent. In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the conversion factor for CY 2016 to ensure that any revisions made to the wage index and rural adjustment were made on a budget neutral basis. We calculated an overall budget neutrality factor of 0.9993 for wage index changes by comparing total estimated payments from our simulation model using the FY 2016 IPPS wage indexes to those payments using the FY 2015 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For the CY 2016 proposed rule, we maintained the current rural adjustment policy, as discussed in section II.E. of this final rule with comment period. Therefore, we set the budget neutrality factor for the rural adjustment is 1.0000.

For the CY 2016 proposed rule, we proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this final rule with comment period. Consistent with that policy, we calculated a CY 2016 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2016 payments under section 1833(t) of the Act, including the CY 2016 cancer hospital payment adjustment, to estimated CY 2016 total payments using the CY 2015 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The CY 2016 estimated payments applying the CY 2016 cancer hospital payment adjustment are identical to estimated payments applying the CY 2015 final cancer hospital payment adjustment. Therefore, we applied a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment.

For the proposed rule, we estimated that pass-through spending for drugs, biologicals, and devices for CY 2016 would equal approximately $136.8 million, which represented 0.25 percent of total projected CY 2016 OPPS spending. Therefore, the conversion factor was adjusted by the difference between the 0.13 percent estimate of pass-through spending for CY 2015 and the 0.25 percent estimate of pass-through spending for CY 2016, resulting in an adjustment for CY 2016 of −0.12 percent. Estimated payments for outliers remained at 1.0 percent of total OPPS payments for CY 2016. We estimated for the proposed rule that outlier payments would be 0.95 percent of total OPPS payments in CY 2015; the 1.0 percent for outlier payments in CY 2016 would constitute a 0.05 percent increase in payment in CY 2016 relative to CY 2015.

We did not receive any public comments on our proposed general methodology for calculating the CY 2016 conversion factor. Therefore, we are finalizing the methodology in this final rule with comment period.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39238), we also proposed to exercise our authority in section 1833(t)(3)(C)(iii) of the Act to further adjust the conversion factor to eliminate the effect of coding and classification changes that we believe resulted in a change in aggregate payments that do not reflect real changes in service-mix related to our final policy to package certain clinical diagnostic laboratory tests in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74939 through 74942). Below we discuss our proposed and final adjustment to the conversion factor to redress the inflation in the OPPS payment rates for CY 2016 resulting from excess packaged payment under the OPPS for laboratory tests that we now understand continue to be paid separately outside the OPPS.

The current clinical diagnostic laboratory test packaging policy packages payment for laboratory tests in the OPPS when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting. Under current policy, payment for a laboratory test is not packaged when: (1) A laboratory test is the only service provided to the beneficiary on that date of service; or (2) a laboratory test is conducted on the same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service. The laboratory tests falling under these two exceptions continue to be paid separately at the CLFS payment rates outside the OPPS.

In addition, we exclude payment for molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81404, and 81479 from packaging (78 FR 74939). In section II.A.3.b.(3) of the proposed rule, we proposed to expand this exclusion to exclude all molecular pathology tests from our packaging policy, including any new codes that also describe molecular pathology tests. Finally, we continue to pay separately for referred specimens billed on a 14X bill type because these services will always consist only of laboratory services. We also make separate (that is, not packaged) payment for laboratory tests billed on a 12X (inpatient Part B) bill type claim when billed for reasons other than rebilling for a denied Part A claim, such as inpatient Part B coverage following exhausted Part A benefits. We refer readers to section II.A.3.b.(3) of this final rule with comment period for a detailed discussion of our laboratory test packaging policy exceptions and to review our proposals, and final policy, to modify our laboratory test packaging policy in light of current experience with this policy.

In monitoring aggregate payments for CY 2014, we observed that OPPS

spending for hospital outpatient services experienced double digit growth in 2014 compared to typical growth of 6 to 8 percent, due to our CY 2014 final policy to package laboratory services, without a comparable reduction in spending for laboratory services paid at the CLFS payment rates outside the OPPS. As part of our CY 2014 final policy to package certain clinical diagnostic laboratory tests, we both revised the OPPS relative payment weights to reflect packaged laboratory services, and we increased the OPPS relative weight scaler to reflect the estimated total cost of packaged laboratory services. In calculating the appropriate increase to the weight scaler for CY 2014, we estimated that we spent approximately $2.4 billion on laboratory services on 13X type bill claims, and we incorporated this aggregate amount of weight into our estimate of the 2013 relative weight when calculating the budget neutral weight scaler to scale all relative weights for CY 2014, except those with a fixed payment amount such as drugs paid at ASP+6 percent (78 FR 74948 through 74949). An adjustment to the overall weight scaler has a comparable effect on final payment as an adjustment to the conversion factor. We also assumed that separate payment would continue for laboratory services billed on 14X bill type claims for referred specimens and for select inpatient Part B claims billed on a 12X bill type claim. Thus, we stated that we expected to experience an increase in OPPS spending due to our final packaging policy and a commensurate reduction in overall payment for Medicare Part B laboratory tests paid at the CLFS rates outside the OPPS.

However, as we discussed in the CY 2016 OPPS/ASC proposed rule (80 FR 39239), upon reviewing actual claims for CY 2014, we observed an unexpectedly high volume of laboratory tests associated with $1 billion in spending for exceptions to our packaging policy for laboratory tests that continued to receive separate payment at the CLFS payment rates outside the OPPS. We did not observe a significant change in the overall volume of laboratory services being furnished. Specifically, we observed a pronounced shift in volume from billing on the 13X bill type claims to the 14X bill type claims beginning January 1, 2014, consistent with our final rule policy and then shifting back to the 13X bill type claims with an ''L1'' modifier when our instructions on billing for laboratory tests that are excepted from our laboratory packaging policy were implemented in July 2014. (We refer readers to Transmittal 2971, Change Request 8776, July 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS), which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2971CP.pdf.*) Because we did not observe a significant change in the number of laboratory services in our claims data, we concluded that the changes in aggregate payments under the OPPS were a result of changes in pricing alone and did not reflect real changes in service-mix.

Therefore, we overestimated the adjustment necessary to account for the new policy to package laboratory tests and underestimated the amount of spending that would continue for laboratory tests paid at the CLFS rates outside the OPPS by approximately $1 billion. This $1 billion effectively resulted in inflation in the OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests for all OPPS services and duplicate payments for certain laboratory tests because we are paying the laboratory tests through packaged payment incorporated into the OPPS payment rates as well as through separate payment at the CLFS payment rates outside the OPPS.

Section 1833(t)(3)(C)(iii) of the Act specifies that if the Secretary determines the adjustments for service-mix for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service-mix, the Secretary may adjust the conversion factor for subsequent years so as to eliminate the effect of such coding or classification changes. Based on this authority, we proposed a reduction of 2.0 percentage points to the proposed CY 2016 conversion factor to redress inappropriate inflation in the OPPS payment rates and prevent CY 2016 payment rates from including $1 billion in excess packaged payment. We also used the ''L1'' modifier information on the CY 2014 claims data that we use to model the OPPS to identify which laboratory services should be packaged into the associated OPPS services when establishing the proposed CY 2016 relative weights. We proposed this reduction in order to eliminate the effect of the coding and classification changes for payment for laboratory tests that resulted in changes in aggregate payments, but which did not result in real changes in service-mix under the OPPS. If we had been able to accurately forecast the amount of continued spending on separately payable laboratory tests that would continue in CY 2014 at the CLFS rates outside the OPPS, we would have incorporated a reduced amount of estimated spending into our CY 2014 OPPS budget neutrality calculations in CY 2014 rulemaking.

We conducted several analyses to better understand the derivation of the overestimated adjustment made in CY 2014. These efforts included an attempt to determine how much spending at the CLFS payment rates outside the OPPS should have been packaged in CY 2014 with full knowledge of the actual volume for exceptions to our final laboratory tests packaging policy now that CY 2014 claims data are available for review. This assessment required some assumptions about what payment would have been at the CY 2014 CLFS payment amounts using the CLFS national limitation amount (NLA) price or the mode price among jurisdictions where an NLA did not exist for all laboratory services in 12X, 13X, and 14X bill type claims less actual payments for those same services and the $2.4 billion in packaged payments. We adjusted our total estimates for incomplete claims data because the data that we use to model the proposed rule are data from CY 2014 claims processed as of December 31, 2014, estimated at 90 percent based on historical claims data. As a result of this analysis, we estimated that we included a gross estimate of roughly $1.1 billion in excess packaged payment in the CY 2014 OPPS payment rates for laboratory tests that were paid separately, as demonstrated by actual CY 2014 claims data. We also did a more straightforward analysis assessing total payment for our exceptions policy, in which we looked at the change in payment on 14X bill type claims for the first part of CY 2014 along with any payment for laboratory services billed with the ''L1'' modifier. This analysis resulted in a similar estimate of roughly $1.003 billion. Because both analyses resulted in an approximate $1 billion estimate of spending at the CLFS rates outside the OPPS that was packaged into the OPPS, we stated that we believe that a prospective adjustment to remove $1 billion from the CY 2016 OPPS payment rates would realign total aggregate OPPS payments to reflect the resources associated with OPPS services. When we calculated the $1 billion as a percent of actual total spending for OPPS services in CY 2014 (approximately $50 billion), we determined an estimated 2.0 percent

reduction to total spending to be applied to the conversion factor in CY 2016. Therefore, in the CY 2016 OPPS/ASC proposed rule, we proposed to apply a 2.0 percent adjustment to the proposed CY 2016 conversion factor to redress the inflation in the OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests we now understand continue to be paid at the CLFS rates outside the OPPS for CY 2016 and subsequent years.

We also stated in the proposed rule that, for the CY 2017 OPPS rulemaking, we plan to review actual CY 2015 claims data and assess whether our proposed adjustment for CY 2016 accurately adjusted for the inflation in the OPPS payment rates under current policy.

We provided a summary file of our analysis of separate payment at the CLFS rates outside the OPPS for laboratory services that are exceptions to our packaging policy which is available in the ''Downloads'' section of the CMS Web site accompanying the proposed rule (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*). We noted that the ''OPPS limited data set'' that we make available to accompany each proposed and final rule is not a complete set of institutional Part B claims, containing only the 12X, 13X, and 14X bill types that we use to model the OPPS rates and excluding claims weeded or trimmed as discussed in our claims accounting document (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*).

For the proposed rule, we also proposed that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we proposed to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of −0.1 percent (that is, the proposed OPD fee schedule increase factor of 1.9 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2016 of $72.478 for hospitals that fail to meet the Hospital OQR requirements (a difference of −1.451 in the conversion factor relative to hospitals that meet the requirements).

Comment: MedPAC and other commenters commended CMS for recognizing that an adjustment to OPPS payment rates was warranted in light of the effects of the laboratory services packaging policy. MedPAC noted that the proposal to adjust payment rates to prevent continued excess payment is consistent with adjustments CMS has made in IPPS, Medicare Advantage, and the home health prospective payment system in the past.

Response: We appreciate the commenters' support.

Comment: Several commenters suggested that the purpose of the proposed adjustment was to recoup overpayments in CY 2014 and CY 2015, and that recouping overpayments made in prior years was inconsistent with a prospective payment system.

Response: The proposed −2.0 percent adjustment to the conversion factor would not recoup ''overpayments'' made for CYs 2014 and 2015. When we classified laboratory tests as OPPS packaged services in 2014, we increased the conversion factor to account for that change, which resulted in excess payment being built into the rates. The proposal to apply a −2.0 percent adjustment to the conversion factor is intended to address the effects of the OPPS classification changes on OPPS payments for CY 2016 that do not reflect real changes in service-mix. If we do not adjust the conversion factor, the excess payment built into the rates would carry through to the CY 2016 OPPS rates.

Comment: A few commenters suggested that the proposed adjustment to the conversion factor was unfairly applied across the board to OPPS services. The commenters suggested that the adjustment should only apply to services that have packaged laboratory tests.

Response: The proposed adjustment to reduce the conversion factor would apply to all OPPS services, but we also established relative weights in a manner that would target payment effects on services whose payment rates previously reflected excess packaged payment for laboratory services. In modeling the CY 2016 OPPS, we did not include costs for laboratory tests that were billed separately in CY 2014 for purposes of calculating the relative weights of all services. This means that services with excess payment due to packaged laboratory tests in CYs 2014 and 2015 would have had the additional weight for those laboratory services removed from their weight calculation for CY 2016. With that weight removed, all other services would have a higher relative weight than they otherwise would if the costs for those packaged laboratory services had been included in the model. As a result, the proposed adjustment to the conversion factor in conjunction with the relative weights primarily affects the payment for services that previously included excess packaged payment for laboratory tests. Section 1833(t)(3)(C)(iii) of the Act authorizes the agency to adjust the conversion factor, and adjustments to payment rates such as this are often applied across the board to all services.

Comment: One commenter questioned the legality of CMS using section 1833(t)(3)(C)(iii) of the Act as the authority to make the conversion factor adjustment because the commenter viewed the 2.0 percent reduction as a correction to an error CMS made in CY 2014, not an adjustment for service-mix.

Response: The commenter misunderstands the basis for the proposed adjustment. Section 1833(t)(3)(C)(iii) of the Act provides that, if the Secretary determines that adjustments for service-mix for a previous year resulted in (or are likely to result in) a change in aggregate payments that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service-mix, the Secretary may adjust the conversion factor for subsequent years to eliminate the effect of such coding or classification changes. This authority applies to the proposed adjustment.

The increase in aggregate OPPS payments for CY 2014 did not reflect real changes in the service-mix for CY 2014, but, rather, was attributable to classification changes relating to the packaging of laboratory tests in the OPPS.

As we noted in the CY 2016 OPPS proposed rule (80 FR 39239), in our claims data, we did not observe a significant change in the overall volume of laboratory services being furnished in CY 2014. Because we did not observe such a change, and because these services that we packaged continued to be billed and paid separately, we concluded, and confirmed based on several analyses, that the changes in aggregate payments under the OPPS for CY 2014 were the result of classification changes and not real changes in service-mix. In addition, as stated above, the excess built into the rates for CY 2014 and CY 2015 would carry through to the CY 2016 OPPS rates in the absence of an adjustment. Accordingly, we determined that the classification changes relating to packaged laboratory services would likely result in a change in aggregate payments for CY 2016 that does not reflect real changes in service-mix. In accordance with section

1833(t)(3)(C)(iii) of the Act, our proposal to adjust the conversion factor was intended to eliminate the effect of the classification changes for CY 2016.

The Secretary's adjustment is consistent with the statute, is reasonable, and is not arbitrary or capricious. We note that section 1833(t)(12) of the Act precludes administrative and judicial review of the Secretary's calculations under section 1833(t)(3) of the Act, including adjustments under section 1833(t)(3)(C)(iii) of the Act.

Comment: Some commenters suggested that CMS implement a transition period for the conversion factor adjustment so that the adjustment is phased in over several years.

Response: We recognize that the adjustment to the conversion factor is significant for CY 2016, but we do not believe a transition period for the adjustment to the conversion factor is appropriate in this situation because it would allow the excess packaged payments built into the rates for CY 2014 and CY 2015 to continue into CY 2016. We believe it is appropriate to adjust for this excess packaged payment as soon as possible.

Comment: Several commenters suggested that CMS present its analysis of the need for this adjustment to the Advisory Panel on Hospital Outpatient Payment (HOP) in the spring of 2016 before implementing this adjustment to allow the HOP Panel to opine on whether this adjustment is warranted.

Response: As we indicated earlier, we believe it is appropriate to make this adjustment for the CY 2016 payment rates because otherwise the excess packaged payments built into the rates for CY 2014 and CY 2015 would continue into CY 2016. If we waited to present this issue to the HOP Panel, we would not be able to implement this adjustment until the CY 2017 payment year.

Comment: One commenter suggested that the increase in ''unrelated'' laboratory services paid under the CLFS in CY 2014 might be a continuation of the broader trend of inpatient services transitioning to outpatient services and might not be related to the laboratory packaging policy implemented in CY 2014.

Response: Our actuaries' analyses included in conjunction with the proposed rule (80 FR 39239 and the ''Summary Analysis Supporting Adjustment for Excess Laboratory Packaging'' on the OPPS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1633-P.html*) indicate that the total amount of laboratory services performed in the outpatient setting did not increase and that the number of laboratory services performed in the outpatient setting that were deemed ''unrelated'' to OPPS services in CY 2014 were greater than we had estimated they would be with the implementation of the laboratory services packaging policy. As a result, we believe that the higher than expected number of ''unrelated'' laboratory services is reflective of the classification changes related to the laboratory packaging policy and not due to services moving from the inpatient setting to the outpatient setting.

Comment: Several commenters suggested that CMS not implement this adjustment because CMS had not specified in the CY 2014 OPPS final rule that $2.4 billion was being included in the CY 2014 OPPS payment rates to account for newly packaged laboratory services. The commentators indicated that CMS did not specify in the CY 2014 OPPS final rule or in the CY 2016 OPPS proposed rule whether CMS was excluding from the $2.4 billion estimate ''unrelated'' laboratory services that under CMS' CY 2014 policy would be separately paid.

Response: The proposed adjustment to the conversion factor would affect OPPS payments for CY 2016, not CY 2014. In the CY 2014 OPPS/ASC final rule with comment period, we discussed the incorporation of the payment weights for outpatient laboratory tests previously paid at the CLFS payment rates (78 FR 74948 through 74949). The calculation of the OPPS relative weights and payment rates for CY 2014 reflects estimates attributable to packaged laboratory services. While we did not specify the estimated dollar amount ($2.4 billion) attributable to packaged laboratory services in the CY 2014 final rule with comment period, we did specify in the CY 2016 OPPS/ASC proposed rule that an estimated $2.4 billion was effectively added to the OPPS payment system to account for packaged laboratory services in the CY 2014 OPPS/ASC final rule with comment period. Insofar as hospitals may have received significant windfalls for CY 2014 and CY 2015, presumably commenters do not intend to challenge the payments for those years (at least with respect to the incorporation of packaged laboratory services). With respect to the OPPS ratesetting process for CY 2016, we referenced the $2.4 billion estimate in the CY 2016 OPPS/ASC proposed rule (as explained above) and thus commenters had notice of the estimate for purposes of commenting on the proposed adjustment in the CY 2016 OPPS/ASC proposed rule.

Comment: Several commenters suggested that CMS not implement this adjustment because the ''Summary Analysis Supporting Adjustment for Excess Laboratory Packaging,'' released with the CY 2016 OPPS/ASC proposed rule, included data that were not publicly available. The commenters indicated that this summary analysis included CY 2014 data processed through May 31, 2015, while the OPPS limited data set released with the proposed rule included data processed through December 31, 2014. In addition, the commenters noted that the summary analysis displayed monthly data that are not available in the OPPS limited data set. The commenters also noted that CMS did not detail every assumption made in calculating the proposed adjustment, and that without these details it would be difficult for commenters to replicate our actuaries' analysis.

Response: The ''Summary Analysis Supporting Adjustment for Excess Laboratory Packaging'' was provided in conjunction with the proposed rule to give stakeholders/commenters additional information about our methodology for determining the amount of the proposed adjustment, even though the data used for purposes of the summary analysis were not the same exact data used for purposes of the proposed rule. For the supplemental summary analysis, we used the most recent data available to us, CY 2014 claims processed through May 31, 2015, which we estimated to be approximately 98 percent complete. The limited data set (LDS) used for the proposed rule was approximately 90 percent complete. While having 90 percent of claims, as opposed to 98 percent, may have made it difficult for stakeholders to exactly replicate our results, we note that the 90 percent LDS yielded very similar results to the 98 percent dataset, and we believe it would have been sufficient to enable stakeholders to meaningfully comment on the proposed adjustment. Likewise, we provided the table in the supplemental analysis with the data presented by month because we believed it would help stakeholders better understand the proposed adjustment, even if these data are not replicable using the LDS. Specifically, we believed that the monthly breakdown of unrelated laboratory test billing would show that unrelated laboratory test billing was fairly consistent across CY 2014 and that the mid-year change in billing methodology

did not affect billing of unrelated laboratory tests in CY 2014.

We performed multiple analyses to better understand the effect of the classification changes relating to packaged laboratory services on aggregate payments, in order to determine the amount of the proposed adjustment described in the proposed rule (80 FR 39239 through 39240). As mentioned earlier in this section and explained in the proposed rule, in one analysis, we analyzed actual claims data for CY 2014 (using data available for the CY 2016 proposed rule) to determine an estimate of the total dollar amount that ''should have been'' packaged into the OPPS for laboratory services in CY 2014 if we had had perfect information about billing patterns of unrelated services when making our original proposal for CY 2014. We first estimated how much we would have paid if all laboratory services were paid at CLFS NLA rates and had not been packaged under the OPPS. To do this, we began with the CY 2014 claims data which we used for the CY 2016 proposed rule. We identified the number of billed laboratory services for each laboratory test and associated the CY 2014 CLFS NLA payment rate with that utilization to determine a total payment amount in CY 2014 for laboratory services at NLA payment rates. We would expect final CLFS payment to be less than total payment at NLA amounts because the CLFS pays the ''lesser of'' the fee schedule amount, the NLA, or changes (section 1833(a)(1)(D) of the Act). The NLA establishes a ceiling on possible payment. We estimated an overall adjustment factor of 0.88 from the difference in total estimated NLA payment in CY 2012 rates and total final actual CLFS payment on the claims. We used that factor to adjust estimated total payment amounts for laboratory services at NLA payment rates in CY 2014 claims to better reflect what actual payment would have been in CY 2014 under CLFS payment methodologies. In addition, we adjusted the payment amounts to account for the difference between CY 2014 claims data and CY 2012 claims data and to account for the fact that the CY 2014 claims data was only 90 percent complete for the CY 2016 proposed rule. Using our standard methodology, we adjusted these data to account for what they would have shown had they been complete at the time of our analysis. We then examined actual CY 2014 claims data to estimate how much was paid separately for laboratory services in CY 2014. The difference between these estimates reflects a reasonable approximation of the payment that would have been packaged into OPPS for laboratory services in CY 2014 if we had had perfect information about billing patterns of unrelated services when making our original proposal for CY 2014. This analysis indicates that we included a gross estimate of roughly $1 billion in packaged payment in the CY 2014 OPPS payment rates for laboratory tests that ultimately were paid separately in CY 2014 (that is, excess packaged payment for laboratory services).

We also performed an analysis to assess the total payment for laboratory services that were billed on an OPPS claim, but were paid separately in CY 2014 because they were unrelated to the OPPS services. Specifically, using CY 2014 data processed through May 31, 2015, we observed that laboratory services billed on the 14X claim increased immediately beginning in January 2014 (as displayed in the ''Summary Analysis Supporting Adjustment for Excess Laboratory Packaging'' posted with the CY 2016 OPPS/ASC proposed rule) corresponding with use of the 14X bill type to report ''unrelated'' laboratory services. Beginning in July 2014, corresponding with the change in billing policy to bill ''unrelated'' laboratory services on a 13X bill type with the ''L1'' modifier, we observed most of the increase in 14X billing shifting to the 13X bill type with the ''L1'' modifier (again, as displayed in the ''Summary Analysis Supporting Adjustment for Excess Laboratory Packaging'' posted with the CY 2016 OPPS/ASC proposed rule). Summing the total increase in 14X billing in CY 2014 (compared to CY 2013) and the total amount billed on 13X claims with an ''L1'' modifier in CY 2014 resulted in a similar estimate of approximately $1 billion in ''unrelated'' laboratory services. Because both analyses resulted in an approximate $1 billion estimate of spending at the CLFS rates outside the OPPS that was packaged into the OPPS, we stated that we believe that a prospective adjustment to remove this $1 billion from the OPPS would realign total aggregate OPPS payments to reflect the resources associated with OPPS services. We calculated the $1 billion as a percent of $50 billion (the approximate actual total spending for OPPS services in CY 2014), which is 2.0 percent. Therefore, based on our analysis of the effects of the classification changes for CY 2014, we proposed a 2.0 percent downward adjustment to the conversion factor for CY 2016. In addition to the proposed rule itself, we provided a significant amount of additional information in the ''Summary Analysis Supporting Adjustment for Excess Laboratory Packaging,'' including a description of our actuaries' details and methods for its analysis, the adjustment input quantities, and outpatient monthly unrelated laboratory test billing. We believe the detail included in the proposed rule and in conjunction with the proposed rule was sufficient for stakeholders to be able to understand CMS' methodology for determining the amount of the proposed adjustment.

Comment: Several commenters suggested that CMS not implement this adjustment because the CY 2014 data year was an inappropriate base year for analysis of the laboratory packing proposal because of the changing methodology for reporting ''unrelated'' laboratory services during CY 2014. Many of these commenters suggested that CMS should wait until CY 2015 data are available before making an adjustment.

Response: As noted in the proposed rule (80 FR 39239) and illustrated in the ''Outpatient Unrelated Lab Billing Shift Quantities'' chart in the ''Summary Analysis Supporting Adjustment for Excess Laboratory Packaging'' files released in conjunction with the CY 2016 OPPS proposed rule, monthly total ''unrelated'' laboratory test billing was very consistent throughout CY 2014, with most ''unrelated'' laboratory test billing shifting from the 14X claim to the 13X claim with the ''L1'' modifier in July 2014. Because monthly total ''unrelated'' billing was consistent over the CY 2014 payment year, we do not believe that the mid-year change in how providers were to bill for ''unrelated'' laboratory services led to an increase in billing for such services in CY 2014. We believe that the consistency in the CY 2014 ''unrelated'' billing patterns across different billing instructions shows that the change in billing requirements for reporting unrelated laboratory services in CY 2014 did not cause a higher than expected amount of unrelated laboratory service payments in CY 2014. We continue to believe that the CY 2014 data regarding ''unrelated'' billing are appropriate for purposes of determining whether an adjustment to the conversion factor is warranted for CY 2016 and the amount of any adjustment. We will monitor ''unrelated'' laboratory test billing patterns in the CY 2015 OPPS claims data as we establish ratesetting for the CY 2017 OPPS payments to confirm this conclusion.

Comment: Several commenters suggested that CMS not implement this adjustment because CMS did not specify

whether the proposed changes to laboratory test packaging policy in the CY 2016 OPPS/ASC proposed rule were factored into the −2.0 percent adjustment to the conversion factor to address excess packaged payment for laboratory services.

Response: The proposed adjustment to the conversion factor for CY 2016 is based on the effects of the OPPS classification changes implemented for CY 2014; the proposed adjustment is not based on the proposed classification changes for CY 2016. We did not propose an adjustment to the conversion factor based on classification changes for CY 2016, but we will monitor the effects of those changes. At this time, we do not believe that a separate adjustment to the conversion factor based on CY 2016 classification changes is warranted. Our analysis indicates that the estimated effect of the CY 2016 classification changes on shifts between aggregate payments for laboratory tests paid separately using CLFS payment rates and those packaged under the OPPS is small and that, if we did make an adjustment to account for those changes, it would be a further reduction to OPPS payments. We will examine CY 2015 claims data when we set CY 2017 OPPS payment rates.

After consideration of the public comments we received, we are finalizing our proposal to adjust the CY 2016 conversion factor by -2.0 percent to eliminate the effects of classification changes on aggregate payments that do not reflect real changes in service-mix.

In summary, for CY 2016, we are finalizing our proposal to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (7) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2016 to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(iv) of the Act. We are using a reduced conversion factor of $72.251 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −$1.474 in the conversion factor relative to hospitals that meet the requirements).

For CY 2016, we are continuing previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of this final rule with comment period.

As a result of these finalized policies, the OPD fee schedule increase factor for the CY 2016 OPPS is 1.7 percent (which is 2.4 percent, the estimate of the hospital inpatient market basket percentage increase, less the 0.5 percentage point MFP adjustment, and less the 0.2 percentage point additional adjustment). For CY 2016, we are using a conversion factor of $73.725 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs. That is, the OPD fee schedule increase factor of 1.7 percent for CY 2016, the required wage index budget neutrality adjustment of 0.9992, the cancer hospital payment adjustment of 0.9994, the −2.0 percent adjustment to the conversion factor to eliminate the effects of classification changes that would otherwise result in an increase in aggregate OPPS payments (due to excess packaged payment under the OPPS for laboratory tests), and the adjustment of −0.13 percentage point of projected OPPS spending for the difference in the pass-through spending result in a conversion factor for CY 2016 of $73.725.

C. Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of this final rule with comment period.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). Therefore, in the CY 2016 OPPS/ASC proposed rule, we proposed to continue this policy for the CY 2016 OPPS. We refer readers to section II.H. of this final rule with comment period for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in section II.A.2.c. of this final rule with comment period, for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2016 pre-reclassified wage index that the IPPS uses to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the original OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add new paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements in § 419.43(c)(2) and (c)(3) of our regulations. For the CY 2016 OPPS, we proposed to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, rural and imputed floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the following sections in the FY 2011 through FY 2016 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of ''frontier States'' as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for

FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; for FY 2015, 79 FR 49971; and for FY 2016, 80 FR 49498.

In addition to the changes required by the Affordable Care Act, we note that the FY 2016 IPPS wage indexes continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural and imputed floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49488 through 49508) for a detailed discussion of all changes to the FY 2016 IPPS wage indexes. In addition, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65842 through 65844) and subsequent OPPS rules for a detailed discussion of the history of these wage index adjustments as applied under the OPPS.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49488 through 49513), the Office of Management and Budget (OMB) issued revisions to the labor market area delineations on February 28, 2013 (based on 2010 Decennial Census data), that included a number of significant changes such as new Core Based Statistical Areas (CBSAs), urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart (OMB Bulletin 13–01). This bulletin can be found at: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf*. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49985), we adopted the use of the OMB labor market area delineations that were based on the 2010 Decennial Census data.

In the CY 2016 OPPS/ASC proposed rule, we proposed to use the FY 2016 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2016. Thus, any adjustments that were proposed for the FY 2016 IPPS post-reclassified wage index would be reflected in the proposed CY 2016 OPPS wage index. (We referred readers to the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24463 through 24477) and the proposed FY 2016 hospital wage index files posted on the CMS Web site.)

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. We proposed to continue this policy for CY 2016. The following is a brief summary of the major FY 2016 IPPS wage index policies and adjustments that we proposed to apply to these hospitals under the OPPS for CY 2016. We further refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49488 through 49508) for a detailed discussion of the final changes to the FY 2016 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they would be eligible for the out-migration wage adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2016, we proposed to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA).

As stated earlier, in the FY 2015 IPPS/LTCH PPS final rule, we adopted the OMB labor market area delineations issued by OMB in OMB Bulletin No. 13–01 on February 28, 2013, based on standards published on June 28, 2010 (75 FR 37246 through 37252) and the 2010 Census data to delineate labor market areas for purposes of the IPPS wage index. For IPPS wage index purposes, for hospitals that were located in urban CBSAs in FY 2014 but were designated as rural under these revised OMB labor market area delineations, we generally assigned them the urban wage index value of the CBSA in which they were physically located for FY 2014 for a period of 3 fiscal years (79 FR 49957 through 49960). To be consistent, we applied the same policy to hospitals paid under the OPPS but not under the IPPS so that such hospitals will maintain the wage index of the CBSA in which they were physically located for FY 2014 for 3 calendar years (until December 31, 2017). Thus, for the CY 2016 OPPS, consistent with the FY 2016 IPPS/LTCH PPS final rule (80 FR 49494 through 49496), this 3-year transition will continue for the second year in CY 2016. For CY 2015, we also finalized a 1-year blended wage index for all hospitals that experienced any decrease in their actual payment wage index exclusively due to the implementation of the new OMB delineations. In the CY 2015 OPPS/ASC final rule with comment period, for purposes of the OPPS, we finalized a policy to apply this 1-year, 50-percent transition blend to hospitals paid under the OPPS but not under the IPPS. Therefore, this one-year transition blend does not apply for the CY 2016 OPPS wage index because it expires at the end of CY 2015.

In addition, for the FY 2016 IPPS, we extended the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2016 (80 FR 49497 through 49498). For purposes of the CY 2016 OPPS, we also proposed to apply the imputed floor policy to hospitals paid under the OPPS but not under the IPPS so long as the IPPS continues an imputed floor policy.

For CMHCs, for CY 2016, we proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. As with OPPS hospitals and for the same reasons, in CY 2015, we applied a 1-year, 50/50 blended wage index to CMHCs that would receive a lower wage index due to the new OMB labor market area delineations. However, this blended wage index does not apply in CY 2016 because it expires at the end of CY 2015. In addition, as with OPPS hospitals and for the same reasons, for CMHCs previously located in urban CBSAs that were designated as rural under the new OMB labor market area delineations, we finalized a policy to maintain the urban wage index value of the CBSA in which they were physically located for CY 2014 for 3 calendar years (until December 31, 2017). Consistent with our current policy, the wage index that applies to CMHCs includes both the imputed floor adjustment and the rural floor adjustment, but does not include the out-migration adjustment because that adjustment only applies to hospitals.

Comment: One commenter noted that the IPPS wage index does not account for the difficulty of recruiting health professionals to rural areas. The

commenter suggested that a higher wage index for rural areas would help these hospitals recruit professionals from other areas to underserved rural areas.

Response: Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner. We continue to believe that using the IPPS wage index as the source of the OPPS wage index is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital. As we discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951), we believe that the IPPS wage index reflects the reality of population shifts and labor market conditions, and provides an accurate representation of geographic variation in wage levels.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to continue to use an OPPS labor-related share of 60 percent of the national OPPS payment for the CY 2016 OPPS. We also are finalizing the use of the final FY 2016 IPPS post-reclassified wage index for urban and rural areas in its entirety, including the frontier State wage index floor, the rural floor, geographic reclassifications, and all other applicable wage index adjustments, as the final CY 2016 wage index for OPPS hospitals and CMHCs based on where the facility is located for both the OPPS payment rate and the copayment standardized amount, as discussed above and as set forth in the CY 2016 OPPS/ASC proposed rule (80 FR 39240 through 39242). We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49488 through 49508) and the final FY 2016 hospital wage index files posted on the CMS Web site. For non-IPPS hospitals under the OPPS, we are finalizing our proposal to continue to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. We also are finalizing our proposal to apply the imputed floor policy to hospitals paid under the OPPS but not under the IPPS so long as the IPPS continues an imputed floor policy, which CMS has extended for an additional year under the IPPS in the FY 2016 IPPS/LTCH PPS final rule. In addition, we are finalizing our proposal to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). The new Table 2 from the FY 2016 IPPS/LTCH PPS final rule (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) identifies counties eligible for the out-migration adjustment and IPPS hospitals that will receive the adjustment for FY 2016. (We note that the new FY 2016 IPPS Table 2 consolidates information on counties eligible for the out-migration adjustment that was previously issued as Table 4J.) We are including the out-migration adjustment information from the new consolidated Table 2 from the FY 2016 IPPS/LTCH PPS final rule as Addendum L to this final rule with comment period with the addition of non-IPPS hospitals that will receive the section 505 out-migration adjustment under the CY 2016 OPPS. Addendum L is available via the Internet on the CMS Web site. With the exception of the out-migration wage adjustment table (Addendum L to this final rule with comment period, which is available via the Internet on the CMS Web site), which includes non-IPPS hospitals paid under the OPPS, we are not reprinting the final FY 2016 IPPS wage indexes referenced in this discussion of the wage index. We refer readers to the CMS Web site for the OPPS at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At this link, readers will find a link to the final FY 2016 IPPS wage index tables and Addendum L.

D. Statewide Average Default CCRs

In addition to using CCRs to estimate costs from charges on claims for ratesetting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. MACs cannot calculate a CCR for some hospitals because there is no cost report available. For these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned above until a hospital's MAC is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report. These hospitals include, but are not limited to, hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a biased CCR (that is, the CCR falls outside the predetermined ceiling threshold for a valid CCR) or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11). In this final rule with comment period, as we proposed, we are updating the default ratios for CY 2016 using the most recent cost report data. We discuss our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39242), for CY 2016, we proposed to continue to use our standard methodology of calculating the statewide average default CCRs using the same hospital overall CCRs that we use to adjust charges to costs on claims data for setting the proposed CY 2016 OPPS relative payment weights. Table 11 published in the proposed rule (80 FR 39243) listed the proposed CY 2016 default urban and rural CCRs by State and compared them to the CY 2015 default CCRs. These proposed CCRs represented the ratio of total costs to total charges for those cost centers relevant to outpatient services from each hospital's most recently submitted cost report, weighted by Medicare Part B charges. We also proposed to adjust ratios from submitted cost reports to reflect the final settled status by applying the differential between settled to submitted overall CCRs for the cost centers relevant to outpatient services from the most recent pair of final settled and submitted cost reports. We then proposed to weight each hospital's CCR by the volume of separately paid line-items on hospital claims corresponding to the year of the majority of cost reports used to calculate the overall CCRs. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66680 through 66682) and prior OPPS rules for a more detailed discussion of our established methodology for calculating the statewide average default CCRs, including the hospitals used in our calculations and our trimming criteria.

For Maryland, we used an overall weighted average CCR for all hospitals in the Nation as a substitute for Maryland CCRs. Few hospitals in Maryland are eligible to receive payment under the OPPS, which limits the data available to calculate an accurate and representative CCR. The weighted CCR is used for Maryland because it takes into account each

hospital's volume, rather than treating each hospital equally. We refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65822) for further discussion and the rationale for our longstanding policy of using the national average CCR for Maryland. In general, observed changes in the statewide average default CCRs between CY 2015 and CY 2016 are modest and the few significant changes are associated with areas that have a small number of hospitals.

We did not receive any public comments on our CY 2016 proposal. Therefore, we are finalizing our proposal, without modification, to apply our standard methodology of calculating the statewide average default CCRs using the same hospital overall CCRs that we used to adjust charges to costs on claims data for setting the final CY 2016 OPPS relative payment weights.

Table 14 below lists the statewide average default CCRs for OPPS services furnished on or after January 1, 2016.

TABLE 14—CY 2016 STATEWIDE AVERAGE CCRS

State	Urban/rural	CY 2016 default CCR	Previous default CCR (CY 2015 OPPS final rule)
ALASKA	RURAL	0.588	0.439
ALASKA	URBAN	0.269	0.294
ALABAMA	RURAL	0.224	0.235
ALABAMA	URBAN	0.168	0.186
ARKANSAS	RURAL	0.223	0.262
ARKANSAS	URBAN	0.218	0.239
ARIZONA	RURAL	0.246	0.228
ARIZONA	URBAN	0.170	0.181
CALIFORNIA	RURAL	0.179	0.178
CALIFORNIA	URBAN	0.190	0.196
COLORADO	RURAL	0.366	0.410
COLORADO	URBAN	0.208	0.219
CONNECTICUT	RURAL	0.366	0.339
CONNECTICUT	URBAN	0.257	0.273
DISTRICT OF COLUMBIA	URBAN	0.298	0.299
DELAWARE	URBAN	0.308	0.314
FLORIDA	RURAL	0.170	0.180
FLORIDA	URBAN	0.150	0.156
GEORGIA	RURAL	0.251	0.256
GEORGIA	URBAN	0.199	0.211
HAWAII	RURAL	0.339	0.337
HAWAII	URBAN	0.313	0.307
IOWA	RURAL	0.305	0.321
IOWA	URBAN	0.256	0.269
IDAHO	RURAL	0.337	0.353
IDAHO	URBAN	0.459	0.463
ILLINOIS	RURAL	0.234	0.252
ILLINOIS	URBAN	0.208	0.217
INDIANA	RURAL	0.314	0.334
INDIANA	URBAN	0.237	0.262
KANSAS	RURAL	0.287	0.300
KANSAS	URBAN	0.209	0.231
KENTUCKY	RURAL	0.202	0.231
KENTUCKY	URBAN	0.203	0.212
LOUISIANA	RURAL	0.256	0.272
LOUISIANA	URBAN	0.202	0.209
MASSACHUSETTS	RURAL	0.324	0.326
MASSACHUSETTS	URBAN	0.330	0.333
MAINE	RURAL	0.470	0.430
MAINE	URBAN	0.395	0.432
MARYLAND	RURAL	0.277	0.296
MARYLAND	URBAN	0.234	0.244
MICHIGAN	RURAL	0.317	0.371
MICHIGAN	URBAN	0.319	0.320
MINNESOTA	RURAL	0.449	0.485
MINNESOTA	URBAN	0.377	0.347
MISSOURI	RURAL	0.238	0.267
MISSOURI	URBAN	0.253	0.274
MISSISSIPPI	RURAL	0.235	0.247
MISSISSIPPI	URBAN	0.169	0.181
MONTANA	RURAL	0.480	0.501
MONTANA	URBAN	0.403	0.386
NORTH CAROLINA	RURAL	0.229	0.280
NORTH CAROLINA	URBAN	0.235	0.246
NORTH DAKOTA	RURAL	0.443	0.660
NORTH DAKOTA	URBAN	0.355	0.395
NEBRASKA	RURAL	0.283	0.290
NEBRASKA	URBAN	0.238	0.255
NEW HAMPSHIRE	RURAL	0.306	0.362
NEW HAMPSHIRE	URBAN	0.306	0.280

TABLE 14—CY 2016 STATEWIDE AVERAGE CCRS—Continued

State	Urban/rural	CY 2016 default CCR	Previous default CCR (CY 2015 OPPS final rule)
NEW JERSEY	URBAN	0.194	0.202
NEW MEXICO	RURAL	0.280	0.296
NEW MEXICO	URBAN	0.290	0.294
NEVADA	RURAL	0.219	0.241
NEVADA	URBAN	0.146	0.149
NEW YORK	RURAL	0.311	0.333
NEW YORK	URBAN	0.298	0.340
OHIO	RURAL	0.295	0.317
OHIO	URBAN	0.212	0.222
OKLAHOMA	RURAL	0.255	0.282
OKLAHOMA	URBAN	0.192	0.203
OREGON	RURAL	0.265	0.287
OREGON	URBAN	0.341	0.352
PENNSYLVANIA	RURAL	0.277	0.283
PENNSYLVANIA	URBAN	0.195	0.197
PUERTO RICO	URBAN	0.590	0.577
RHODE ISLAND	URBAN	0.290	0.297
SOUTH CAROLINA	RURAL	0.188	0.191
SOUTH CAROLINA	URBAN	0.197	0.207
SOUTH DAKOTA	RURAL	0.367	0.286
SOUTH DAKOTA	URBAN	0.224	0.214
TENNESSEE	RURAL	0.198	0.203
TENNESSEE	URBAN	0.177	0.188
TEXAS	RURAL	0.238	0.251
TEXAS	URBAN	0.179	0.203
UTAH	RURAL	0.493	0.481
UTAH	URBAN	0.325	0.335
VIRGINIA	RURAL	0.195	0.219
VIRGINIA	URBAN	0.233	0.241
VERMONT	RURAL	0.434	0.439
VERMONT	URBAN	0.336	0.353
WASHINGTON	RURAL	0.349	0.300
WASHINGTON	URBAN	0.308	0.330
WISCONSIN	RURAL	0.317	0.328
WISCONSIN	URBAN	0.296	0.294
WEST VIRGINIA	RURAL	0.276	0.312
WEST VIRGINIA	URBAN	0.294	0.300
WYOMING	RURAL	0.433	0.429
WYOMING	URBAN	0.311	0.262

E. Adjustment for Rural SCHs and EACHs Under Section 1833(t)(13)(B) of the Act

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 419.43(g) of the regulations to clarify that EACHs also are eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Pub. L. 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2015. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For the CY 2016 OPPS, we proposed to continue our policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS,

excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs (80 FR 39244).

Comment: Several commenters supported the proposed policy of a 7.1 percent payment adjustment.

Response: We appreciate the commenters' support.

Comment: A few commenters suggested that CMS perform a new analysis to determine if a different rural adjustment amount is warranted. The commenters noted that they performed their own analysis which suggested that a higher adjustment was warranted for SCHs and that an adjustment was warranted for small rural hospitals that were not SCHs. One commenter suggested that CMS revisit its original analysis because an adjustment for rural SCHs may no longer be warranted.

Response: We plan to review whether a revised analysis is warranted for future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal for CY 2016 to continue our policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. OPPS Payment to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), Congress established section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (often referred to as ''held harmless'').

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount'' and the determination of the base PCR are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, respectively) as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are greater than other hospitals' costs, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recent submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. For CYs 2012 and 2013, the target PCR for purposes of the cancer hospital payment adjustment was 0.91. For CY 2014, the target PCR for purposes of the cancer hospital payment adjustment was 0.89. For CY 2015, the target PCR was 0.90, as discussed in the CY 2015 OPPS/ASC final rule with comment period correction notice (80 FR 9629).

2. Payment Adjustment for Certain Cancer Hospitals for CY 2016

For CY 2016, we proposed to continue our policy to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals using the most recent submitted or settled cost report data that were available at the time of the development of the CY 2016 OPPS/ASC proposed rule (80 FR 39245). To calculate the proposed CY 2016 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of the proposed rule, used to estimate costs for the CY 2016 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2014 claims data that we used to model the impact of the proposed CY 2016 APC relative payment weights (3,794 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2016 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging

from 2013 to 2014. We then removed the cost report data of the 47 hospitals located in Puerto Rico from our dataset because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 18 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,729 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS are approximately 90 percent of reasonable cost (weighted average PCR of 0.90). Therefore, we proposed that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a PCR equal to 0.90 for each cancer hospital. Table 12 published in the proposed rule indicated the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2016 due to the cancer hospital payment adjustment policy.

We indicated that the actual amount of the CY 2016 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2016 payments and costs. We noted that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed as usual after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

Comment: Several commenters supported the proposed cancer hospital payment adjustment for CY 2016.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing the proposed methodology for calculating the cancer hospital payment adjustment for CY 2016. For this final rule with comment period, we are using the most recent cost report data through September 30, 2015 to update the adjustment. This update yields a target PCR of 0.92. We limited the dataset to the hospitals with CY 2014 claims data that we used to model the impact of the CY 2016 APC relative payment weights (3,781 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2016 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2012 to 2015. We then removed the cost report data of the 49 hospitals located in Puerto Rico from our dataset because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 11 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,721 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS are approximately 92 percent of reasonable cost (weighted average PCR of 0.92). Therefore, we are finalizing that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a PCR equal to 0.92 for each cancer hospital.

Table 15 below indicates estimates in percentage terms of the CY 2016 payment adjustment for each cancer hospital. The actual amount of the CY 2016 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2016 payments and costs.

TABLE 15—ESTIMATED CY 2016 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider No.	Hospital name	Estimated percentage increase in OPPS payments for CY 2016
050146	City of Hope Comprehensive Cancer Center	21.6
050660	USC Norris Cancer Hospital	21.9
100079	Sylvester Comprehensive Cancer Center	25.1
100271	H. Lee Moffitt Cancer Center & Research Institute	27.3
220162	Dana-Farber Cancer Institute	51.1
330154	Memorial Sloan-Kettering Cancer Center	46.9
330354	Roswell Park Cancer Institute	31.4
360242	James Cancer Hospital & Solove Research Institute	35.4
390196	Fox Chase Cancer Center	23.7
450076	M.D. Anderson Cancer Center	50.9
500138	Seattle Cancer Care Alliance	57.3

G. Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2015, the outlier threshold was met when the hospital's

cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $2,775 (the fixed-dollar amount threshold) (79 FR 66834). If the cost of a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the proposed OPPS. Our estimate of total outlier payments as a percent of total CY 2014 OPPS payment, using CY 2014 claims available for this final rule with comment period and the revised OPPS expenditure estimate for the FY 2016 President's Budget Mid-Session Review, is approximately 0.9 percent of the total aggregated OPPS payments. Therefore, for CY 2014, we estimate that we paid 0.1 percentage points below the CY 2014 outlier target of 1.0 percent of total aggregated OPPS payments.

Using CY 2014 claims data and CY 2015 payment rates, we currently estimate that the aggregate outlier payments for CY 2015 will be approximately 0.9 percent of the total CY 2015 OPPS payments. The difference between 0.9 percent and the 1.0 percent target is reflected in the regulatory impact analysis in section XXI. of this final rule with comment period. We provide estimated CY 2016 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts—Provider-Specific Data file on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

2. Outlier Calculation

In the CY 2016 OPPS/ASC proposed rule (80 FR 39246), we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We proposed that a portion of that 1.0 percent, an amount equal to 0.49 percent of outlier payments (or 0.0049 percent of total OPPS payments) would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.D. of the proposed rule and this final rule with comment period, we proposed to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under either proposed renumbered APC 5851 (Level 1 Partial Hospitalization (3 services) for CMHCs) (existing APC 0172) or proposed renumbered APC 5852 (Level 2 Partial Hospitalization (4 or more services) for CMHCs) (existing APC 0173), exceeds 3.40 times the payment rate for proposed renumbered APC 5852, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed renumbered APC 5852 payment rate. For further discussion of CMHC outlier payments, we refer readers to section VIII.D. of the proposed rule and this final rule with comment period.

To ensure that the estimated CY 2016 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $3,650.

We calculated the proposed fixed-dollar threshold of $3,650 using the standard methodology most recently used for CY 2015 (79 FR 66833 through 66834). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2015 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2016 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2014 claims using the same inflation factor of 1.0985 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24632 through 24633). We used an inflation factor of 1.0481 to estimate CY 2015 charges from the CY 2014 charges reported on CY 2014 claims. The methodology for determining this charge inflation factor is discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24632). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors are appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we proposed to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2016 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2016 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2016, we proposed to apply an adjustment factor of 0.9795 to the CCRs that were in the April 2015 OPSF to trend them forward from CY 2015 to CY 2016. The methodology for calculating this proposed adjustment is discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24633) and finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49784).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2015 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.9795 to approximate CY 2016 CCRs) to charges on CY 2014 claims that were adjusted (using the proposed charge inflation factor of 1.0985 to approximate CY 2016 charges). We simulated aggregated CY 2016 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2016 OPPS payments. We estimated that a proposed fixed-dollar threshold of $3,650, combined with the proposed multiple threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we proposed that, if a CMHC's cost for partial hospitalization services, paid under either proposed renumbered APC 5851 (existing APC 0172) or proposed renumbered APC 5852 (existing APC 0173), exceeds 3.40 times the payment rate for proposed

renumbered 5852, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed renumbered APC 5852 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we proposed to continue the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIII. of this final rule with comment period.

Comment: A few commenters suggested that the proposed outlier fixed dollar threshold of $3,650 was too high for CMS to pay the target aggregate outlier payment amount of 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. The commenters noted that 2014 and 2015 estimated outlier payments were below 1.0 percent, despite a lower fixed-dollar threshold.

Response: As indicated earlier, we introduced a fixed-dollar threshold in order to better target outlier payments to those high-cost and complex procedures where a very costly service could present a hospital with significant financial loss. We maintain the target outlier percentage of 1.0 percent of estimated aggregate total payment under the OPPS and have a fixed-dollar threshold so that OPPS outlier payments are made only when the hospital would experience a significant loss for supplying a particular service. While the commenters expressed concern based on the assumption that OPPS outlier payments would decrease under an increased fixed-dollar threshold, we note that the threshold may increase or decrease from year to year, to maintain the 1.0 percent outlier spending target. The methodology we use to calculate the fixed-dollar threshold for the prospective payment year factors is based on several data inputs that may change from prior payment years. For instance, updated hospital CCR data and changes to the OPPS payment methodology influence projected outlier payments in the prospective year. For this final rule with comment period, we used the same methodology for calculating the outlier fixed-dollar threshold that we used for the proposed rule but used updated data. However, these updated data inputs for this final rule with comment period do yield a lower threshold than for the proposed rule.

3. Final Outlier Calculation

Consistent with historical practice, we used updated data for this final rule with comment period for outlier calculations. For CY 2016, we are applying the overall CCRs from the July 2015 OPSF file after adjustment (using the CCR inflation adjustment factor of 0.9701 to approximate CY 2016 CCRs) to charges on CY 2014 claims that were adjusted (using the charge inflation factor of 1.0766 to approximate CY 2016 charges). These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar thresholds for the FY 2016 IPPS/LTCH PPS final rule (80 FR 49784). We simulated aggregated CY 2016 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payments will continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2016 OPPS payments. We estimated that a fixed-dollar threshold of $3,250, combined with the multiple threshold of 1.75 times the APC payment rate, will allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, if a CMHC's cost for partial hospitalization services, paid under either renumbered APC 5851 (existing APC 0172) or renumbered APC 5852 (existing APC 0173), exceeds 3.40 times the payment rate for renumbered APC 5852, the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the renumbered APC 5852 payment rate.

H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2016 OPPS/ASC final rule with comment period, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this final rule with comment period and the relative payment weight determined under section II.A. of this final rule with comment period. Therefore, the national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site) was calculated by multiplying the CY 2016 scaled weight for the APC by the CY 2016 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIII. of this final rule with comment period.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39247 through 39249), we demonstrated the steps on how to determine the APC payments that will be made in a calendar year under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''Q4,'' ''R,'' ''S,'' ''T,'' ''U,'' or ''V'' (as defined in Addendum D1 to the proposed rule, which is available via the Internet on the CMS Web site), in a circumstance in

which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements. We note that, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66799), we created new status indicator ''J1'' to reflect the comprehensive APCs discussed in section II.A.2.e. of this final rule with comment period. We also note that we deleted status indicator ''X'' as part of the CY 2015 packaging policy for ancillary services, discussed in section II.A.3. of this final rule with comment period. In the CY 2016 OPPS/ASC proposed rule, we proposed to create new status indicator ''J2'' to reflect the new C–APC 8011 (Comprehensive Observation Services) and new status indicator ''Q4'' to reflect conditionally packaged laboratory tests. In this CY 2016 OPPS/ASC final rule with comment period, we are finalizing the new status indicators ''J2'' and ''Q4'' as proposed, as discussed in sections II.A.2.e.(2) and II.A.3.b.(3) of this final rule with comment period, respectively.

We did not receive any public comments on these steps under the methodology that we included in the proposed rule to determine the APC payments for CY 2016. Therefore, we are using the steps in the methodology specified below, as we proposed, to demonstrate the calculation of the final CY 2016 OPPS payments using the same parameters.

Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the full CY 2016 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 * (\text{national unadjusted payment rate})$.

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that under the CY 2016 OPPS policy for continuing to use the OMB labor market area delineations based on the 2010 Decennial Census data for the wage indexes used under the IPPS, a hold harmless policy for the wage index may apply, as discussed in section II.C. of this final rule with comment period. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2016 under the IPPS, reclassifications through the MGCRB, section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Pub. L. 98–21. (For further discussion of the changes to the FY 2016 IPPS wage indexes, as applied to the CY 2016 OPPS, we refer readers to section II.C. of this final rule with comment period.) As we proposed, we are continuing to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act of 2010.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Pub. L. 108–173. Addendum L to this final rule with comment period (which is available via the Internet on the CMS Web site) contains the qualifying counties and the associated wage index increase developed for the FY 2016 IPPS, which are listed in Table 2 in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49326) and available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a *is the labor-related portion of the national unadjusted payment rate (wage adjusted).*

$X_a = .60 * (\text{national unadjusted payment rate}) * \text{applicable wage index}$.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

$Y = .40 * (\text{national unadjusted payment rate})$.

$\text{Adjusted Medicare Payment} = Y + X_a$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we used a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to renumbered APC 5072 (Level 2 Excision/Biopsy/Incision and Drainage) (previously APC 0019). The CY 2016 full national unadjusted payment rate for APC 5072 is approximately $480.64. The reduced national unadjusted payment rate for renumbered APC 5072 for a hospital that fails to meet the Hospital OQR Program requirements is approximately $471.03. This reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for renumbered APC 5072.

The FY 2016 wage index for a provider located in CBSA 35614 in New York is 1.2991. The labor-related portion of the full national unadjusted payment is approximately $374.64 (.60 * $480.64 * 1.2991). The labor-related portion of the reduced national unadjusted payment is approximately $367.15 (.60 * $471.03 * 1.2991). The nonlabor-related portion of the full national unadjusted payment is approximately $192.26 (.40 * $480.64). The nonlabor-related portion of the reduced national unadjusted payment is approximately $188.41 (.40 * $471.03). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is approximately $566.90 ($374.64 + $192.26). The sum of the portions of the reduced national adjusted payment is approximately $555.56 ($367.15 + $188.41).

I. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in calendar years thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, may be found in section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. OPPS Copayment Policy

In the CY 2016 OPPS/ASC proposed rule (80 FR 39249), for CY 2016, we proposed to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we proposed to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2016, were shown in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site). As discussed in section XIII.E. of the proposed rule and this final rule with comment period, for CY 2016, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC, and, after

recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).

- If HCPCS codes are added to an APC, and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in that CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which is consistent with the Congressional goal of achieving a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459). We believe the proposed reorganization of APCs discussed in section III.D. of the proposed rule and finalized under section III.D. of this final rule with comment period hastens this movement toward copayments equal to 20 percent of an APC for reorganized APCs that previously had copayment percentages greater than 20 percent.

We did not receive any comments on the copayment percentage. For the reasons set forth in this final rule with comment period, we are finalizing our proposed CY 2016 copayment methodology without modification.

3. Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using renumbered APC 5072 (previously APC 0019), $96.13 is approximately 20 percent of the full national unadjusted payment rate of $480.64. For APCs with only a minimum unadjusted copayment in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/ national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this final rule with comment period. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this final rule with comment period.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC. The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this final rule with comment period, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B.*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B.*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.980.

The unadjusted copayments for services payable under the OPPS that are effective January 1, 2016, are shown in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site). We note that the national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the full CY 2016 OPD fee schedule increase factor discussed in section II.B. of this final rule with comment period.

In addition, as noted above, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New CPT and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures and medical services;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new CPT and Level II HCPCS codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that may more accurately describe items or services furnished and provides payment or more accurate payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public

comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. For those items, procedures, or services not paid separately under the hospital OPPS, they are assigned to appropriate status indicators. Section XI. of this final rule with comment period provides a discussion of the various status indicators used under the OPPS. Certain payment indicators provide separate payment while others do not.

In Table 16 below, we summarize our comment process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS.

TABLE 16—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2015	Level II HCPCS Codes	April 1, 2015	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.
July 1, 2015	Level II HCPCS Codes	July 1, 2015	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2015	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.
October 1, 2015	Level II HCPCS Codes	October 1, 2015	CY 2016 OPPS/ASC final rule with comment period.	CY 2017 OPPS/ASC final rule with comment period.
January 1, 2016	Level II HCPCS Codes	January 1, 2016	CY 2016 OPPS/ASC final rule with comment period.	CY 2017 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2016	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.

This process is discussed in detail below. We have separated our discussion into two sections based on whether we solicited public comments in the CY 2016 OPPS/ASC proposed rule or whether we are soliciting public comments in this CY 2016 OPPS/ASC final rule with comment period. We note that we sought public comments in the CY 2015 OPPS/ASC final rule with comment period on the interim APC and status indicator assignments for new CPT and Level II HCPCS codes that were effective January 1, 2015. We also sought public comments in the CY 2015 OPPS/ASC final rule with comment period on the interim APC and status assignments for new Level II HCPCS codes that became effective October 1, 2014. These new and revised codes, with an effective date of October 1, 2014, or January 1, 2015, were flagged with comment indicator ''NI'' (New code, interim APC assignment; comments will be accepted on the interim APC assignment for the new code) in Addendum B to the CY 2015 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and an APC and payment rate, if applicable, and were subject to public comment following publication of the CY 2015 OPPS/ASC final rule with comment period. We are responding to public comments and finalizing our interim OPPS treatment of these codes in this CY 20165 OPPS/ASC final rule with comment period.

Further, we received public comments on some new codes that were assigned to comment indicator ''NI'' in Addendum B of the CY 2015 OPPS/ASC final rule with comment period. We also received public comments on new CPT codes that will be effective January 1, 2016, that were assigned to comment indicator ''NP'' in Addendum B of the CY 2016 OPPS/ASC proposed rule. We respond to those comments in section III.C. of this CY 2016 OPPS/ASC final rule with comment period.

1. Treatment of New CY 2015 Level II HCPCS and CPT Codes Effective April 1, 2015 and July 1, 2015 for Which We Solicited Public Comments in the CY 2016 OPPS/ASC Proposed Rule

Through the April 2015 OPPS quarterly update CR (Transmittal 3217, Change Request 9097, dated March 13, 2015), and the July 2015 OPPS quarterly update CR (Transmittal 3280, Change Request 9205, dated June 5, 2015), we recognized several new HCPCS codes for separate payment under the OPPS.

Effective April 1, 2015, we made effective eight new Level II HCPCS codes and also assigned them to appropriate interim OPPS status indicators and APCs. Through the April 2015 OPPS quarterly update CR, we allowed separate payment for eight new Level II HCPCS codes. Specifically, as displayed in Table 14 of the CY 2016 proposed rule (80 FR 39251), we provided separate payment for HCPCS codes C2623, C9445, C9448, C9449, C9450, C9451, C9452, and Q9975. We note that HCPCS code C9448 was deleted on June 30, 2015, and replaced with HCPCS code Q9978, effective July 1, 2015.

In the CY 2016 OPPS/ASC proposed rule, we solicited public comments on the proposed APC and status indicator assignments for the Level II HCPCS codes implemented on April 1, 2015 and listed in Table 14 of the proposed rule (80 FR 39251). Specifically, we solicited public comments on HCPCS codes C2623, C9445, C9448, C9449, C9450, C9451, C9452, and Q9975. We note that HCPCS code C9448 was deleted on June 30, 2015, and replaced with HCPCS code Q9978, effective July 1, 2015. We indicated that the proposed payment rates for these codes, where applicable, could be found in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site).

For the CY 2016 update, the HCPCS Workgroup replaced the temporary drug HCPCS C-codes and Q-codes that were listed in Table 14 of the proposed rule with permanent HCPCS J-codes effective January 1, 2016. Because the replacement HCPCS J-codes describe the

same drugs with the same dosage descriptors as their predecessor HCPCS C-codes and Q-codes, they will continue to receive pass-through payment status in CY 2016. Therefore, we are assigning the replacement HCPCS J-codes to the same APCs and status indicators as their predecessor HCPCS codes, as shown in Table 17 below.

We did not receive any public comments on the proposed APC and status indicator assignments for the new Level II HCPCS codes implemented in April 2015. Therefore, we are finalizing the proposed APC assignments and status indicators for the new Level II HCPCS codes implemented in April 2015, as indicated in Table 17 below. The final payment rates for these codes, where applicable, can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 17—FINAL CY 2016 STATUS INDICATORS AND APC ASSIGNMENTS FOR THE NEW LEVEL II HCPCS CODES THAT WERE IMPLEMENTED IN APRIL 2015

CY 2015 CPT/HCPCS code	CY 2016 CPT/HCPCS code	CY 2016 long descriptor	Final CY 2016 status indicator	Final CY 2016 APC
C2623	C2623	Catheter, transluminal angioplasty, drug-coated, non-laser	H	2623
C9445	J0596	Injection, c1 esterase inhibitor (recombinant), Ruconest, 10 units	G	9445
C9448 *	J8655	Netupitant 300 mg and palonosetron 0.5 mg	G	9448
C9449	J9039	Injection, blinatumomab, 1 microgram	G	9449
C9450	J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450
C9451	J2547	Injection, peramivir, 1 mg	G	9451
C9452	J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	9452
Q9975 **	J7205	Injection, factor viii fc fusion (recombinant), per iu	G	1656

* HCPCS code C9448 was deleted on June 30, 2015, and replaced with HCPCS code Q9978, effective July 1, 2015.

** HCPCS code C9136 (Injection, factor viii, fc fusion protein (recombinant), per i.u.) was deleted on March 31, 2015 and replaced with HCPCS code Q9975.

Effective July 1, 2015, we made effective several new CPT and Level II HCPCS codes and also assigned them to appropriate interim OPPS status indicators and APCs. Through the July 2015 OPPS quarterly update CR (Transmittal 3280, Change Request 9205, dated June 5, 2015), we assigned interim OPPS status indicators and APCs for two new Category III CPT codes and eight Level II HCPCS codes that were made effective July 1, 2015. Specifically, as displayed in Table 15 of the CY 2016 proposed rule (80 FR 39252), we made interim OPPS status indicators and APC assignments for Category III CPT codes 0392T and 0393T, and Level II HCPCS codes C2613, C9453, C9454, C9455, Q5101, Q9976, Q9977, and Q9978. We note that CPT code 0392T replaced HCPCS code C9737 (Laparoscopy, surgical, esophageal sphincter augmentation with device (*e.g.,* magnetic band)), beginning July 1, 2015. Because CPT code 0392T describes the same procedure as HCPCS code C9737, we proposed to assign the CPT code to the same APC and status indicator as its predecessor HCPCS C-code, as shown in Table 15 of the proposed rule.

Table 15 of the proposed rule (89 FR 39252) listed the CPT and Level II HCPCS codes that were implemented on July 1, 2015, along with the proposed status indicators, proposed APC assignments, and proposed payment rates, where applicable, for CY 2016. We solicited public comments on the proposed APC and status indicator assignments.

One commenter addressed CPT code 0392T which relates to gastrointestinal procedures and services and which replaced HCPCS code C9737. We have responded to this comment in section II.A.2.e. of this final rule with comment period. We did not receive any public comments on the proposed APC and status indicator assignments for Category III CPT code 0393T and Level II HCPCS codes C2613, C9453, C9454, C9455, Q9976, Q9977, and Q9978 for CY 2016.

In this final rule with comment period, we are adopting as final, without modification, the proposed APC and status indicator assignments for CPT code 0393T and for Level II HCPCS codes C2613, C9453, C9454, C9455, Q9976, Q9977, Q9978. However, we are finalizing the APC and status indicator assignments for HCPCS code Q5101 (Zarxio) with modification. Specifically, we are assigning HCPCS code Q5101 to APC 1822 and status indicator ''G'' (pass-through drugs and biologicals). We noted in the CY 2016 OPPS/ASC proposed rule (80 FR 39252) that Zarxio (the drug described by HCPCS code Q5101) was currently not being marketed. However, once pricing information was made available, the drug would be paid separately under the OPPS. Zarxio was marketed on September 3, 2015, and therefore, we began making separate payments under the OPPS beginning on this date. From September 3, 2015, through December 31, 2015, HCPCS code Q5101 is assigned status indicator ''K'' (Nonpass-through drugs and nonimplantable biologicals, including therapeutic radiopharmaceuticals). Because Zarxio has been approved for pass-through status beginning January 1, 2016, we are changing its OPPS status indicator from ''K'' to ''G'' beginning January 1, 2016.

For the CY 2016 update, the HCPCS Workgroup replaced temporary HCPCS codes C9453, C9454, C9455, and Q9978 with permanent HCPCS J codes effective January 1, 2016. Because the replacement HCPCS J- codes describe the same drugs with the same dosage descriptors as their predecessor HCPCS C codes and Q codes, they will continue to receive pass-through payment status in CY 2016. Therefore, we are assigning the replacement HCPCS J-codes to the same APCs and status indicators as their predecessor HCPCS codes, as shown in Table 18 below. Table 18 lists the final APCs and status indicator assignments for the new category III CPT and Level II HCPCS codes that were implemented on July 1, 2015. The final payment rates for these codes, where applicable, can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 18—FINAL CY 2016 STATUS INDICATORS AND APC ASSIGNMENTS FOR THE NEW CATEGORY III CPT AND LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2015

CY 2015 CPT/HCPCS code	CY 2016 CPT/HCPCS code	CY 2016 long descriptor	Final CY 2016 status indicator	Final CY 2016 APC
C2613	C2613	Lung biopsy plug with delivery system	H	2613
C9453	J9299	Injection, nivolumab, 1 mg	G	9453
C9454	J2502	Injection, pasireotide long acting, 1 mg	G	9454
C9455	J2860	Injection, siltuximab, 10 mg	G	9455
Q5101 *	Q5101*	Injection, Filgrastim (G–CSF), Biosimilar, 1 microgram	G	1822
Q9976	J1443	Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron	E	N/A
Q9977	Q9977 **	Compounded Drug, Not Otherwise Classified	D	N/A
Q9978	J8655	Netupitant 300 mg and palonosetron 0.5 mg	G	9448
0392T	0392T	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band).	J1	5362
0393T	0393T	Removal of esophageal sphincter augmentation device	Q2	5361

* HCPCS code Q5101, which described the drug Zarxio, was approved by the FDA on March 6, 2015. Separate payment for Zarxio was effective September 3, 2015, the date the drug was marketed.

** HCPCS code Q9977 will be deleted December 31, 2015, and a replacement code will not be established.

2. Process for New Level II HCPCS Codes That Became Effective October 1, 2015 and New Level II HCPCS Codes That Will Be Effective January 1, 2016 for Which We Are Soliciting Public Comments in This CY 2016 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective October 1 and January 1 in the final rule with comment period thereby updating the OPPS for the following calendar year. These codes are released to the public through the October and January OPPS quarterly update CRs and via the CMS HCPCS Web site (for Level II HCPCS codes). For CY 2016, these codes are flagged with comment indicator ''NI'' in Addendum B to this OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. Specifically, the status indicators and the APC assignments for codes flagged with comment indicator ''NI'' are open to public comment in this final rule with comment period, and we will respond to these public comments in the OPPS/ASC final rule with comment period for the next year's OPPS/ASC update. In the CY 2016 OPPS/ASC proposed rule (80 FR 39252 through 39253), we proposed to continue this process for CY 2016. Specifically, for CY 2016, we proposed to include in Addendum B to the CY 2016 OPPS/ASC final rule with comment period the following new HCPCS codes:

- New Level II HCPCS codes effective October 1, 2015, that would be incorporated in the October 2015 OPPS quarterly update CR;
- New Level II HCPCS codes effective January 1, 2016, that would be incorporated in the January 2016 OPPS quarterly update CR.

As stated above, the October 1, 2015 and January 1, 2016 codes are flagged with comment indicator ''NI'' in Addendum B to this CY 2016 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2016. We are inviting public comments on the interim status indicator and APC assignments and payment rates for these codes, if applicable, that will be finalized in the CY 2017 OPPS/ASC final rule with comment period.

3. Treatment of New and Revised CY 2016 Category I and III CPT Codes That Will Be Effective January 1, 2016, for Which We Solicited Public Comments in the CY 2016 OPPS/ASC Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We noted that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the MPFS proposed rule, we do not anticipate that these HCPCS G codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid establishing HCPCS G codes and the resulting delay in utilization of the most current CPT codes. In addition, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), solicit public comments, and finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2016 OPPS update, we received the CY 2016 CPT codes from AMA in time for inclusion in the CY 2016 OPPS/ASC proposed rule. In the proposed rule (80 FR 39253), we indicated that the new and revised CY 2016 Category I and III CPT codes can be found in OPPS Addendum B to the proposed rule and were assigned to new comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and

status indicator. We refer readers to section XI.B. of the CY 2016 OPPS/ASC proposed rule for further discussion on the proposed new comment indicator ''NP.''

Further, in the proposed rule, we reminded readers that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we included the long descriptors for the new and revised CY 2016 CPT codes in Addendum O to the proposed rule (which is available via the Internet on the CMS Web site) so that the public could adequately comment on our proposed APCs and status indicator assignments. Because CPT procedure codes are 5 alpha-numeric characters and CMS systems only utilize 5-character HCPCS codes, we stated that we developed alternative 5-character placeholder codes for the proposed rule. We indicated that the placeholder codes can be found in Addendum O, specifically under the column labeled ''CY 2016 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code,'' to the proposed rule. We also indicated that the final CPT code numbers would be included in this CY 2016 OPPS/ASC final rule with comment period. We note that not every code listed in Addendum O of the proposed rule was subject to comment. For the new/revised Category I and III CPT codes, we requested public comments on only those codes that were assigned to comment indicator ''NP.'' We indicated that public comments would not be accepted for new Category I CPT laboratory codes that were not assigned to ''NP'' comment indicator in Addendum O to the proposed rule. We stated that comments to these codes must be submitted at the Clinical Laboratory Fee Schedule (CLFS) Public Meeting, which was scheduled for July 16, 2015.

In summary, we solicited public comments on the proposed CY 2016 status indicators and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2016. The CPT codes are listed in Addendum B to the proposed rule with short descriptors only. We listed them again in Addendum O to the proposed rule with long descriptors. We also proposed to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2016 OPPS/ASC final rule with comment period.

Commenters addressed several of the new CPT codes that were assigned to comment indicator ''NP'' in Addendum B of the CY 2016 OPPS/ASC proposed rule. We respond to those comments in section III.D. of this CY 2016 OPPS/ASC final rule with comment period.

The final status indicators, APC assignments, and payment rates for the new CPT codes that will be effective January 1, 2016 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

B. OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department (OPD) services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in § 419.31 of the regulations. We use Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to the items and services listed in § 419.2(b) of the regulations. A further discussion of packaged services is included in section II.A.3. of this final rule with comment period.

Under the OPPS, we generally pay for hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. In the CY 2016 OPPS/ASC proposed rule (80 FR 39254), for CY 2016, we proposed that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in proposed renumbered APC 5012 (Level 2 Examinations and Related Services) (existing APC 0632). The APC relative payment weights were scaled to proposed renumbered APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting. We noted that, historically, we have proposed APC relative payment weights relative to the hospital costs of services included in existing APC 0634. In the proposed rule, we proposed to reassign HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) from existing APC 0634 to proposed renumbered APC 5012 (for CY 2015, this is existing APC 0632). Proposed new APC 5012 includes other services that are clinically similar with similar resource costs to the service described by HCPCS code G0463, such as HCPCS code G0402 (Initial preventive physical examination). Accordingly, for the CY 2016 OPPS update, we proposed to delete existing APC 0634 and replace it with proposed renumbered APC 5012.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39254), for CY 2016, we proposed that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in proposed renumbered APC 5012 (existing APC 0632).

We did not receive any public comments on the proposed reassignment for HCPCS code G0463 from APC 0634 to proposed renumbered APC 5012. However, some commenters expressed concern about CMS' use of a single clinic visit code (HCPCS G0463) and a single APC payment for all clinic Evaluation and Management (E/M) visits. We refer readers to section VII. of this CY 2016 OPPS/ASC final rule with comment period for a discussion of public comments and our responses and our finalized policies on payments for hospital outpatient visits for CY 2016.

In this final rule with comment period, we are finalizing our proposal, without modification, to assign HCPCS code G0463 to APC 5012 and to delete existing APC 0634 because it will be replaced with APC 5012, effective January 1, 2016.

2. Application of the 2 Times Rule

In accordance with section 1833(t)(2) of the Act and § 419.31 of the regulations, we annually review the items and services within an APC group to determine, with respect to comparability of the use of resources, if the highest cost for an item or service in the APC group is more than 2 times greater than the lowest cost for an item or service within the same APC group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 claims (or less than 1,000 claims) is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost. In the CY 2016 OPPS/ASC proposed rule (80 FR 39254), for CY 2016, we proposed to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as low-volume items and services.

For the CY 2016 OPPS, we identified the APCs with violations of the 2 times rule. Therefore, we proposed changes to the procedure codes assigned to these APCs in Addendum B to the proposed rule. We noted that Addendum B does not appear in the printed version of the **Federal Register** as part of the CY 2016 OPPS/ASC proposed rule. Rather, it is published and made available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*. In these cases, to eliminate a violation of the 2 times rule or to improve clinical and resource homogeneity, we proposed to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2016 included in the proposed rule are related to changes in costs of services that were observed in the CY 2014 claims data newly available for CY 2016 ratesetting. We also proposed changes to the status indicators for some procedure codes that were not specifically and separately discussed in the proposed rule. In these cases, we proposed to change the status indicators for these procedure codes because we believe that another status indicator would more accurately describe their payment status from an OPPS perspective based on the policies that we are proposing for CY 2016. In addition, we proposed to rename existing APCs or create new clinical APCs to complement the proposed procedure code reassignments. Addendum B to the CY 2016 OPPS/ASC proposed rule identified with a comment indicator ''CH'' those procedure codes for which we proposed a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2015 OPPS Addendum B Update (available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*). In contrast, Addendum B to this final rule with comment period (available via the Internet on the CMS Web site) identifies with the ''CH'' comment indicator the final CY 2016 changes compared to the HCPCS codes' status as reflected in the October 2015 Addendum B update.

3. APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we proposed for CY 2016, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

Based on the CY 2014 claims data that were available for the CY 2016 proposed rule, we identified three APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs that we proposed to make exceptions for under the 2 times rule for CY 2016. We did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as existing APC 0375 (proposed for CY 2016 to be renumbered APC 5881 (Ancillary Outpatient Services When Patient Dies)), which had a proposed APC payment rate for a single service of $5,653.37. (We note that, in section II.A.2.e. of this final rule with comment period, we are converting renumbered APC 5881 to a comprehensive APC for CY 2016. However, the APC cost is still not relevant to determine whether there is a violation of the 2 times rule in that comprehensive APC.) We only identified those APCs, including those with criteria-based costs, with violations of the 2 times rule. For a detailed discussion of these criteria, we refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18457 and 18458).

We note that, for cases in which a recommendation by the Panel appears to result in or allow a violation of the 2 times rule, we may accept the Panel's recommendation because those recommendations are based on explicit consideration (that is, a review of the latest OPPS claims data and group discussion of the issue) of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 16 of the proposed rule (80 FR 39255) listed the three APCs that we proposed to make exceptions for under the 2 times rule for CY 2016 based on the criteria cited above and claims data submitted between January 1, 2014, and December 31, 2014, and processed on or before December 31, 2014. We stated in the proposed rule that, for the final rule with comment period, we intended to use claims data for dates of service between January 1, 2014, and December 31, 2014, that were processed on or before June 30, 2015, and updated CCRs, if available. For this final rule with comment period, after we reassigned some codes, a violation of the 2 times rule no longer exists in APCs 5221 and 5673.

We applied the criteria described earlier to determine whether to make exceptions to the 2 times rule for three APCs: APC 5165 (Level 5 ENT Procedures); APC 5731 (Level 1 Minor

Procedures) and APC 5841 (Psychotherapy). Based on our analysis of the updated CY 2014 claims data available for this final rule with comment period (and consideration of any related finalized changes to APC assignments), we determined that APCs 5165, 5731 and 5841 meet the exceptions criteria because these APC groupings optimize resource and clinical homogeneity. Therefore, we are making these three APCs exceptions to the 2 times rule.

Furthermore, although APC 5165 does not appear with a 2 times rule indicator in the 2 times rule document that is posted with the CY 2016 OPPS/ASC final rule data files, an exception to the 2 times rule is required so that a complexity adjustment is not made for CPT 60252 from APC 5165 to APC 5166.

After consideration of the public comments we received and our review of the CY 2014 costs from hospital claims and cost report data available for this final rule with comment period, we are finalizing three exceptions to the 2 times rule: APCs 5165, 5731 and 5841. We are not finalizing our proposal to make exceptions for APC 5221 and APC 5673. Table 19 below lists the three APCs that we are excepting from the 2 times rule for CY 2016 based on the criteria above and a review of updated claims data. The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

TABLE 19—FINAL APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2016

CY 2016 APC	CY 2016 APC title
5165	Level 5 ENT Procedures.
5731	Level 1 Minor Procedures.
5841	Psychotherapy.

The final costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

C. New Technology APCs

1. Background

In the November 30, 2001 final rule (66 FR 59903), we finalized changes to the time period a service was eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

Currently, there are 37 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0—$10)) through the highest cost band assigned to APC 1574 (New Technology—Level XXXVII ($9,500—$10,000)). In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently. We note that we did not propose to renumber the New Technology APCs in the CY 2016 OPPS/ASC proposed rule.

We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1574, vary with increments ranging from $10 to $500. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level VII ($500—$600)) is made at $550.

Every year we receive several requests for higher payment amounts under the New Technology APCs for specific procedures paid under the OPPS because they require the use of expensive equipment. We are taking this opportunity to reiterate our response in general to the issue of hospitals' capital expenditures as they relate to the OPPS and Medicare.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital inpatient market basket increase. We believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries, and we believe that our payment rates are adequate to ensure access to services.

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the techniques and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per use costs for which requesters believe Medicare should make full payment. However, we believe that it is most appropriate to set payment rates based on costs that are associated with providing care to Medicare beneficiaries. As claims data for new services become available, we use these data to establish payment rates for new technology.

2. Additional New Technology APC Groups

Currently, there are 37 levels of New Technology APC groups with two parallel status indicators; one set with a status indicator of ''S'' and the other set with a status indicator of ''T.'' To improve our ability to pay appropriately for new technology services and procedures, in the CY 2016 OPPS/ASC proposed rule (80 FR 39256), we proposed to expand the New Technology APC groups by adding 9 more levels, specifically, adding New Technology Levels 38 through 46. We proposed this expansion to accommodate the assignment of the retinal prosthesis implantation procedure to a New Technology APC, which is discussed further below. Therefore, for the CY 2016 OPPS update, we proposed to establish a new set of New Technology APCs 1575 through 1583 (for Levels 38 through 46) with OPPS status indicator ''S'' and a

new set of New Technology APCs 1585 through 1593 (for Levels 38 through 46) with OPPS status indicator ''T.'' These two new sets of APCs have the same payment levels with one set subject to the multiple procedure payment reduction (status indicator ''T'') and the other set not subject to the multiple procedure payment reduction (status indicator ''S''). Each proposed set of new technology APC groups has identical group titles, payment rates, and minimum unadjusted copayments, but a different status indicator. Table 17 of the proposed rule included the complete list of the proposed additional 18 New Technology APCs for CY 2016.

Comment: One commenter noted that the inconsistency in the increment increases in the new levels for the New Technology APCs, specifically that Level 38 through Level 41 increased in increments of $5,000, while Level 42 through Level 46 increased in increments of $10,000. The commenter suggested that increments of $5,000 is more appropriate and provides more accurate payment for providers as well as consistency among payment levels beginning at Level 38.

Response: As stated above, for CY 2015, there are 37 levels of New Technology APC groups with two parallel status indicators; one set with a status indicator of ''S'' and the other set with a status indicator of ''T.'' The cost bands for these New Technology APCs range from $0 to $50 in increments of $10, from $50 to $100 in increments of $50, from $100 to $2,000 in increments of $100, and from $2,000 to $10,000 in increments of $500. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1530 (New Technology—Level 30 ($6,000-$6,500)) is made at $6,250. We believe that the increments for New Technology APC Levels 38 through 46 are appropriate because they maintain a similar proportionality to the total payment as the original New Technology APCs, and they allow us to price new technology procedures and services on a temporary basis with sufficient accuracy without an excessive and cumbersome number of cost bands. We will monitor these APCs during our annual review and establish New Technology APC cost bands in the future as warranted.

Comment: Several commenters supported expanding the New Technology APCs by adding New Technology Levels 38 through 46. They believed that the addition of these new cost bands provides flexibility for CMS to properly assign qualifying services and technologies to the most appropriate payment level, as well as an opportunity for the collection of more accurate claims data to ensure appropriate payments when the procedures and services transition out of the New Technology APC cost bands to clinical APCs. The commenters also recommended revising the payment level descriptions for the New Technology APCs by adding one dollar to the lower end of the payment range (for example, Level 1502 at $51-$100) for the various levels to avoid pricing overlap. In addition, the commenters suggested that CMS remain open to the idea of creating new payment band levels in the future, as needed, to accommodate the growing number of new procedures, services, and technologies that can be safely performed and delivered in the hospital outpatient setting.

Response: We appreciate the commenters' support for our proposal to add New Technology Levels 38 through 46 for CY 2016. However, because the payment rate for each New Technology APC is at the midpoint of the specified range, we do not believe that revising the limits of these ranges for the New Technology APCs is necessary to eliminate what commenters believe is a pricing overlap. In addition, when we lack claims data (as we do for new services that have not be reported on hospital outpatient claims), our cost estimates typically suggest a range as represented by a New Technology APC cost band. These estimates are not so precise that they result in an exact dollar amount that would correspond to a dollar amount limit of a New Technology APC range. We typically estimate an approximate range that we believe corresponds to the approximate cost of the new service and match that range to the closest New Technology APC. Therefore, the overlap of the limits of the ranges of adjacent New Technology APCs makes no difference.

We agree with the commenters that adding New Technology APC cost bands on an as needed basis is appropriate. In addition to the additional New Technology APCs that we proposed, we are establishing two additional New Technology APC levels (4 new APCs in total, for which two APCs are assigned status indicator ''S'' and two APCs are status indicator ''T''). These APCs are depicted in Table 20.

TABLE 20—ADDITIONAL NEW TECHNOLOGY APCS FOR CY 2016

APC No.	APC title	Status indicator
1584	New Technology—Level 47 ($80,000–$90,000)	S
1585	New Technology—Level 48 ($90,000–$100,000)	S
1598	New Technology—Level 47 ($80,000–$90,000)	T
1599	New Technology—Level 48 ($90,000–$100,000)	T

The explanation as to why we are creating these additional New Technology APCs is contained below in the discussion of the New Technology APC for the retinal prosthesis implant procedure.

After consideration of the public comments we received, we are finalizing our proposal, with a modification, to add New Technology Levels 38 through 46 for CY 2016. We also are adding two additional levels, New Technology Levels 47 and 48. Table 21 below includes the final complete list of the additional 22 New Technology APC groups for CY 2016.

TABLE 21—ADDITIONAL NEW TECHNOLOGY APC GROUPS FOR CY 2016

New CY 2016 APC	CY 2016 APC group title	Final CY 2016 status indicator
1575	New Technology—Level 38 ($10,000–$15,000)	S
1576	New Technology—Level 39 ($15,000–$20,000)	S
1577	New Technology—Level 40 ($20,000–$25,000)	S
1578	New Technology—Level 41 ($25,000–$30,000)	S
1579	New Technology—Level 42 ($30,000–$40,000)	S
1580	New Technology—Level 43 ($40,000–$50,000)	S
1581	New Technology—Level 44 ($50,000–$60,000)	S
1582	New Technology—Level 45 ($60,000–$70,000)	S
1583	New Technology—Level 46 ($70,000–$80,000)	S
1584	New Technology—Level 47 ($80,000–$90,000)	S
1585	New Technology—Level 48 ($90,000–$100,000)	S
1589	New Technology—Level 38 ($10,000–$15,000)	T
1590	New Technology—Level 39 ($15,000–$20,000)	T
1591	New Technology—Level 40 ($20,000–$25,000)	T
1592	New Technology—Level 41 ($25,000–$30,000)	T
1593	New Technology—Level 42 ($30,000–$40,000)	T
1594	New Technology—Level 43 ($40,000–$50,000)	T
1595	New Technology—Level 44 ($50,000–$60,000)	T
1596	New Technology—Level 45 ($60,000–$70,000)	T
1597	New Technology—Level 46 ($70,000–$80,000)	T
1598	New Technology—Level 47 ($80,000–$90,000)	T
1599	New Technology—Level 48 ($90,000–$100,000)	T

The final payment rates for New Technology APC groups 1575 through 1598 (with status indicator ''S'') and APC groups 1585 through 1599 (with status indicator ''T'') can be found in Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site).

3. Procedures Assigned to New Technology APC Groups for CY 2016

As we explained in the CY 2002 OPPS final rule with comment period (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. However, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, in the CY 2016 OPPS/ASC proposed rule (80 FR 39256), for CY 2016, we proposed to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been obtained (66 FR 59902).

We did not receive any public comments related to this proposal. Therefore, we are finalizing our CY 2016 proposal, without modification, to retain services within New Technology APCs until we gather sufficient claims data to assign the services to a clinically appropriate APC. Thus, a service can be assigned to a New Technology APC for more than 2 years if we have insufficient claims data to reassign the service to a clinical APC, or it could be reassigned to a clinical APC in less than 2 years if we have adequate claims data.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39256), we proposed to assign two surgical procedures to New Technology APCs. Specifically, we proposed to continue to assign HCPCS code C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) to New Technology APC 1564 (New Technology—Level 27 ($4,500–$5,000)) and to reassign CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) from APC 0673 (Level 2 Intraocular Procedures) to proposed newly established New Technology APC 1593 (New Technology—Level 46 ($70,000–$80,000) to pay appropriately for the procedures.

a. Transprostatic Urethral Implant Procedure

Currently, in CY 2015, there is one procedure that is receiving payment through a New Technology APC. Specifically, the surgical procedure described by HCPCS code C9740 is assigned to New Technology APC 1564 (New Technology—Level 27 ($4,500–$5,000)), with a payment rate of $4,750. This procedure was assigned to New Technology APC 1564 on April 1, 2014, when the HCPCS C-code was established.

For the CY 2016 OPPS update, based on our review of the claims data for HCPCS code C9740 from April through December 2014, we found 100 single claims (out of 128 total claims) with a geometric mean cost of approximately $5,648. Because there is not a full year of claims data and only 100 single claims are in our database for HCPCS code C9740, in the CY 2016 OPPS/ASC proposed rule, we proposed to maintain the assignment of HCPCS code C9740 to New Technology APC 1564 for CY 2016. As described in section IV.B. of the proposed rule, we note that, based on the costs of the device relative to the procedure in this APC, the procedures assigned to APC 1564 would be device-intensive for CY 2016. The proposed CY 2016 payment rate for HCPCS code C9740 was included in Addendum B to

the proposed rule (which is available via the Internet on the CMS Web site).

Comment: Several commenters supported CMS' proposal to retain HCPCS code C9740 in New Technology APC 1564 for CY 2016. The commenters stated that retaining this surgical procedure in a new technology APC for another year will allow CMS to continue collecting the claims data necessary to identify an appropriate APC assignment for the procedure. The commenters also supported the proposed designation of APC 1564 as a device-intensive APC so that the procedure assigned to the APC can be performed and paid adequately in the ASC setting. However, one commenter disagreed with the APC assignment for HCPCS code C9740. The commenter believed that, based on the cost data, HCPCS code C9740 should be assigned to New Technology APC 1567 (New Technology—Level 30 ($6,000–$6,500)), with a payment rate of approximately $6,250.

Response: Based on the latest claims data used for this final rule with comment period, which is based on claims submitted between January 1, 2014, and December 31, 2014, and processed on or before June 30, 2015, we are reassigning HCPCS code C9740 from New Technology APC 1564 to New Technology APC 1565 (New Technology—Level 28 ($5,000–$5,500)). Specifically, we found a geometric mean cost of approximately $5,627 based on 130 single claims (out of 161 total claims) for HCPCS code C9740, which is comparable to the payment rate of $5,250 for New Technology APC 1565. We note that HCPCS code C9740 is the only code assigned to New Technology APC 1565. We do not believe HCPCS code C9740 should be assigned to either New Technology APC 1566 (New Technology—Level 29 ($5500–$6000)), with a payment rate of approximately $5,750 or New Technology APC 1567 (New Technology—Level 30 ($6000–$6500)), with a payment rate of approximately $6,250) because the payment rates for these APCs are significantly higher than the geometric mean cost of approximately $5,627 for HCPCS code C9740. Therefore, in this final rule with comment period, we are revising the APC assignment for HCPCS code C9740 to New Technology APC 1565 for CY 2016. We note that HCPCS code C9740 is the only procedure assigned to New Technology APC 1565, which is a device-intensive APC for CY 2016. We anticipate that the CY 2015 claims data (which will be used for CY 2017 ratesetting) for HCPCS code C9740 will be sufficient for the assignment of the code to a clinical APC in CY 2017.

Comment: One commenter suggested that CMS reassign HCPCS code C9739 (Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants), from clinical APC 5374 (Level 4 Urology and Related Services) to C–APC 5375 (Level 5 Urology and Related Services). The commenter believed that, similar to HCPCS code C9740, HCPCS code C9739 should be assigned to a device-intensive APC. In addition, the commenter believed that because both procedures describe an Urolift implant procedure and the only difference is that HCPCS code C9739 involves 1 to 3 transprostatic implants while HCPCS code C9740 involves 4 or more implants, both procedure codes should be assigned to device-intensive APCs.

Response: We agree with the commenter's suggestion to assign HCPS code C9739 to APC 5375. Analysis of the latest claims data used for this final rule revealed a geometric mean cost of approximately $4,263 based on 53 single claims (out of 54 total claims) for HCPCS code C9739. We believe that the geometric mean cost for HCPCS code C9739 is similar to other procedures assigned to APC 5375, which has a geometric mean cost of approximately $3,551. Therefore, for CY 2016, we are reassigning HCPCS code C9739 to APC 5375.

Comment: One commenter suggested that a device HCPCS C-code or HCPCS code L8699 (Prosthetic implant, not otherwise specified) should be required on all claims that report HCPCS code C9739 or C9740. The commenter reported that, based on the review of the CY 2016 OPPS/ASC proposed rule claims data, approximately 50 percent of the claims did not have a device code reported, thus making it impossible to determine the number of implants used. The commenter requested the establishment of device edits to ensure that implant costs are included in the claims to facilitate ratesetting.

Response: We do not believe that we should establish device edits for every procedure code, including HCPCS code C9739 or C9740. We rely on hospitals to report procedures, services, and items accurately. As we have stated in previous final rules, it is extremely important that hospitals use all of the required HCPCS codes to report the performance of all services they furnish, consistent with the code descriptors, CPT and/or CMS instructions, and correct coding principles, whether payment for the services is made separately or packaged. The accuracy of the OPPS payment rates depends on the quality and completeness of the claims data that hospitals submit for the services they furnish to Medicare beneficiaries.

However, in the CY 2016 OPPS/ASC proposed rule, we proposed to establish claims processing edits such that a device HCPCS code must be reported on the same claim form for any procedure code assigned to a device-intensive APC (80 FR 39268). We further stated that claims submitted with a procedure code requiring a device that is assigned to a device-intensive APC but without any device HCPCS code on the claim would be returned to the provider. We are finalizing this proposal for CY 2016. Specifically, only the procedures that require the implantation of a device that are assigned to a device-intensive APC will require a device code on the claim and claims processing edits will apply only to those APCs that are listed in Table 42 of this final rule with comment period. Further discussion of this final policy can be found in section IV.B. of this final rule with comment period. Because HCPCS code C9740 is assigned to a device-intensive APC for CY 2016, we expect hospitals to report the appropriate device code with the implant procedure. In this case, we also would expect hospitals to report HCPCS code L8699 when reporting HCPCS code C9740. This will ensure that device costs are always reported on the claim and are appropriately captured in claims that CMS uses for ratesetting.

In summary, after consideration of the public comments we received, we are finalizing our proposals, with modification. Specifically, we are reassigning HCPCS code C9740 from New Technology APC 1564 to New Technology APC 1565, and reassigning HCPCS code C9739 from clinical APC 5374 to APC 5375 for CY 2016. We note that the APC to which HCPCS code C9740 is assigned is designated as a device-intensive APC, which will require reporting the appropriate device code (in this case, HCPCS code L8699) when the surgical procedure describing HCPCS C9740 is reported on the claim. The final CY 2016 payment rates for HCPCS codes C9739 and C9740 are included in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

b. Retinal Prosthesis Implant Procedure

CPT code 0100T describes the implantation of a retinal prosthesis. This surgical procedure is currently assigned to APC 0673, which has a CY 2015 payment rate of approximately $3,123. The retinal prosthesis device that is used in the procedure described by CPT code 0100T is described by HCPCS code C1841 (Retinal prosthesis,

includes all internal and external components). The first retinal prosthesis (Argus® II Retinal Prosthesis System) was approved by the FDA in 2013 for adult patients with advanced retinitis pigmentosa. Pass-through status was granted for HCPCS code C1841 beginning October 1, 2013, and is proposed to expire on December 31, 2015. We refer readers to section IV.A.1.b. of this final rule with comment period for the discussion of the expiration of pass-through for HCPCS code C1841.

After pass-through status expires for a medical device, the payment for the device is packaged into the payment for the associated surgical procedure. The surgical procedure in which the Argus device (HCPCS code C1841) is implanted is described by CPT code 0100T. Review of the CY 2014 OPPS claims data used for the CY 2016 OPPS/ASC proposed rule showed only one single claim for CPT code 0100T with HCPCS code C1841 on the claim. Due to the newness of this surgical procedure and its associated implantable device and the extremely low number of CY 2014 HOPD claims for this procedure, in the CY 2016 OPPS/ASC proposed rule (80 FR 39257), we proposed to reassign CPT code 0100T from existing APC 0673 (Level III Intraocular Procedures) to proposed newly established New Technology APC 1593 (New Technology—Level 46 ($70,000–$80,000)), with a payment of approximately $75,000 for CY 2016. We refer readers to section III.C.2. of the proposed rule and this final rule with comment period for a discussion of the proposed expansion of the New Technology APC levels. We stated in the proposed rule (80 FR 39257) that ''[w]e are proposing a CY 2016 OPPS payment of approximately $75,000 for proposed new APC 1593, which would be the payment for CPT code 0100T (not including the retinal prosthesis), plus the proposed maximum FY 2016 IPPS new technology add-on payment for a case involving the Argus® II Retinal Prosthesis System of $72,028.75 (80 FR 24425).'' In the proposed rule (80 FR 39257), we also stated that we believe that, given the newness of this procedure and the severe paucity of OPPS claims data, this approach provides a reasonable payment amount that is similar to the payment for the same procedure provided in the hospital inpatient setting. Once we have more claims data, we indicated that we will reassess the APC placement of the retinal prosthesis implantation procedure in light of our standard rate setting methodology. We invited public comments on this proposal.

Comment: Several commenters expressed concern over the proposed payment rate of $75,000 for CPT code 0100T. The commenters reported that the cost of the Argus II device is approximately $144,000 while the cost of the surgical procedure to implant the device is between approximately $5,000 and $10,000. The commenters urged CMS to establish a payment rate of approximately $150,000 to accurately pay hospitals for the full cost of providing the procedure and furnishing the device. Other commenters reported confusion about the proposed policy. Based on their reading of the proposal, the commenters believed that CMS is proposing to pay (1) $75,000 for New Technology APC 1593 plus (2) the IPPS New Technology payment amount of approximately $72,029, which would result in a total procedure payment of approximately $147,029. The commenters requested clarification on the proposed total procedure payment. Another commenter indicated that a total payment of $75,000 for the device and surgical procedure is inappropriate and further disagreed with CMS' use of the IPPS new technology add-on payment as a proxy for the Argus II procedure cost because this add-on payment is set at 50 percent of costs of the new technology.

Response: We appreciate the commenters' request for clarification. In the CY 2016 OPPS/ASC proposed rule, we proposed to pay for the surgical implant procedure including the retinal prosthesis device under newly proposed New Technology APC 1593. The following sentence in the proposed rule (80 FR 39257) may be the source of some commenters' confusion: ''[w]e are proposing a CY 2016 OPPS payment of approximately $75,000 for proposed new APC 1593, which would be the payment for CPT code 0100T (not including the retinal prosthesis), plus the proposed maximum FY 2016 IPPS new technology add-on payment for a case involving the Argus® II Retinal Prosthesis System of $72,028.75.'' What we meant by that sentence is the payment amount of $75,000 for APC 1593 would be comprised of the approximate sum of: (1) The payment amount for the procedure ($3,123, which is the CY 2015 payment rate for the procedure described by CPT code 0100T); and (2) the payment amount for the device ($72,028.75—the proposed IPPS payment amount for the device). That is, the approximate $75,000 payment for APC 1593 is the total payment amount, which includes payment for both the procedure and the device.

The final rule claims data contain additional claims data for CPT code 0100T. There are 5 total claims (2 single claims) with a geometric mean cost of approximately $95,866. Although this remains a very low volume of claims, we prefer to base the cost estimate for this procedure (which include the cost of the device) on the hospital outpatient claims data rather than using the IPPS new technology add-on payment as a proxy for the procedure cost. However, we do not believe that there are a sufficient number of claims upon which to base a clinical APC for the retinal prosthesis procedure. Therefore, we are creating a New Technology APC (Level 48) for CPT code 0100T with the cost band range of $90,000 to $100,000 and a payment amount of $95,000. In addition, because the proposed additional New Technology APCs ended with Level 46 ($70,000–$80,000), we also are creating a New Technology Level 47 with the cost band range of $80,000 to $90,000 and a payment amount of $85,000 to fill in the gap between New Technology APC Level 46 and Level 48.

Comment: One commenter recommended the establishment of a HCPCS G-code for the Argus implant procedure and the assignment of this G-code to a new technology APC with a payment rate of $150,000.

Response: We disagree with establishing a HCPCS G-code and assigning it to a new technology APC with a payment rate of $150,000 because CPT code 0100T accurately describes the procedure associated with implanting the Argus II device.

Comment: One commenter recommended, as an alternative to the New Technology APC payment, that CMS continue to pay separately for CPT code 0100T and HCPCS code C1841. Specifically, the commenter requested that CMS pay separately for surgical procedure CPT code 0100T and also extend the pass-through status for the device HCPCS code C1841 through December 31, 2016 because of very limited claims data.

Response: We stated in the CY 2016 OPPS/ASC proposed rule that pass-through payment status for device HCPCS code C1841 would expire on December 31, 2015 because it was approved for pass-through status effective October 1, 2013 (80 FR 39264). We also proposed to package and assign device HCPCS code C1841 to OPPS status indicator ''N'' to indicate that the payment for this code would be included in the surgical procedure CPT code 0100T. We do not agree that

extending the pass-through status would be appropriate because we believe it would be inconsistent with the statutory pass-through provision. Section 1833(t)(6)(B)(iii) requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years.

After consideration of the public comments we received, we are assigning CPT code 0100T to New Technology APC 1599, which has a final payment of $95,000 for CY 2016. This payment rate includes the payment for the retinal prosthesis system as well as all other items and supplies used in the surgical procedure to implant the device. Because payment for retinal prosthesis is included in CPT code 100T, we are finalizing our proposal to assign HCPCS code C1841 to OPPS status indicator ''N'' to indicate that this code is packaged under the hospital OPPS. We also are designating APC 1599 as a device-intensive APC because almost all of the cost of the implantation procedure is attributable to the cost of the device. Because CPT code 0100T is assigned to a device-intensive APC, a device HCPCS C-code will be required on claims with CPT code 0100T according to the device edit policy described in section IV. of this final rule with comment period.

D. OPPS Ambulatory Payment Classification (APC) Group Policies

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and to revise the groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Therefore, every year we review and revise the APC assignments for many procedure codes and diagnosis codes based on our evaluation of these factors using the latest OPPS claims data. Although we do not discuss every APC change in the proposed and final rules, these changes are listed in the OPPS Addendum B of the proposed and final rules. Specifically, procedure and diagnosis codes with revised APC and/or status indicator assignments are identified by comment indicator ''CH'' (Active HCPCS code in current year and next calendar year, status indicator and/or APC assignment has changed) in the OPPS Addendum B payment file.

In our efforts to improve clinical and resource homogeneity among the APC groupings and update the hospital OPPS, we conducted a comprehensive review of the current structure of the APCs and codes assignments for CY 2015. Consequently, as part of our broader efforts to thoroughly review, revise, and consolidate APCs to improve both resource and clinical homogeneity, we proposed in the CY 2015 OPPS/ASC proposed rule (79 FR 40981 through 40983) to restructure the first set of clinical families, specifically the ophthalmology and gynecology APCs. We proposed to restructure the APCs for these clinical families based on the following principles:

- Improved clinical homogeneity;
- Improved resource homogeneity;
- Reduced resource overlap in APCs within a clinical family; and
- Greater simplicity and improved understanding of the structure of the APCs.

Based on our review, for CY 2015, we finalized the APC restructuring for the ophthalmology and gynecology APCs. For the complete discussion on the APC restructuring for the ophthalmology APCs, we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66857 through 66859). Similarly, for the complete discussion on the APC restructuring for the gynecology APCs, we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66849 through 66851).

For the CY 2016 update, as a part of our continued review of the structure of the APCs, in the CY 2016 OPPS/ASC proposed rule (80 FR 39257), we proposed to restructure nine APC clinical families based on the same principles used for restructuring the ophthalmology and gynecology APCs for CY 2015. We discuss below our proposed restructuring for the nine APC clinical families. We note that, in conjunction with the proposed restructuring, we proposed to renumber several families of APCs to provide consecutive APC numbers for consecutive APC levels within a clinical family for improved identification of APCs and ease of understanding the APC groupings. For example, the seven APC levels for urology procedures were proposed to be renumbered as APC 5371 (Level 1 Urology and Related Services), APC 5372 (Level 2 Urology and Related Services), APC 5373 (Level 3 Urology and Related Services), APC 5374 (Level 4 Urology and Related Services), APC 5375 (Level 5 Urology and Related Services), APC 5376 (Level 6 Urology and Related Services), and APC 5377 (Level 7 Urology and Related Services). We stated in the proposed rule that we believe that consecutive numbering of the APCs will enhance the public understanding of the APC groups and will make it easier for them to communicate to the agency about issues concerning APCs. We note that, under this initiative, we did not propose to change the numbering of the composite APCs or the New Technology APCs for CY 2016.

Comment: Several commenters expressed concern about the lack of detail in the proposed rule on the proposed consolidation and restructuring of the nine APC groups. The commenters stated that CMS provided few details in the proposed rule to enable commenters to adequately assess the full impact of the proposed APC reconfiguration, and requested a delay in the implementation of the proposal until more information is available. They also stated that CMS did not provide impact tables to show the projected impact that the proposed APC consolidation would have on Medicare payments by departments or specialties, or provide the rationale behind the decisions for each combination of APC groups, which they believed further complicated analysis of each proposed APC group. Some commenters indicated that they had difficulty analyzing the impact and interrelationship of the different proposed policies to adequately determine Medicare payments to hospitals. Several commenters requested that CMS not finalize the proposal and stated that the proposed APC groupings do not reflect clinical or resource homogeneity. Some commenters believed that CMS should develop and establish criteria before finalizing the reconfiguration of the nine APC groups.

However, many other commenters supported the consolidation and restructuring of the nine clinical family APCs but requested modification to the APC groupings. In particular, the commenters requested the reassignment of several procedures and services to certain APCs for the final rule. In addition, several commenters requested further information in the final rule, and urged CMS to include a separate impact analysis for each restructured APC clinical family showing the distributional impact of the restructuring across CMS' usual categories (such as urban/rural location, bed size, type of ownership and teaching status).

Response: Based on our experience with the existing APCs under the OPPS, we believe that establishing more inclusive categories of procedures and services is more appropriate for future ratesetting under the OPPS. Therefore, we believe that the proposed restructured APCs have a more clinically appropriate granularity, while improving resource similarity. We also

believe the proposed restructure and consolidation of APCs more appropriately categorizes all of the procedures and services within each of the nine APC groups such that the procedures and services within each proposed newly configured APC are more comparable with respect to clinical characteristics and resource use.

In addition, we disagree that we should delay or not finalize the proposed consolidation and restructuring of the nine APC groups pending provision of the extensive data that the commenters requested. We make available a considerable amount of data for public analysis each year for both the proposed rule and the final rule. While we are not developing and providing the extensively detailed information that the commenters requested, we are providing the public use files of claims and a detailed narrative description of our data process that the public can use to perform any desired analyses (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

We note that we included the impact of the CY 2016 OPPS proposals on payment to different classes of hospitals in Table 65 of the proposed rule (80 FR 39362 through 39363). We believe our estimate of the impact of these proposed changes provided valuable information to hospitals. We believe that it would be impractical and nonproductive to develop impact tables for each of the primary clinical families that were proposed to be reorganized. Hospitals generally do not perform a limited set of services confined to one clinical family. Therefore, we believe that impacts reflecting the interaction and collective effect of the proposed APC restructuring best depict how most hospitals will fare under the proposed reorganization. Many commenters submitted comments relating to particular services and were able to provide detailed analysis in their comments based on the data and other information provided with the proposed rule.

Further, we do not agree that we should develop and establish additional criteria before finalizing the proposed consolidation and restructuring of the nine APC groups. The OPPS statute provides that procedures grouped in APCs must be similar clinically and in terms of resource use. In various sections of this final rule with comment period, we have applied those criteria and responded to many of the public comments we received, which included evaluations of the recommended changes to the APC assignments, based on those criteria. Each year, under the OPPS, we revise and make changes to the APC groupings based on the latest hospital outpatient claims data to appropriately place procedures and services in APCs based on clinical characteristics and resource similarity.

Therefore, after consideration of the public comments we received, we are finalizing, with some modifications that are discussed below in the sections specific to each clinical family, the proposed consolidation and restructuring of the nine clinical families of APCs for CY 2016. Each of the nine clinical families, the public comments we received, and our responses on those families are discussed below. The final payment rates for the nine individual clinical family APCs are included in Addendum A to this final rule with comment period.

1. Airway Endoscopy Procedures

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we examined the APCs that contain airway endoscopy procedures. In the CY 2016 OPPS/ASC proposed rule (80 FR 39257), for CY 2016, we proposed to restructure the OPPS APC groupings for airway endoscopy procedures to more appropriately reflect the costs and clinical characteristics of the procedures within each APC grouping in the context of the OPPS. The current APCs for airway endoscopy procedures are divided into upper airway and lower airway endoscopy APC series. After reviewing these APCs, we believe that consolidating the current upper airway and lower airway APC series into a single APC grouping for airway endoscopy procedures would result in improved resource homogeneity for the various airway endoscopy procedures, while maintaining clinical homogeneity. Therefore, for CY 2016, we proposed to restructure and consolidate the APCs that include airway endoscopy procedures into a single APC grouping. Table 18 of the proposed rule listed the current CY 2015 APCs that contain the airway endoscopy procedures, and Table 19 of the proposed rule listed the proposed CY 2016 APCs that would result from our consolidation and restructuring of the current airway endoscopy procedure APCs into a single APC grouping. The proposed restructured/renumbered CY 2016 airway endoscopy APCs were: Proposed APC 5151 (Level 1Airway Endoscopy); proposed APC 5152 (Level 2 Airway Endoscopy); proposed APC 5153 (Level 3 Airway Endoscopy); proposed APC 5154 (Level 4 Airway Endoscopy); and proposed APC 5155 (Level 5 Airway Endoscopy.

We invited public comments on this proposal.

Comment: Several commenters supported the proposed restructuring of the airway endoscopy APCs. However, the commenters submitted a list of procedure codes (indicated in Table 22 below) that they requested CMS to reassign to higher-level APCs in the airway endoscopy grouping based on greater resource similarity of the procedures described by the codes listed by the commenters compared to the procedures described by the proposed codes assigned to the proposed APCs. In addition, the HOP Panel recommended that CMS reassign the procedures described by CPT codes 31652 and 31653 from proposed APC 5153 to proposed APC 5154 because the Panel agreed with the presenter that the procedures described by these new codes are most similar to the procedures assigned to CPT code 31629, which is assigned to APC 5154. One commenter requested that CMS assign the procedure described by CPT code 31652 to APC 5154 and the procedure described by CPT code 31653 to APC 5155. Another commenter requested that CMS reassign the procedure described by CPT code 31515 from proposed APC 5152 to proposed APC 5154 because the commenter believed that this procedure is more clinically similar to other procedures (described by CPT codes 31629 and 31645) assigned to proposed APC 5154. One commenter requested that CMS create a Level 6 Airway Endoscopy APC and assign the procedures described by CPT codes 31636, 31634, and 31647 to this newly APC because the costs of these procedures are not similar to the costs of other procedures assigned to APC 5155.

Response: We agree in part with the commenters' requested code reassignments and with the Panel's recommendation. However, we do not believe that the procedure described by CPT code 31515 should be reassigned to proposed APC 5154, that the procedure described by CPT code 31653 should be assigned to proposed APC 5153 instead of proposed APC 5155, or that we should create a Level 6 Airway Endoscopy APC. We are reassigning seven of the eight recommended procedure codes (as listed in Table 22 below) to the next higher level airway endoscopy APC to improve the resource homogeneity of all the procedures assigned to the airway endoscopy APCs. We do not agree with the commenter

that the procedure described by CPT code 31515 should be assigned to the higher level APC 5154 instead of APC 5152. The geometric mean cost of the procedure described by CPT code 31515 is approximately $444, and the geometric mean cost of APC 5152 is approximately $393. The geometric mean cost of APC 5154 is approximately $2,084. We believe that, given the significant difference in resource use and similarity between the procedure described by CPT code 31515 and the procedures assigned to APC 5154, assigning the procedure described by CPT code 31515 to APC 5154 would be an inappropriate APC assignment. We also believe that, based on the clinical characteristics of the new airway endoscopy procedure grouping described by CPT code 31653, the procedure is most appropriately assigned to APC 5154, which is one level higher than what was proposed. In addition, we do not believe it is necessary to create a sixth level to the Airway Endoscopy APC grouping to appropriately pay for the procedures described by CPT codes 31636, 31634, and 31647. The procedures described by these CPT codes are low volume procedures, and even if the procedures represented a significant volume in the CY 2014 claims data, assigning these procedures to APC 5155 would not result in a violation of the 2 times rule for the APC.

Table 22 below shows the airway endoscopy procedure codes with the commenters' specific APC recommendations and the final CMS decisions, final APC assignment, and final status indicator assignment for CY 2016.

TABLE 22—AIRWAY ENDOSCOPY PROCEDURE CODES WITH COMMENTERS' SPECIFIC APC RECOMMENDATIONS AND FINAL CMS DECISIONS

CPT/HCPCS code	Short descriptor	Proposed CY 2016 SI	Proposed CY 2016 APC	Commenter requested APC	CMS Decision	Final CY 2016 SI	Final CY 2016 APC
31295	Sinus endo w/balloon dil	T	5154	5155	Agree	T	5155
31296	Sinus endo w/balloon dil	T	5154	5155	Agree	T	5155
31297	Sinus endo w/balloon dil	T	5154	5155	Agree	T	5155
31515	Laryngoscopy for aspiration	T	5152	5154	Disagree	T	5152
31626	Bronchoscopy w/markers	T	5154	5155	Agree	T	5155
31628	Bronchoscopy/lung bx each	T	5153	5154	Agree	T	5154
31652*	Bronch ebus samplng 1/2 node	T	5153	5154	Agree	T	5154
31653**	Bronch ebus samplng 3/> node	T	5153	5154	Agree	T	5154

*CPT code 31652 will be effective January 1, 2016. This code was listed as code 3160A (the 5-digit CMS placeholder code) in Addendum B, O, and Q2 of the CY 2016 OPPS/ASC proposed rule.

**CPT code 31653 will be effective January 1, 2016. This code was listed as code 3160B (the 5-digit CMS placeholder code) in Addendum B, O, and Q2 of the CY 2016 OPPS/ASC proposed rule.

Comment: One commenter requested that CMS assign status indicator ''T'' (instead of status indicator ''N'') to new CY 2016 CPT codes 0406T (Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant) and 0407T (Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with biopsy, polypectomy or debridement). (We note that CPT codes 0406T and 0407T were listed as 040XF and 040XG, respectively, in Addendum B, O, and Q2 of the CY 2016 OPPS/ASC proposed rule.) The commenter suggested, as an alternative, that these codes be assigned status indicator ''Q2'' (T-packaged). In addition, the commenter recommended that CMS assign CPT code 0406T to APC 5153 and CPT code 0407T to APC 5154. The commenter believed that these procedures should be paid separately under the OPPS because they are performed as standalone surgical procedures according to the code descriptors.

Response: We disagree with the commenter that the procedures described by CPT codes 0406T and 0407T are performed as standalone procedures. We believe that procedures describing the placement of a drug-eluting sinus implant under the OPPS are performed as part of several more comprehensive and extensive endoscopic sinus surgical procedures. Therefore, we are finalizing our proposal to package payment for the procedures described by CPT codes 0406T and 0407T, and to assign these procedures to status indicator ''N'' for CY 2016.

After consideration of the public comments we received, we are finalizing the proposed structure of the airway endoscopy APCs with the code reassignments shown in Table 22 above. Table 23 below lists the final CY 2016 APCs that result from our consolidation and restructuring of the current airway endoscopy procedure APCs into a single APC grouping. The procedures assigned to each APC are listed in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

TABLE 23—FINAL CY 2016 AIRWAY ENDOSCOPY APCS

Final CY 2016 APC	CY 2016 APC group title
5151	Level 1 Airway Endoscopy.
5152	Level 2 Airway Endoscopy.
5153	Level 3 Airway Endoscopy.
5154	Level 4 Airway Endoscopy.
5155	Level 5 Airway Endoscopy.

2. Cardiovascular Procedures and Services

a. Cardiac Contractility Modulation (CCM) Therapy

In Addendum B to the CY 2016 OPPS/ASC proposed rule, we proposed to assign 11 new CY 2016 cardiac contractility modulation (CCM) therapy system CPT codes to various APCs, which are listed in Table 24 below. We also assigned these codes to comment indicator ''NP'' in Addendum B to the proposed rule to indicate that the codes are new for CY 2016 with a proposed APC assignment and that public comments would be accepted on their proposed APC assignments. We note these codes will be effective January 1, 2016. However, in the proposed rule, the codes were listed as 04XX1 through 04XX (the 5-digit CMS placeholder code) in Addendum B, O, and Q2 of the CY 2016 OPPS/ASC proposed rule.

TABLE 24—PROPOSED CY 2016 OPPS APCS AND STATUS INDICATORS FOR THE CARDIAC CONTRACTILITY MODULATION CPT PROCEDURE CODES

CY 2016 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2016 CPT code	Short descriptor	Proposed CY 2016 OPPS status indicator	Proposed CY 2016 OPPS APC
04XX1	0408T	Insj/rplc cardiac modulj sys	J1	5223
04XX2	0409T	Insj/rplc cardiac modulj pls gn	J1	5223
04XX3	0410T	Insj/rplc car modulj atr elt	J1	5222
04XX4	0411T	Insj/rplc car modulj vnt elt	J1	5222
04XX5	0412T	Rmvl cardiac modulj pls gen	J1	5222
04XX6	0413T	Rmvl car modulj tranvns elt	Q2	5221
04XX7	0414T	Rmvl & rpl car modulj pls gn	J1	5224
04XX8	0415T	Repos car modulj tranvns elt	T	5181
04XX9	0416T	Reloc skin pocket pls gen	T	5054
04X10	0417T	Prgrmg eval cardiac modulj	Q1	5741
04X11	0418T	Interro eval cardiac modulj	Q1	5741

Comment: One commenter disagreed with CMS' proposed APC assignments for certain cardiac contractility modulation (CCM) Category III CPT codes that are new in CY 2016 and therefore do not have associated claims data available. Specifically, the commenter requested four CPT codes be reassigned to the following APCs:

- CPT code 408T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes) to APC 5232 (Level 2 ICD and Similar Procedures);
- CPT code 0409T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only) to APC 5231 (Level 1 ICD and Similar Procedures);
- CPT code 0412T (Removal of permanent cardiac contractility modulation system; pulse generator only) to APC 5221 (Level 1 Pacemaker and Similar Procedures); and
- CPT code 0414T (Removal and replacement of permanent cardiac contractility modulation system pulse generator only) to APC 5231 (Level 1 ICD and Similar Procedures).

The commenter believed that the three codes for inserting or replacing the system or pulse generator are more similar clinically and in device complexity and resource use to implantable cardioverter-defibrillators (ICD) procedures. In addition, the commenter stated that the procedure time and device costs for CCM procedures exceed those for pacemaker procedures. The commenter believed the recommended APC assignment for removal of the CCM pulse generator codes better aligns with other similar removal procedure codes.

Response: We agree with the commenter that there would be greater homogeneity, both clinically and in terms of resource use, by reassigning CCM procedures for insertion and/or replacement of the CCM device (described by CPT code 0409T) from the pacemaker APCs to the ICD APCs. We also agree with the commenter that procedures for removal of the CCM device (described by CPT codes 0412T and 0414T) are more homogenous clinically and in terms of resource use with pacemaker procedures. Therefore, we are accepting the commenter's recommendation to reassign the procedures described by CPT codes 0409T and 0414T to APC 5231 and to reassign the procedures described by CPT code 0412T to APC 5221. However, we disagree with the commenter's recommendation to reassign the procedure described by CPT 0408T to APC 5232. Based on the latest available hospital claims data used for this final rule with comment period, we believe that the procedure described by CPT code 0408T should be assigned to APC 5231 because of its clinical and resource homogeneity with other procedures assigned to APC 5231. Table 24 below summarizes the commenter's requested APC assignment for each of the codes along with our decision and the final APC and status indicator assignments.

TABLE 24—CARDIAC CONTRACTILITY MODULATION PROCEDURE CODES WITH COMMENTER'S RECOMMENDED SPECIFIC APC ASSIGMENT, FINAL CMS DECISION, AND FINAL APC AND STATUS INDICATOR ASSIGNMENT

CPT/HCPCS code	Short descriptor	Proposed CY 2016 status indicator	Proposed CY 2016 APC	Commenter requested APC	CMS decision	Final CY 2016 status indicator	Final CY 2016 APC
0408T	Insj/rplc cardiac modulj sys	J1	5223	5232	Disagree	J1	5231
0409T	Insj/rplc cardiac modulj pls gn	J1	5223	5231	Agree	J1	5231
0412T	Rmvl cardiac modulj pls gen	J1	5222	5221	Agree	Q2	5221
0414T	Rmvl & rpl car modulj pls gn	J1	5224	5231	Agree	J1	5231

The final status indicator, APC assignment, and payment rate for these codes, where applicable, can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

b. Cardiac Rehabilitation

Currently, there are four established CPT/HCPCS codes that describe cardiac rehabilitation services:

• CPT code 93797 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session));
• CPT code 93798 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session));
• HCPCS code G0422 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session); and
• HCPCS code G0423 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring without exercise, per session).

In CY 2015, we assigned all four of these codes to APC 0095 (Cardiac Rehabilitation), which has a geometric mean cost of approximately $107. In the CY OPPS/ASC 2016 proposed rule, we discussed that the costs for the two intensive cardiac rehabilitation codes had increased, such that the geometric mean costs for the four cardiac rehabilitation codes that we calculated based on the CY 2014 hospital claims data available for the proposed rule were as follows: For CPT code 93797, the geometric mean cost was approximately $102. For CPT code 93798, the geometric mean cost was approximately $111. For HCPCS code G0422, the geometric mean cost was approximately $262). For HCPCS code G0423, the geometric mean cost was approximately $493. In the proposed rule, we stated that if we grouped all four of these codes into a single APC, a 2 times rule violation would result. Therefore, we proposed two levels of cardiac rehabilitation for CY 2016: APC 5771 (Level 1 Cardiac Rehabilitation), which contained the two standard cardiac rehabilitation codes (CPT codes 93797 and 93798); and APC 5772 (Level 2 Cardiac Rehabilitation), which contained the two intensive cardiac rehabilitation codes (HCPCS codes G0422 and G0423).

Our analysis of the latest CY 2014 hospital claims data available for this final rule with comment period revealed that the geometric mean costs of the intensive cardiac rehabilitation codes have decreased to levels that are more consistent with the prior year's geometric mean costs for these codes. The geometric mean costs for the four codes, using the latest available final rule claims data, are as follows: For CPT code 93797, the geometric mean cost is approximately $100. For CPT code 93798, the geometric mean cost is approximately $109. For HCPCS code G0422, the geometric mean cost is approximately $149. For HCPCS code G0423, the geometric mean cost is approximately $158. Therefore, because the geometric mean costs for all four codes based on the latest available final rule data are relatively similar, we believe that the current CY 2015 single APC configuration for cardiac rehabilitation is more appropriate than the two levels we proposed for CY 2016 and ensures that the procedures assigned to the APC do not cause a violation of the 2 times rule. Analysis using the latest available final rule claims data showed that the 2 time rule violation that existed with the data for the proposed rule no longer exists. Therefore, for CY 2016, we are assigning all four of the cardiac rehabilitation codes (CPT codes 93797 and 93798 and HCPCS code G0422 and G0423) to new APC 5771 (Cardiac Rehabilitation), with a geometric mean cost of approximately $109.

c. Cardiac Telemetry

For CY 2016, we proposed to reassign the procedure described by CPT code 93229 (External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional) from APC 0213 (Level 1 Extended EEG, sleep, and Cardiovascular Studies) to proposed APC 5722 (Level 2 Diagnostic Tests and Related Services), with a proposed payment rate of approximately $220.

Comment: One commenter disagreed with the proposed APC assignment for the procedure described by CPT code 93229 to proposed APC 5722. The commenter stated that the proposed payment rate for APC 5722 does not accurately reflect the full cost of providing the service described by CPT code 93229. The commenter also stated that hospitals are miscoding the service, and as a result, the proposed payment for this service is significantly understated. The commenter noted that, based on its internal analysis, several hospitals reported costs under $100 for services described by CPT code 93229. The commenter stated that when this service is provided under the MPFS, the payment is valued at $680.05. The commenter believed that the true cost of providing this service is closer to $795, and recommended that CMS reassign the services described by CPT code 93229 to proposed APC 5724 (Level 4 Diagnostic Tests and Related Services), with a proposed payment rate of approximately $880.

Response: As we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66847), CPT code 93229 became effective January 1, 2009. We believe that 5 years is sufficient time for hospital coders to understand the procedure described by CPT code 93229 and how to appropriately report this service on hospital claims. Based on our analysis of the CY 2014 hospital outpatient claims data used for this final rule with comment period, we are unable to determine whether hospitals are miscoding the service described by CPT code 93229. It is generally not our policy to judge the accuracy of hospital coding and charging for purposes of ratesetting (75 FR 71838). We rely on hospitals to accurately report the use of HCPCS codes in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report services on claims and charges and costs for the services on their Medicare hospital cost report appropriately. However, we do not specify the methodologies that hospitals use to set charges for this or any other service.

We acknowledge that payment under the MPFS is made separately for the procedure described by CPT code 93229. However, the MPFS and the OPPS are different payment systems with entirely different ratesetting methodologies. Each is established under a different set of regulatory and statutory principles and the policies established under the physician fee schedule do not have bearing on the payment policies under the OPPS. For example, the OPPS uses actual annual hospital claims data to calculate payment rates, while the MPFS relies on estimates of relative value units (RVUs) from the American Medical Association/Specialty Society Relative Value Update Committee (RUC).

Furthermore, as has been our practice since the implementation of the OPPS in 2000, we review, on an annual basis, the APC assignments for the procedures and services paid under the OPPS. Based on the latest hospital outpatient claims data used for this final rule with comment period, our analysis does not support the assignment of the procedure described by CPT code 93229 to APC 5724. We examined the latest hospital outpatient claims data for CPT code 93229 for dates of service between January 1, 2014, and December 31, 2014, that were processed on or before June 30, 2014. Our analysis of the claims data

shows a geometric mean cost of approximately $170 for CPT code 93229 based on 2,153 single claims (out of 3,554 total claims). We do not believe that it is appropriate to assign CPT code 93229 to APC 5724 because its geometric mean cost is approximately $896, which is significantly higher than the geometric mean cost of approximately $170 for CPT code 93229, and assigning CPT code 93229 to APC 5724 would result in an overpayment for the procedure. We believe that APC 5722 is the most appropriate APC assignment for the procedure described by CPT code 93229 based on its clinical and resource homogeneity to the other diagnostic tests and procedures assigned to this APC.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to reassign the procedure described by CPT code 93229 to APC 5722 for CY 2016. The final payment rate for CPT code 93229 can be found in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

3. Diagnostic Tests and Related Services

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we examined the APCs that contain diagnostic tests and related services. For CY 2016, we proposed to restructure the OPPS APC groupings for diagnostic tests and related services to more appropriately reflect the costs and clinical characteristics of the services within each APC grouping in the context of the OPPS. The current APCs for diagnostic tests and related services are divided according to organ system or physiologic test type. After reviewing these APCs, we believe that the current APC structure is based on clinical categories that do not necessarily reflect the significant differences in the delivery of these services in the HOPD. The current level of granularity for these APCs results in groupings that are unnecessarily narrow for the purposes of a prospective payment system. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39258), for CY 2016, we proposed to restructure and consolidate the APCs that include diagnostic tests and related services. We believe that this proposed restructuring and consolidation of APCs into larger APC groupings would more appropriately reflect a prospective payment system that is based on payment groupings and not code-specific payment rates, while maintaining clinical and resource homogeneity. Table 20 of the proposed rule listed the current CY 2015 APCs that contain nonimaging diagnostic tests, and Table 21 of the proposed rule listed the CY 2016 APCs that would result from our proposed consolidation and restructuring of the current diagnostic test and related services APCs. We invited public comments on this proposal.

Comment: A few commenters requested that CMS unpackage the payment for cochlear implant procedures described by CPT codes 92601 through 92604, and the procedures for programming an auditory brainstem implant described by CPT code 92640, and to assign these procedure codes to status indicator ''S'' instead of status indicator ''Q1.'' The commenters stated that these services are independent evaluations that are generally not related to other diagnostic tests or therapeutic services. Instead, according to these commenters, these procedures are very specific services used in the treatment for a limited population of patients with cochlear implants. One commenter provided a summary of an analysis of the claims data that it believed supports the position that payment for these services are often packaged with other unrelated OPPS services. One commenter requested that CMS unpackage the payment for procedures described by CPT code 92557 (Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556)) because payments for these procedures are packaged with payment for other unrelated services a majority of the time.

Response: We agree with the commenters regarding the cochlear implant procedures described by CPT codes 92601 through 92604 and CPT code 92640. After further review of the clinical context in which these services are performed in the HOPD, we believe that separate payment (identified by status indicator ''S'') for these services is more appropriate than a conditional packaged payment triggered by status indicator ''Q1.'' Therefore, we are changing the status indicator assignments for these five procedure codes from ''Q1'' to ''S'' for CY 2016.

With regard to the procedure described by CPT code 92557, we disagree with the commenter. We believe that audiometry is an ancillary diagnostic test that is appropriately conditionally packaged similar to many other diagnostic tests. Hearing loss has multiple potential etiologies and an evaluation of the auditory system is an important part of various diagnostic tests. It is not relevant that this service is performed by an audiologist because several different kinds of services are performed in the HOPD by various health care professionals, depending upon their area of expertise. In addition, the professional that performs the service is not a prerequisite for payment packaging determinations. We note that, under the hospital OPPS, when a conditionally packaged service is performed on a different date of service and separate from other services, it is paid separately.

Comment: One commenter supported the proposed restructuring of the diagnostic test APCs. However, the commenter suggested that, because the procedures assigned to APC 5761 (Level 1 Audiometry) and APC 5762 (Level 2 Audiometry) are diagnostic tests, these procedures should be assigned to either the newly reorganized diagnostic test APCs or to one of the minor procedure APCs to which similar procedure are assigned.

Response: We agree, in principle, with the commenter that it would be consistent with the new diagnostic test APCs structure, which includes all forms of diagnostic tests except audiometry, to also assign the audiometry procedure codes in the two audiometry APCs to one of the diagnostic test APCs or, in some cases, to one of the minor procedure APCs. Therefore, for CY 2016, we are reassigning all of the procedures in APCs 5761 and 5762 as shown in Table 25 below. In addition, we are deleting APCs 5761 and 5762. In Table 25 below, we summarize the commenter's requested APC assignment for each of the procedure codes along with our decision and the final APC assignment.

TABLE 25—REASSIGNMENT OF CODES CURRENTLY ASSIGNED TO LEVEL 1 AND 2 AUDIOMETRY

CPT/HCPCS code	Proposed CY 2016 APC	Commenter/requested APC	CMS decision	Final CY 2016 APC
0208T	5761	No Recommendation	N/A	5732
0209T	5761	No Recommendation	N/A	5732

TABLE 25—REASSIGNMENT OF CODES CURRENTLY ASSIGNED TO LEVEL 1 AND 2 AUDIOMETRY—Continued

CPT/HCPCS code	Proposed CY 2016 APC	Commenter/requested APC	CMS decision	Final CY 2016 APC
0210T	5761	No Recommendation	N/A	5732
0211T	5761	No Recommendation	N/A	5732
0212T	5762	No Recommendation	N/A	5721
92550	5762	5721	Agree	5721
92552	5762	5721	Disagree	5734
92553	5762	No Recommendation	N/A	5721
92555	5761	5732	Agree	5732
92556	5761	5732	Agree	5732
92557	5762	5721 or 5722	Agree	5721
92561	5762	5734	Agree	5734
92562	5762	5721	Agree	5721
92563	5761	No Recommendation	N/A	5732
92564	5761	No Recommendation	N/A	5732
92565	5761	5732	Agree	5732
92567	5761	5732	Agree	5732
92570	5762	5721	Agree	5721
92571	5761	No Recommendation	N/A	5732
92572	5762	No Recommendation	N/A	5721
92575	5761	No Recommendation	N/A	5732
92576	5761	5732	Agree	5732
92577	5762	5721	Disagree	5723
92579	5762	5721	Agree	5721
92582	5762	5721	Agree	5721
92583	5761	5732	Agree	5732
92596	5761	5732	Agree	5732
92601	5762	5721 or 5722	Agree	5721
92602	5762	5721 or 5722	Agree	5721
92603	5762	5721 or 5722	Agree	5721
92604	5762	5721 or 5722	Agree	5721
92620	5762	5721	Agree	5721
92625	5762	5721	Agree	5721
92626	5762	5721	Agree	5721
92640	5762	5721or 5722	Agree	5721
92700	5761	5732	Disagree	5731

We note that, for each of the procedure codes with which we disagree with the commenter's requested APC assignment, we believe that the final APC assignment is more appropriate based on the greater similarity of resource use.

Comment: One commenter requested that CMS reassign the procedures described CPT codes 95909 (Nerve conduction studies; 5–6 studies) and 95910 (Nerve conduction studies; 7–8 studies) from APC 5722 to APC 5723 based on the procedures' similar resource use when compared to the resource use for the procedure described by CPT code 95961 (Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of attendance by a physician or other qualified health care professional).

Response: We disagree with the commenter. The procedure described by CPT code 95909 has a geometric mean cost of approximately $221 and the procedure described by CPT code 95910 has a geometric mean cost of approximately $275. The procedure described by CPT code 95961 has a geometric mean cost of approximately $2,143 based on 4 single claims. Based on the latest hospital outpatient claims data used for this final rule with comment period, the geometric mean costs of the procedures described by CPT codes 95909 and 95910 are not comparably similar to the geometric mean cost of the procedure described by CPT code 95961. Therefore, we are not reassigning the procedures described by CPT codes 95909 and 95910 to APC 5723, as the commenter suggested.

Comment: One commenter requested that the procedures described by CPT codes 95965 (Magnetoencephalography (MEG), recording and analysis; for spontaneous brain magnetic activity (*e.g.,* epileptic cerebral cortex localization)) and 95966 (Magnetoencephalography (MEG), recording and analysis; for evoked magnetic fields, single modality (*e.g.,* sensory, motor, language, or visual cortex localization)) be reassigned to an APC other than the proposed APC 5724. Although the commenter believed that MEG procedures are not clinically similar to the other procedures assigned to APC 5724, the commenter did not specify to which APC it believed these procedures should be assigned.

Response: We disagree with the commenter. MEG procedures are neurological diagnostic tests and are assigned to an APC with other neurological diagnostic tests with comparably similar geometric mean costs. In addition, these procedures are currently assigned to the highest level APC, specifically APC 5724 (Level 4 Diagnostic Tests and Related Services), in the diagnostic tests APC series. We do not believe that there is a more appropriate APC assignment for MEG procedures. Therefore, we are finalizing our proposal to assign the MEG CPT codes 95965 and 95966 to APC 5724 for CY 2016.

Comment: One commenter requested that CMS assign the procedures described by CPT codes 95800 (Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (*e.g.,* by airflow or peripheral arterial tone), and sleep time) and 95806 (Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (*e.g.,* thoracoabdominal movement) to APC

5722 (Level 2 Diagnostic Tests & Related Services), based on similarities in clinical characteristics and resource use to other procedures assigned to APC 5722. The commenter also requested that CMS assign CPT code 95801 (Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (*e.g.,* by airflow or peripheral arterial tone)) to APC 5721 (Level 1 Diagnostic Tests & Related Services), based on similarity in clinical characteristics and resource use to other procedures assigned to APC 5721. Other commenters requested that CMS assign the procedures described by CPT codes 95805 (Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness) and 95782 (Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist) to APC 5724 (Level 4 Diagnostic Tests & Related Services), based on similarities in clinical characteristics and resource use to the other procedures assigned to APC 5724.

Response: We agree with the commenters' recommendation on the APC assignment of the procedures described by CPT codes 95805 and 95782. We believe that APC 5724 is a more appropriate APC group assignment for these codes based on similarities in clinical characteristics and resource use to the other procedures assigned to APC 5724 (as opposed to the proposed assignment to APC 5723). However, we disagree with the commenters' recommendation for the APC assignment for CPT codes 95800, 95801, and 95806; we believe that the proposed APC assignments are most appropriate based on similarities in clinical characteristics and resource use.

After consideration of the public comments we received, we are finalizing for CY 2016 the proposed APC structure for the diagnostic tests APCs, which is displayed in Table 26 below. The procedures assigned to each APC are listed in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

TABLE 26—CY 2016 DIAGNOSTIC TESTS AND RELATED SERVICES APCS

CY 2016 APC	CY 2016 APC title
5721	Level 1 Diagnostic Tests and Related Services.
5722	Level 2 Diagnostic Tests and Related Services.
5723	Level 3 Diagnostic Tests and Related Services.
5724	Level 4 Diagnostic Tests and Related Services.

4. Excision/Biopsy and Incision and Drainage Procedures

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we examined the APCs for incision and drainage procedures as well as excision/biopsy procedures. The current APC structure for these procedures is organized into two series: Incision and drainage procedures; and excision/biopsy procedures.

Based on our evaluation of the current APC structure and the latest hospital outpatient claims data available for the CY 2016 OPPS/ASC proposed rule, in the proposed rule (80 FR 39259), we proposed to reconfigure the structure of these APCs by combining the incision and drainage procedures with the excision/biopsy procedures to more accurately reflect the resource costs and clinical characteristics of the procedures within each APC. Many of the procedures assigned to these two series are clinically similar. Therefore, we believe that a single series encompassing incision and drainage procedures and excision/biopsy procedures groups clinically similar procedures without unnecessary granularity. We stated in the proposed rule that we believe that the proposed consolidation and restructuring of these APCs would more appropriately reflect a prospective payment system that is based on payment for APC groupings with clinically similar procedures while maintaining resource homogeneity. Moreover, we believe that the proposed APC groupings would more accurately accommodate and align new services paid under the hospital OPPS within clinical APCs that contain services with similar clinical attributes and resource costs. Therefore, for CY 2016, we proposed to consolidate and restructure the APCs that describe incision and drainage procedures as well as the excision/biopsy procedures by combining these procedures into a single APC series. Table 22 of the proposed rule listed the current CY 2015 APCs that contain the incision and drainage procedures and the excision/biopsy procedures, and Table 23 of the proposed rule listed the CY 2016 APCs that would result from the consolidating and restructuring of the APCs into a single APC series. We invited public comments on this proposal.

Comment: Commenters generally supported the proposed APC reconfiguration and consolidation for the incision and drainage and excision/biopsy APCs. However, some commenters expressed concerns regarding the APC assignment for the procedures described by the following 19 CPT codes included in the proposed reconfiguration:

- CPT code 10080 (Incision and drainage of pilonidal cyst; simple);
- CPT code 10081 (Drainage of pilonidal cyst; complicated);
- CPT code 11603 (Excision, malignant lesion including margins, trunk, arms, or legs; excised diameter 2.1 to 3.0 cm);
- CPT code 11641 (Excision, malignant lesion including margins, face, ears, eyelids, nose, lips; excised diameter 0.6 to 1.0 cm);
- CPT code 11642 (Excision, malignant lesion including margins, face, ears, eyelids, nose, lips; excised diameter 1.1 to 2.0 cm);
- CPT code 11750 (Excision of nail and nail matrix, partial or complete (*e.g.,* ingrown or deformed nail), for permanent removal);
- CPT code 15782 (Dermabrasion; regional, other than face;
- CPT code 15999 (Unlisted procedure, excision pressure ulcer);
- CPT code 21725 (Division of sternocleidomastoid for torticollis, open operation; with cast application);
- CPT code 21930 (Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm);
- CPT code 23931 (Incision and drainage, upper arm or elbow area; bursa);
- CPT code 35206 (Repair blood vessel lesion);
- CPT code 35226 (Repair blood vessel, direct; lower extremity);
- CPT code 38300 (Drainage of lymph node abscess or lymphadenitis, simple);
- CPT code 47399 (Unlisted procedure, liver);
- CPT code 48999 (Unlisted procedure, pancreas);
- CPT code 57022 (Incision and drainage of vaginal hematoma; obstetrical/postpartum);
- CPT code 62269 (Biopsy of spinal cord, percutaneous needle);and
- CPT code 69005 (Drain external ear, abscess or hematoma; complicated).

The commenters recommended that CMS reassign these 19 procedure codes to a higher level APC based on similarity in clinical characteristics.

Response: Based on our analysis of the latest hospital outpatient claims data used for this final rule with comment period, we agree with the commenters' recommendations for APC assignment for the procedures described by the following CPT codes: 11603; 21930; 23931; 57022; and 62269. However, we do not agree with the commenters' recommendations to reassign the procedures described by the following CPT codes because our final rule claims data show that the resource costs of these procedures are not comparable to the resource costs of other procedures in the APCs recommended: 10080; 11641; 11642; 11750; 15999; 21725; 35226; 47399; and 48999.

As indicated above, several of the CPT codes recommended by the commenters describe unlisted procedures. We remind readers that, as a matter of established OPPS policy described in the CY 2005 OPPS final rule with comment period (69 FR 65724 through 65725), we assign all unlisted CPT/HCPCS codes, such as CPT codes 15999, 47399, and 48999, to the lowest level APC within the appropriate clinical category. By definition, ''unlisted,'' ''unclassified,'' ''not otherwise specified,'' or ''not otherwise classified'' codes do not describe the services being performed, and the services coded using ''unlisted'' codes vary over time as new CPT and HCPCS codes are developed. Therefore, it is impossible for any level of analysis of past hospital claims data to support appropriate assignment of the service for the upcoming year to an APC in which there is clinical and resource integrity of the groupings and relative weights. We continue to believe that the appropriate default APC assignment, in the absence of a code that describes the service being furnished, is the lowest level APC within the clinical category to which the unlisted code is assigned. The assignment of the unlisted codes to the lowest level APC in the clinical category provides a reasonable means for payment for the service until there is a code that specifically describes the procedure or service. In addition, we believe that this policy encourages the creation of codes where appropriate and ensures that overpayment for services that are not clearly identified on the claim does not occur. Our assignment of CPT codes 15999, 47399, and 48999 to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage) is consistent with this policy. The hospital cost data for unlisted CPT/HCPCS codes are not used for ratesetting and, furthermore, the costs of unlisted CPT/HCPCS codes are not subject to the 2 times rule. For further information on the 2 times rule, we refer readers to sections III.B.2 and 3. of this final rule with comment period.

Comment: One commenter specifically recommended that CMS assign the following CPT codes from APC 5071 to APC 5073 (Level 3 Excision/Biopsy/Incision and Drainage): 15782 (Dermabrasion; regional, other than face); 38300 (Drainage of lymph node abscess or lymphadenitis; simple); and 69005 (Drainage external ear, abscess or hematoma; complicated).

Response: As listed in the OPPS Addendum B of the proposed rule, we proposed to reassign the procedure described by CPT code 15782 to APC 5072 (Level 2 Excision/Biopsy/Incision and Drainage), not to APC 5071 as the commenter stated. In addition, as listed in the OPPS Addendum B of the proposed rule, we proposed to assign the procedures described by CPT codes 38300 and 69005 to APC 5071.

Based on our analysis of the latest hospital outpatient claims data used for this final rule with comment period, we disagree with the commenter's suggested APC assignment. Our analysis of the latest hospital outpatient claims data used for this final rule reveal that these three procedures would be more appropriately reassigned to APC 5074 (Level 4 Excision/Biopsy/Incision and Drainage), rather than APC 5071, based on their clinical and resource homogeneity to the other procedures assigned to APC 5074. We note that APC 5074 is the highest level APC within this group. Consequently, we are finalizing our proposal, with modification, to reassign the procedures described by CPT codes 15782, 38300, and 69005 to APC 5074 for CY 2016.

Comment: Some commenters specifically agreed with the proposed APC assignment for the excision/biopsy and incision and drainage procedures described by CPT codes10081 (Incision and drainage of pilonidal cyst; complicated) and 35206 (Repair blood vessel, direct; upper extremity), and requested that CMS finalize them for CY 2016.

Response: We appreciate the commenters' support and are finalizing our proposed APC assignments for CPT codes 10081 and 35206 for CY 2016 in this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposed APC reconfiguration for the excision/biopsy and incision and drainage APCs. In addition, we are finalizing the proposed APC assignments for the procedures within the excision/biopsy and incision and drainage APCs, with modifications to the APC assignment for CPT codes 11603, 15782, 21930, 23931, 38300, 57022, 62269, and 69005. Table 27 below lists the 19 CPT codes, the commenters' requested APC assignments, CMS' final decision, the final status indicators, and the final APC assignments for CY 2016.

TABLE 27—EXCISION/BIOPSY AND INCISION AND DRAINAGE PROCEDURE CODES WITH COMMENTERS' SPECIFIC APC RECOMMENDATIONS, FINAL CMS DECISIONS, FINAL STATUS INDICATORS, AND FINAL APC ASSIGNMENT FOR CY 2016

CPT/HCPCS code	Short descriptor	Proposed CY 2016 SI	Proposed CY 2016 APC	Commenters' requested APC	CMS decision	Final CY 2016 SI	Final CY 2016 APC
10080	Drainage of pilonidal cyst	T	5071	5072	Disagree	T	5071
10081	Drainage of pilonidal cyst	T	5072	5072	Agree	T	5072
11603	Exc tr-ext mal+marg 2.1–3 cm	T	5072	5073	Agree	T	5073
11641	Exc f/e/e/n/l mal+mrg 0.6–1	T	5072	5073	Disagree	T	5072
11642	Exc f/e/e/n/l mal+mrg 1.1–2	T	5072	5073	Disagree	T	5072
11750	Removal of nail bed	T	5071	5072	Disagree	T	5071
15782	Dermabrasion other than face	T	5072	5073	Disagree	T	5074
15999	Removal of pressure sore	T	5071	5074	Disagree	T	5071
21725	Revision of neck muscle	T	5071	5121	Disagree	T	5071
21930	Exc back les sc <3 cm	T	5073	5074	Agree	T	5074
23931	Drainage of arm bursa	T	5071	5074	Agree	T	5074
35206	Repair blood vessel lesion	T	5182	5182	Agree	T	5182
35226	Repair blood vessel lesion	T	5072	5182	Disagree	T	5072
38300	Drainage lymph node lesion	T	5071	5073	Disagree	T	5074

TABLE 27—EXCISION/BIOPSY AND INCISION AND DRAINAGE PROCEDURE CODES WITH COMMENTERS' SPECIFIC APC RECOMMENDATIONS, FINAL CMS DECISIONS, FINAL STATUS INDICATORS, AND FINAL APC ASSIGNMENT FOR CY 2016—Continued

CPT/HCPCS code	Short descriptor	Proposed CY 2016 SI	Proposed CY 2016 APC	Commenters' requested APC	CMS decision	Final CY 2016 SI	Final CY 2016 APC
47399	Liver surgery procedure	T	5071	5074	Disagree	T	5071
48999	Pancreas surgery procedure	T	5071	5074	Disagree	T	5071
57022	I & d vaginal hematoma pp	T	5071	5074	Agree	T	5074
62269	Needle biopsy spinal cord	T	5071	5073	Agree	T	5073
69005	Drain external ear lesion	T	5071	5073	Disagree	T	5074

Table 28 below lists the CY 2016 APCs that result from the consolidating and restructuring of the APCs into a single APC series. The final payment rates for the specific CPT codes for incision and drainage procedures and excision/biopsy procedures are included in Addendum B to this final rule with comment period. The final payment rates for the specific APCs to which these procedures are assigned are included in Addendum A to this final rule with comment period. Both OPPS Addenda A and B are available via the Internet on the CMS Web site.

TABLE 28—FINAL CY 2016 APCS FOR EXCISION/BIOPSY/INCISION AND DRAINAGE PROCEDURES

CY 2016 APC	CY 2016 APC group title
5071	Level 1 Excision/Biopsy/Incision and Drainage.
5072	Level 2 Excision/Biopsy/Incision and Drainage.
5073	Level 3 Excision/Biopsy/Incision and Drainage.
5074	Level 4 Excision/Biopsy/Incision and Drainage.

5. Eye Surgery and Other Eye-Related Procedures

a. Implantable Miniature Telescope (CPT Code 0308T)

CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) is a relatively new procedure. This code became effective in CY 2013. The procedure is a cataract (or IOL) extraction with the implantation of a special kind of IOL, the Implantable Miniature Telescope (IMT), which has the appearance of an IOL with a thick central optic. The payment rate for this procedure in CY 2014 was approximately $15,551, and in CY 2015, the payment rate for this procedure is approximately $23,084. The proposed CY 2016 payment rate is approximately $11,680. CPT code 0308T is the only code assigned to APC 5494 (Level 4 Intraocular Procedures), which is a C–APC. In the latest final rule CY 2014 claims data, there are 40 total claims and 39 single claims. This is a low volume procedure, in part because most of the cases (like most cataract surgery) are performed in an ASC.

Comment: One commenter believed that the significant payment rate decrease from CY 2015 to the proposed 2016 rate is due to some hospitals submitting miscoded claims that have relatively low associated costs. The commenter asserted that some hospitals are reporting CPT code 0308T for procedures other than IMT implantation, and that these miscoded claims have costs that are much lower than the cost of the procedure described by CPT code 0308T. The commenters stated that the evidence to support its assertion is the presence of non-macular degeneration diagnosis codes on these purportedly miscoded claims (geographic atrophy from end-stage macular degeneration is the indication for the IMT). The commenter also believed that the hospitals that submitted the miscoded claims do not perform any IMT surgery. The commenter requested that CMS exclude these miscoded claims from the claims data in calculating the CY 2016 payment rate for the procedure described by CPT code 0308T. Alternatively, the commenter requested that CMS invoke the equitable adjustment authority under section 1833(t)(2)(E) of the Act and base the payment rate for the procedure described by CPT code 0308T on the median cost for all of the claims instead of the geometric mean cost. The commenter believed that, because the median cost is less sensitive to extreme observations (such as claims with very low cost or very high cost), the median cost should be used to calculate the payment rate for the procedure described by CPT code 0308T, which has a low total claims volume. The commenter stated that using the median cost instead of the geometric mean cost would dampen the negative effect of the claims with very low cost and mitigate the payment reduction from CY 2015 for the procedure described by CPT code 0308T.

Response: We understand that when there are a very low volume of claims in the dataset, each claim has a greater effect on the geometric mean cost, as compared to a medium or large volume of claims in the dataset. Regarding the request that we exclude certain claims that the commenter argued are miscoded and contain inaccurate cost information, we reiterate our position on this matter in an earlier rule: ''Beyond our standard OPPS trimming methodology . . . that we apply to those claims that have passed various types of claims processing edits, it is not our general policy to judge the accuracy of hospital coding and charging for purposes of ratesetting'' (75 FR 71838). We generally do not remove claims from the claims accounting when stakeholders believe that hospitals included incorrect information on some claims. Therefore, we are not excluding claims from the ratesetting calculation for the procedure described by CPT code 0308T for CY 2016.

However, we agree with the commenter that, given the very low volume of claims for this relatively high-cost device intensive surgical procedure (that is the only procedure assigned to APC 5494), the median cost would be a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for the procedure described by CPT code 0308T. The median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. Therefore, for CY 2016, we are using our equitable adjustment authority under section 1833(t)(2)(E) of the Act to use the median cost to calculate the payment rate for the procedure described by CPT code 0308T, which is the only code assigned to APC 5494. The median cost of the procedure described by CPT code 0308Tis $18,365, and the geometric mean cost is $13,833. Unlike the retinal prosthesis procedure, the procedure

described by CPT code 0308T has a low volume of claims data upon which to base a payment rate. This procedure also differs from other procedures for which we have not taken further measures when stakeholders believe that incorrect hospital coding negatively affected payment rates, because it is not grouped to an APC with procedures that have robust claims data upon which an APC geometric mean cost can be calculated. In future rulemaking, we will consider proposing a general policy for the payment rate calculation for very low-volume device-intensive APCs similar to APC 5494.

b. Other Ocular Procedures

Comment: A few commenters were concerned that the current structure of APC 5492 (Level 2 Intraocular Procedures) results in inadequate payment for certain procedures assigned to APC 5492. In particular, these commenters were primarily concerned about the procedure described by CPT code 66180, which, beginning in CY 2015, represented an overall procedure that was formerly represented by two separate codes, one code for the shunt placement and one code for the graft placement. The commenters requested that CMS reexamine the intraocular procedures series of APCs and the code assignments and consider alternatives that would provide a payment that was more reflective of the costs of the higher cost procedures currently assigned to APC 5492. Two commenters requested that CMS create a new APC with a mean cost between that of APC 5492 and APC 5493, and assign the procedure described by CPT code 66180 to this new APC.

Response: We reexamined the procedure code assignments and latest claims data for the intraocular procedures series of four APCs. We do not agree that an additional APC level within this series is warranted. However, we do believe that reassigning some of the codes that were proposed to be assigned to APC 5492 into APC 5491 results in a more balanced APC 5491 (Level 1 Intraocular Procedures) and (Level 2 Intraocular Procedures). Therefore, we are reassigning all procedures that were proposed to be assigned to Level 2 with a mean cost of less than $3,000 to Level 1. This reassignment of procedure codes results in a higher mean cost range for APC 5492 ($3,538 versus $3,438 in the proposed rule).

Comment: One commenter requested that CMS reassign CPT code 0207T (Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral) from APC 5732 (Level 2 Minor Procedures) to APC 5502 (Level 2 Extraocular, Repair, and Plastic Eye Procedures). The commenter stated that the procedure described by CPT code 0207T is used for patients with meibomian gland dysfunction. The commenter pointed out that, for CY 2016, CPT code 0207T has nine single claims (29 total claims) with a mean cost of $82.20; APC 5732 has a mean cost of $31.93; and APC 5502 has a mean cost of $728.78. The commenter asserted that most of the small number of claims filed for the procedure described by CPT code 0207T was filed in error by a hospital that performed a different procedure with significantly lower costs than the procedure described by CPT code 0207T. The commenter requested that CMS exclude these claims in our ratesetting calculation because it believed that these claims were miscoded. The commenter believed that if CMS excluded these incorrectly coded claims, the mean cost of the procedure described by CPT code 0207T would be similar to the mean cost of the procedures assigned to APC 5502. The commenter also stated that the procedure described by CPT code 0207T is more appropriately assigned to APC 5502 because APC 5502 contains procedures that focus on the eyelids and ocular adnexa (as does the procedure described by CPT code like 0207T), while APC 5732 contains a variety of minor procedures, many of which are not eye-related.

Response: We agree in part with the commenter. We agree that APC 5732 is not the most appropriate APC for the assignment of the procedure described by CPT code 0207T. However, we believe that, based on the mean cost of the claims for the procedure described by CPT code 0207T, APC 5734 (Level 4 Minor Procedures) is more appropriate from a resource perspective than APC 5502 (with a mean cost of $728.78), which is what the commenter requested. APC 5734 has a mean cost of $95.47, which is close to the $82.20 mean cost of the procedure described by CPT code 0207T. Clinically, although APC 5502 does contain primarily eyelid procedures, these are surgical procedures assigned to the APC. The procedure described by CPT code 0207T is not a surgical procedure. The Minor Procedure series of four APCs (5731 through 5734) is not limited to a particular anatomical region of the body. This series contains some eye-related procedures as well as many other types of procedures. All of the procedures assigned to one of the Minor Procedure APCs are minor in nature and are relatively low cost.

Regarding the request by the commenter that we not use a subset of claims in the claims ratesetting calculation for the procedure described by CPT code 0207T, we again reiterate our position: ''Beyond our standard OPPS trimming methodology . . . that we apply to those claims that have passed various types of claims processing edits, it is not our general policy to judge the accuracy of hospital coding and charging for purposes of ratesetting'' (75 FR 71838). Therefore, we are not excluding claims from the ratesetting calculation the procedure described by CPT code 0207T. For CY 2016, the procedure described by CPT code 0207T is assigned to APC 5734 (Level 4 Minor Procedures).

6. Gastrointestinal (GI) Procedures

As a part of our comprehensive review of the structure of the APCs and procedure code assignments for CY 2016, we examined the APCs that contain gastrointestinal (GI) procedures. As explained below, as a result of our findings from this review, for CY 2016, in the CY OPPS/ASC proposed rule, we proposed to restructure the APC groupings for GI procedures to more appropriately reflect the costs and the clinical characteristics of the procedures within each APC grouping in the context of the OPPS.

The current APCs for GI procedures are partially organized according to location in the GI tract and type of surgery performed (endoscopy versus incisional surgery). After reviewing these APCs for GI procedures, we believe that the current APC construction is based on clinical categories that do not appropriately represent a consistent set of clinical categories throughout the entire spectrum of GI-related procedures. The current level of granularity for some of the GI APCs results in groupings that are unnecessarily narrow for the purposes of a prospective payment system. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39259 through 39260), for CY 2016, we proposed to restructure and consolidate the APCs that contain GI procedures. In the proposed rule, we stated that we believe that consolidating these procedures under broader APC groupings primarily based on separating upper and lower GI procedures into two series with additional APCs containing abdominal and peritoneal procedures would more appropriately reflect a prospective payment system that is based on payment for clinically consistent APC groupings rather than code-specific

payment rates while maintaining resource homogeneity. Furthermore, we believe that the proposed APC groupings would more accurately accommodate and align new services within clinical APCs with similar resource costs. Table 24 of the proposed rule listed the current CY 2015 APCs that contain GI procedures, and Table 25 of the proposed rule listed the CY 2016 APCs that would result from the proposed consolidation and restructuring of the current GI procedure APCs into a single APC series. We invited public comments on this proposal.

Comment: Several commenters requested that CMS review the proposed APC assignment for new CPT code 43210 (Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed) (whose predecessor code was HCPCS code C9724). The commenters believed that the proposed assignment of CPT code 43210 to APC 5302 (Level 2 Upper GI Procedures) does not reflect the resources used to perform the procedure and that the proposed payment rate is not adequate to cover the cost of the equipment, ancillary supplies and other facility overhead to perform the procedure. The commenters requested that CMS assign CPT code 43210 to one of the following APCs: (1) C–APC 5362 (Level 2 Laparoscopy), because of the clinical similarity of the procedure to the procedure described by HCPCS code 43280 (Laparoscopy, surgical, esophagogastric fundoplasty (*e.g.,* Nissen, Toupet procedures); (2) a New technology APC; or (3) a new APC for transoral surgical procedures because of the uniqueness of the procedure described by CPT code 43210.

Response: We agree in part with the commenters. We agree that APC 5302 is not the most appropriate APC assignment for the procedure described by new CPT code 43210 or its predecessor code, HCPCS code C9724. However, we do not agree with the commenters' request to reassign CPT code 43210 to proposed C–APC 5362 (Level 2 Laparoscopy) based on its similar clinical purpose to the procedure described by HCPCS code 43280. While both of these procedures are surgical procedures used in the treatment of gastroesophageal reflux disease, unlike the procedures assigned to C–APC 5362, the procedure described by CPT code 43210 is not a laparoscopy procedure, and C–APC 5362 is limited to laparoscopy procedures. Therefore, the procedure described by CPT code 43210 is not sufficiently clinically similar to the other procedures assigned to C–APC 5362 to warrant reassignment to C–APC 5362. We also disagree with the commenters' requests for reassignment to a new technology APC or the creation of a new APC for transoral surgical procedures. The procedure described by CPT code 43210 (and its predecessor HCPCS code C9724) is not new because HCPCS C9724 became effective in CY 2005. In addition, as we discuss below, we believe that there is an appropriate clinical APC to which CPT code 43210 can be assigned. Therefore, it is not appropriate to assign the code to a New Technology APC. Regarding the request for a new, dedicated APC for CPT code 43210, the volume of available claims for the predecessor code (HCPCS code C9724) is too low to warrant a separate, new APC for this procedure. Because CPT code 43210 is new for CY 2016, there are no CY 2014 claims, and there is only one CY 2014 claim for HCPCS code C9724. We believe that HCPCS code 43210 is sufficiently similar to the procedures assigned to C–APC 5331 (Complex GI Procedures) in terms of resource utilization and clinical complexity. Therefore, we are assigning CPT code 43210 and its predecessor code, HCPCS code C9724, to C–APC 5331 for CY 2016. Because C–APC 5331 is a comprehensive APC, we are assigning CPT code 43210 to status indicator ''J1.''

Comment: Some of the commenters who supported the restructuring of the gastrointestinal procedure APCs requested APC reassignments of several codes, which are listed in Table 29 below.

Response: We agreed with some of the requests for reassignments of the codes to different APCs and disagreed with other requests. Our determinations for each code reassignment request are noted in Table 29 below.

TABLE 29—GASTROINTESTINAL PROCEDURE CODES WITH SPECIFIC COMMENTER APC RECOMMENDATIONS, FINAL CMS DECISIONS, AND FINAL APC ASSIGNMENTS AND STATUS INDICATORS FOR CY 2016

CPT/HCPCS code	Short descriptor	Proposed CY 2016 status indicator	Proposed CY 2016 APC	Commenter requested APC	CMS decision	Final CY 2016 status indicator	Final CY 2016 APC
43240	Egd w/transmural drain cyst	T	5303	5331	Disagree	T	5303
44403	Colonoscopy w/resection	T	5312	5313	Disagree	T	5312
45349	Sigmoidoscopy w/resection	T	5312	5313	Disagree	T	5312
45390	Colonoscopy w/resection	T	5312	5313	Disagree	T	5312
46608	Anoscopy remove for body	T	5312	5313	Disagree	T	5312
45303	Proctosigmoidoscopy dilate	T	5312	5313	Disagree	T	5312
45332	Sigmoidoscopy w/fb removal	T	5312	5313	Disagree	T	5312
45337	Sigmoidoscopy & decompress	T	5312	5313	Disagree	T	5312
45338	Sigmoidoscopy w/tumr remove	T	5312	5313	Disagree	T	5312
45346	Sigmoidoscopy w/ablation	T	5312	5313	Disagree	T	5312
44390	Colonoscopy for foreign body	T	5312	5313	Disagree	T	5312
44394	Colonoscopy w/snare	T	5312	5313	Disagree	T	5312
44405	Colonoscopy w/dilation	T	5312	5313	Disagree	T	5312
44408	Colonoscopy w/decompression	T	5312	5313	Disagree	T	5312
45379	Colonoscopy w/fb removal	T	5312	5313	Disagree	T	5312
45386	Colonoscopy w/balloon dilat	T	5312	5313	Disagree	T	5312
45388	Colonoscopy w/ablation	T	5312	5313	Disagree	T	5312
45393	Colonoscopy w/decompression	T	5312	5313	Disagree	T	5312
91110	GI tract capsule endoscopy	T	5301	5211/New APC	Disagree	T	5301
91111	Esophageal capsule endoscopy	T	5301	5211/New APC	Disagree	T	5301

TABLE 29—GASTROINTESTINAL PROCEDURE CODES WITH SPECIFIC COMMENTER APC RECOMMENDATIONS, FINAL CMS DECISIONS, AND FINAL APC ASSIGNMENTS AND STATUS INDICATORS FOR CY 2016—Continued

CPT/HCPCS code	Short descriptor	Proposed CY 2016 status indicator	Proposed CY 2016 APC	Commenter requested APC	CMS decision	Final CY 2016 status indicator	Final CY 2016 APC
91112	GI wireless capsule measure	T	5301	5211/New APC	Disagree	T	5301
91022	Duodenal motility study	S	5722	5723	Agree	S	5724
91037	Esoph imped function test	S	5722	5723	Disagree	S	5722
91038	Esoph imped funct test >1hr	S	5722	5723	Agree	T	5723
43753	Tx gastro intub w/asp	Q1	5734	5722	Agree	S	5722
43754	Dx gastr intub w/asp spec	Q1	5734	5722	Agree	S	5722
43755	Dx gastr intub w/asp specs	S	5721	5722	Disagree	S	5721
43756	Dx duod intub w/asp spec	Q1	5522	5722	Disagree	S	5522
C9724	Eps stomach plic	D	5303	New APC/New Tech	Disagree	D	5331
43210	Egd esophagogastrc fndoplsty	T	5302	New APC/New Tech	Disagree	J1	5331
0336T	Lap ablat uterine fibroids	J1	5362	5352	Disagree	J1	5362
47370	Laparo ablate liver tumor rf	J1	5362	5352	Disagree	J1	5362
47371	Laparo ablate liver cryosurg	J1	5362	5352	Disagree	J1	5362
50542	Laparo ablate renal mass	J1	5362	5352	Disagree	J1	5362

We disagree with the commenters who requested that CPT code 43240 (Esophagogastroduodenoscopy, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter[s]/stent[s], when performed, and endoscopic ultrasound, when performed) be reassigned from proposed APC 5303 (Level 3 Upper GI Procedures) to C–APC 5331 (Complex GI Procedures). The geometric mean cost of the procedure described by CPT code 43240 is approximately $1,818, and the geometric mean cost of APC 5303 is approximately $2,072. The geometric mean cost of APC 5331 is approximately $3,781. We believe that, given the geometric mean costs of APCs 5303 and 5331, APC 5303 is the more appropriate APC assignment for the procedure described by CPT code 43240.

We also disagree with the commenters who requested that lower GI endoscopic mucosal resection CPT codes (CPT codes 44403, 45349, and 45390) be reassigned from APC 5312 (Level 2 Lower GI Procedures) to APC 5313 (Level 3 Lower GI Procedures) based on resource and clinical homogeneity. These three CPT codes became effective in CY 2015. We believe that the current APC assignment for these codes is appropriate based on similarity of clinical characteristics. Once we have claims data for these CPT codes. we will reevaluate their APC assignment in accordance with the yearly review of APC assignments and determine if a reassignment is appropriate based on the claims data.

We also disagree with the commenters who requested reassignment of the CPT codes listed in Table 29 above that represent foreign body removal, ablation, and decompression of volvulus, colonoscopy through stoma and flexible sigmoidoscopy, specifically CPT codes 44608, 45332, 45337, 45338, 45346, 44390, 44394, 44405, 44408, 45379, 45386, 45388, and 45393 from APC 5312 (Level 2 Lower GI Procedures) to APC 5313 (Level 3 Lower GI Procedures). The commenters stated that the resource utilization for these codes is similar to resource utilization for procedures that employ similar techniques with proctoscopy that are assigned to APC 5313. A majority of the procedures that were requested to be reassigned to APC 5313 have geometric mean costs of approximately $880 or lower, which is significantly lower than the geometric mean cost of $1,739 for APC 5313. Therefore, we do not believe that reassignment of these codes would be appropriate.

We do not agree with the commenters' request to reassign CPT codes 91110, 91111, and 91112 from APC 5301 (Level 1 Upper GI Procedures) to APC 5211 (Level 1 Electrophysiologic Procedures) due to resource use and clinical dissimilarities with procedures assigned to APC 5301, which is limited to cardiac electrophysiology procedures. We also do not agree that these procedures are clinically dissimilar enough from other procedures in APC 5301 to require creation of a new APC dedicated to these procedures.

We disagree with the commenters who requested that the procedure described by CPT code 91037 be reassigned to APC 5723 (Level 3 Diagnostic Tests and Related Services) based on clinical and resource similarity. The geometric mean cost of the procedure described by CPT code 91037 is approximately $199, which is more similar to the geometric mean cost of APC 5722 (approximately $231) than the geometric mean cost of APC 5723 (approximately$415). In addition, assignment of the procedure described by CPT code 91037 to APC 5723 would result in a violation of the 2 times rule in APC 5723. However, we agree with the commenters that CPT code 91022 is more appropriately assigned to APC 5724 (Level 4 Diagnostic Tests and Related Services) based on resource similarity to other services assigned to APC 5724.

We disagree with the commenters who requested that CPT code 43755 be reassigned from APC 5721 (Level 1Diagnostic Tests and Related Services) to APC 5722 (Level 2 Diagnostic Tests and Related Services). The geometric mean cost of the services described by CPT code 43755 is approximately $141, and the geometric mean cost of APC 5721 is approximately $136. The geometric mean cost of APC 5722 is approximately $231. We believe that, given the geometric mean cost of APCs 5721 and 5722, APC 5721 is the more appropriate APC assignment for the services described by CPT code 43755.

We disagree with the commenters who requested that CPT codes 0336T, 47370, 47371, and 50542 from C–APC 5362 (Level 2 Laparoscopy) be reassigned to APC 5352 (Level 2 Percutaneous Abdominal/Biliary Procedures and Related Procedures). These are laparoscopy procedures and are assigned to an APC to which other

clinically similar procedures are assigned.

After consideration of the public comments we received, we are finalizing the proposed structure of the gastrointestinal procedures with the code reassignments shown in Table 29 above. Table 30 below lists the CY 2016 APCs that result from the consolidation and restructuring of the current GI procedure APCs into a single APC series. The procedures assigned to each APC are listed in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

TABLE 30—CY 2016 APCS FOR GASTROINTESTINAL PROCEDURES

CY 2016 APC	CY 2016 APC group title
5301	Level 1 Upper GI Procedures.
5302	Level 2 Upper GI Procedures.
5303	Level 3 Upper GI Procedures.
5311	Level 1 Lower GI Procedures.
5312	Level 2 Lower GI Procedures.
5313	Level 3 Lower GI Procedures.
5314	Level 4 Lower GI Procedures.
5331	Complex GI Procedures.
5341	Peritoneal and Abdominal Procedures.
5351	Level 1 Percutaneous Abdominal/Biliary Procedures and Related Procedures.
5352	Level 2 Percutaneous Abdominal/Biliary Procedures and Related Procedures.
5391	Level 1 Tube/Catheter Changes/Thoracentesis/Lavage.
5392	Level 2 Tube/Catheter Changes/Thoracentesis/Lavage.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39260), we proposed to accept the Panel's recommendation with regard to the APC assignment for four lower endoscopy stent procedures described by HCPCS codes that were established in CY 2015. The Panel recommended that the four CPT codes listed in Table 26 of the proposed rule be moved from their currently assigned APC to C–APC 0384 (GI Procedures with Stents) (CPT codes 44384 (Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed), 44402 (Colonoscopy through stoma; with endoscopic stent placement (including pre- and post-dilation and guide wire passage, when performed), 45347 (Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed), and 45389 (Colonoscopy, flexible; with endoscopic stent placement (includes pre- and post-dilation and guide wire passage, when performed). The Panel's recommendation was based on an analysis of the similarities in clinical characteristics and resource utilization between the procedures described by these four CPT codes and the procedures described by other CPT codes within existing (CY 2015) APCs 0142, 0143 and 0147. (We note that, in section II.A.2.e. of the preamble of the proposed rule, we proposed to renumber and retitle C–APC 0384 as ''C–APC 5331 (Complex GI Procedures)'' for CY 2016.)

Comment: Commenters supported the proposal to assign CPT codes 44384, 44402, 45347, and 45389 to C–APC 5331 (Complex GI Procedures).

Response: We appreciate the commenters' support.

We are finalizing our proposal to reassign CPT codes 44384, 44402, 45347, and 45389 to C–APC 5331 (Complex GI Procedures).

7. Gynecologic Procedures and Services

As listed in Addendum A to the CY 2016 OPPS/ASC proposed rule, we proposed to add another level to the existing gynecologic APCs, specifically, a Level 6 Gynecologic Procedures APC, and designated it as APC 5416.

Comment: One commenter applauded CMS for revisiting the gynecologic procedure APCs and adding APC 5416 (Level 6 Gynecologic Procedures) for CY 2016. The commenter believed that expanding the number of APCs for the gynecologic procedures is a positive change and further suggested that CMS be open to reassignment of CPT codes within and across APCs as part of rulemaking in CY 2016 and in future years.

Response: We appreciate the commenter's support. We believe that the addition of this new APC groups gynecologic procedures more appropriately based on their resource costs and clinical characteristics.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to add the Level 6 APC 5416 to the existing gynecologic APC groups. The final CY 2016 payment rate for APC 5416 can be found in Addendum A to this final rule with comment period (which is available via the Internet on the CMS Web site).

The AMA Editorial Committee established new CPT code 0404T (Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency), to be effective on January 1, 2016. In the CY 2016 OPPS/ASC proposed rule, we proposed to assign this new code (which we listed as code 04XXD (the 5-digit CMS placeholder code) in Addendum B, O, and Q2 to the proposed rule) to APC 5415 (Level 5 Gynecologic Procedures), with a proposed payment rate of approximately $3,713. We also proposed to assign CPT code 0404T to comment indicator ''NP'' in Addendum B to the proposed rule to indicate that the code is new for CY 2016 with a proposed APC assignment and that public comments would be accepted on the proposed APC assignment.

Comment: One commenter disagreed with the proposed APC assignment for new CPT code 0404T for CY 2016, and requested that the procedure be reassigned to one of the following APCs: 5362 (Level 2 Laparoscopy); 5192 (Level 2 Endovascular Procedures); or 5416 (Level 6 Gynecologic Procedures). The commenter believed that the procedure described by CPT code 0404T is similar, based on clinical characteristics and resource costs, to other procedures that are assigned to APCs 5362, 5192, and 5416. In addition, the commenter stated that the facility cost to perform this procedure is approximately $4,850, which includes the $3,965 single-use kit.

Response: Under the OPPS, we generally assign a payment rate to a new Category III CPT code based on input from a variety of sources, including, but not limited to, review of resource costs and clinical homogeneity of the service to existing procedures, input from our medical advisors, and other information available to us. Based on our understanding of the procedure, we agree with the commenter that CPT code 0404T would be more appropriately assigned to APC 5416 because its resource costs and clinical homogeneity is similar to the other procedures in APC 5416. Therefore, we are not adopting our proposal to assign CPT code 0404T to APC 5415 for CY 2016. Rather, we are assigning CPT code 0404T to APC 5416. The final CY 2016 payment rate for CPT code 0404T can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

8. Imaging Services

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we examined the APCs that contain imaging services. For CY 2016, we proposed to restructure the OPPS APC groupings for imaging services to more appropriately reflect the costs and clinical characteristics of the procedures within each APC grouping in the context of the OPPS. The current APCs for imaging services

are divided at the highest level between diagnostic radiology (for example, x-ray, CT, MRI, and ultrasound) and nuclear medicine imaging. After reviewing these APCs, we believe that the current APC structure is based on clinical categories that do not necessarily reflect significant differences in the delivery of these services in the HOPD. The current level of granularity for these APCs results in groupings that are unnecessarily narrow for the purposes of a prospective payment system. This excessive granularity is especially apparent with the APCs for x-ray based imaging services and nuclear medicine imaging services. Many of these APCs are currently structured according to organ or physiologic system that does not necessarily reflect either significant differences in resources or how these services are delivered in the HOPD.

Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39261), for CY 2016, we proposed to restructure and consolidate the APCs that include radiology and nuclear medicine services. We stated that we believe that this proposed restructuring and consolidation would result in APC groupings that would more appropriately reflect a prospective payment system that is based on payment for clinically consistent APC groupings and not code-specific payment rates, while maintaining clinical and resource homogeneity. Furthermore, the proposed APC groupings would more accurately accommodate and align new services into clinical APCs with similar resource costs. Table 27 of the proposed rule listed the current CY 2015 APCs that contain radiology and nuclear medicine services, and Table 28 of the proposed rule listed the proposed CY 2016 APCs that would result from the proposed consolidation and restructuring of the current radiology and nuclear medicine services APCs. We invited public comments on this proposal.

Comment: Many commenters generally supported the proposed restructuring of the imaging-related APCs. However, several commenters generally disagreed with the proposed restructuring of the nuclear medicine and positron emission tomography (PET) APCs. The commenters acknowledged that CMS has recognized the clinical differences between the imaging modalities and maintained separate APCs for them since the implementation of the OPPS. However, the commenters opposed collapsing the current 17 nuclear medicine and PET APCs into three levels (Level 1 through Level 3 Nuclear Medicine and Related Services) for CY 2016, and recommended that CMS maintain a distinct APC for all PET procedures. Several other commenters, including nonhospital imaging centers and the HOP Panel, recommended that CMS separate PET procedures from the non-PET nuclear imaging tests in proposed APC 5593 (Level 3 Nuclear Medicine and Related Services). Commenters believed that grouping PET procedures with non-PET procedures (also referred to as SEPCT) would reduce the payment for PET procedures below the cost of PET tests because of the more significant capital equipment costs for PET. Further, commenters stated that the proposed APC grouping of PET procedures with non-PET procedures would result in underpayments, and imaging centers that provide PET-only services will not be able to offset the payment reduction by providing non-PET services, some of which CMS proposed to increase the payment rate in CY 2016.

Response: We agree with the HOP Panel's and the commenters' recommendation to separate PET tests into a separate APC because PET imaging services involve higher resource costs and are of a clinically distinct imaging modality from non-PET or SPECT imaging services. Therefore, we are adding a fourth level to the nuclear medicine and related services APC group (APC 5594 (Level 4 Nuclear Medicine and Related Services), and are reassigning the PET procedures that were proposed to be assigned to APC 5593 (Level 3 Nuclear Medicine and Related Services) to APC 5594. While APC 5594 contains all of the PET scan procedures, it is not necessarily limited only to PET scan services. It is established as the fourth and highest level in the nuclear medicine APC grouping, and non-PET scan nuclear medicine tests may be assigned to this APC as appropriate.

Comment: Some commenters urged CMS to maintain the existing, separately payable status indicators (that is, ''S'' or ''T'') for several codes within the proposed nine reconfigured APC groupings instead of assigning them to a conditional packaging status indicator (that is, ''Q1'' or ''Q2''). One commenter provided a list of 70 codes, and requested that CMS assign them to separately payable status indicators. Among the 70 codes are 34 imaging services codes that, as a result of the proposed APC restructuring, were proposed for CY 2016 to be assigned to one of the following APCs, which are all three conditionally packaged APCs: APC 5521 (Level 1 X-Ray and Related Services); APC 5522 (Level 2 X-Ray and Related Services); or APC 5531 (Level 1 Ultrasound and Related Services).

Response: Prior to developing our proposal, we reviewed all of the services associated with the proposed nine APC families. We believe that the procedures and services that we proposed to assign to a conditional packaging status indicator are ancillary and dependent in relation to the other procedures within the same family groupings with which they are most commonly furnished. Therefore, based on our review and input from CMS clinical staff, we believe that the codes that we proposed to conditionally package are appropriate. In addition, the APCs to which the 34 codes listed by the commenter are proposed to be assigned for CY 2016 are designated as conditionally packaged APCs. For example, APC 5521 (Level 1 X-Ray and Related Services) is the successor APC to CY 2015 APC 0260 (Level 1 X-Ray & Related Services), which was designated in CY 2015 as a conditionally packaged APC; APC 5522 (Level 2 X-Ray and Related Services) is the successor APC to CY 2015 APC 0261 (Level 2 X-Ray & Related Services), which was designated in CY 2015 as a conditionally packaged APC; and APC 5531 (Level 1 Ultrasound and Related Services) is the successor APC to CY 2015 APC 0265 (Level 1 Ultrasound & Related Services), which was designated in CY 2015 as a conditionally packaged APC. Therefore, we believe that these 34 imaging services that are assigned to proposed new APCs 5521, 5522, and 5531 are appropriately assigned a conditionally packaged status indicator. Further, based on the clinical nature of the services and our understanding of the procedures, we believe that assigning these services to a conditional packaging status indicator will create incentives for hospitals and their physician partners to work together to establish appropriate protocols that will eliminate unnecessary services where they exist and institutionalize approaches to providing necessary services more efficiently. Therefore, we are finalizing our proposal to assign the 34 imaging services procedure codes identified by the commenter status indicator ''Q1'' for CY 2016.

Comment: A few commenters who supported the restructuring of the imaging-related procedure APCs requested APC reassignments of many specific codes, which are listed in Table 31 below.

Response: We agree with some of the commenters' request for APC reassignments and/or status indicator reassignments of procedure codes describing imaging-related procedures.

Our decisions to accept or reject the recommended code assignments to APCs also are indicated in Table 31 below.

TABLE 31—IMAGING-RELATED PROCEDURE CODES WITH SPECIFIC COMMENTERS' RECOMMENDATIONS, FINAL CMS DECISIONS, FINAL APC ASSIGNMENTS, AND FINAL APC STATUS INDICATORS

CPT/HCPCS code	Short descriptor	Proposed CY 2016 status indicator	Proposed CY 2016 APC	Commenter requested APC	CMS decision	Final CY 2016 status indicator	Final CY 2016 APC
70370	Throat x-ray & fluoroscopy	Q1	5521	5522	Disagree	Q1	5521
71030	Chest x-ray 4/> views	Q1	5521	5522	Disagree	Q1	5521
72200	X-ray exam si joints	Q1	5521	5522	Agree	Q1	5522
76496	Fluoroscopic procedure	Q1	5521	5522	Disagree	Q1	5521
72050	X-ray exam neck spine 4/5 vws	Q1	5522	5523	Disagree	Q1	5522
72110	X-ray exam l-2 spine 4/> vws	Q1	5522	5523	Disagree	Q1	5522
72074	X-ray exam thorac spine 4/> vw	Q1	5522	5523	Disagree	Q1	5522
77074	X-rays bone survey limited	Q1	5522	5523	Disagree	Q1	5522
74240	X-ray upper gi delay w/o kub	Q1	5522	5523	Disagree	Q1	5522
76010	X-ray nose to rectum	Q1	5522	5523	Agree	Q1	5523
72052	X-ray exam neck spine 6/> vws	Q1	5522	5523	Disagree	Q1	5522
74246	Contrst x-ray uppr gi tract	Q1	5522	5523	Disagree	Q1	5522
76120	Cine/video x-rays	Q1	5522	5523	Disagree	Q1	5522
74270	Contrast x-ray exam of colon	Q1	5522	5523	Disagree	Q1	5522
74241	X-rayupper gi delay w/kub	Q1	5522	5523	Disagree	Q1	5522
70371	Speech evaluation complex	Q1	5522	5523	Disagree	Q1	5522
77075	X-rays bone survey complete	Q1	5522	5523	Disagree	Q1	5522
74247	Contrst x-ray uppr gi tract	Q1	5522	5523	Disagree	Q1	5522
49465	Fluoro exam of g/colon tube	Q1	5522	5523	Disagree	Q1	5522
73092	X-ray exam of arm infant	Q1	5522	5523	Disagree	Q1	5522
70320	Full mouth x-ray of teeth	Q1	5522	5523	Agree	Q1	5523
74260	X-ray exam of small bowel	Q1	5522	5523	Agree	Q1	5523
70310	X-ray exam of teeth	Q1	5522	5523	Agree	Q1	5523
74290	Contrast x-ray gallbladder	Q1	5522	5523	Agree	Q1	5523
74430	Contrast x-ray bladder	Q2	5523	5524	Disagree	Q2	5523
74450	X-ray urethra/bladder	Q2	5523	5524	Disagree	Q2	5523
74455	X-ray urethra/bladder	Q2	5523	5524	Agree	Q2	5524
74740	X-ray female genital tract	Q2	5523	5524	Agree	Q2	5524
C9733	Non-ophthalmic fva	Q2	5523	5524	Agree	Q2	5524
G0120	Colon ca scrn; barium enema	S	5524	5525	Disagree	S	5524
74445	X-ray exam of penis	Q2	5524	5525	Disagree	Q2	5524
78457	Venous thrombosis imaging	S	5524	5525	Disagree	S	5592
78456	Acute venous thrombus image	S	5525	5526	Disagree	S	5525
75807	Lymph vessel x-ray trunk	Q2	5525	5526	Agree	Q2	5526
70190	X-ray exam of eye sockets	Q1	5522	5521	Agree	Q1	5521
74210	Contrst x-ray exam of throat	Q1	5522	5521	Disagree	Q1	5522
72040	X-ray exam neck spine 2–3 vw	Q1	5522	5521	Disagree	Q1	5522
76101	Complex body section x-ray	S	5523	5522	Agree	Q1	5522
78458	Ven thrombosis images bilat	S	5524	5523	Disagree	S	5591
74470	X-ray exam of kidney lesion	Q2	5525	5524	Agree	Q2	5524
75898	Follow-up angiography	Q2	5526	5525	Agree	Q2	5525
75827	Vein x-ray chest	Q2	5526	5525	Agree	Q2	5525
75872	Vein x-ray skull epidural	Q2	5526	5525	Disagree	Q2	5526
70470	Ct head/brain w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
70482	Ct orbit/ear/fossa w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
70488	Ct maxillofacial w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
70492	Ct sft tsue nck w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
70496	Ct angiography head	Q3	5571	5572	Disagree	Q3	5571
70498	Ct angiography neck	Q3	5571	5572	Disagree	Q3	5571
71275	Ct angiography chest	Q3	5571	5572	Disagree	Q3	5571
72127	Ct neck spine w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
72130	Ct chest spine w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
72133	Ct lumbar spine w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
72191	Ct angiograph pelv w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
72194	Ct pelvis w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
73202	Ct uppr extremity w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
73206	Ct angio upr extrm w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
73702	Ct lwr extremity w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
73706	Ct angio lwr extr w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
74170	Ct abdomen w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
74175	Ct angio abdom w/o & w/dye	Q3	5571	5572	Disagree	Q3	5571
75574	Ct angio hrt w/3d image	S	5571	5572	Disagree	S	5571
75635	Ct angio abdominal arteries	Q2	5571	5572	Disagree	Q2	5571
72126	Ct neck spine w/dye	Q3	5572	5571	Disagree	Q3	5572
73201	Ct upper extremity w/dye	Q3	5572	5571	Disagree	Q3	5572

TABLE 31—IMAGING-RELATED PROCEDURE CODES WITH SPECIFIC COMMENTERS' RECOMMENDATIONS, FINAL CMS DECISIONS, FINAL APC ASSIGNMENTS, AND FINAL APC STATUS INDICATORS—Continued

CPT/HCPCS code	Short descriptor	Proposed CY 2016 status indicator	Proposed CY 2016 APC	Commenter requested APC	CMS decision	Final CY 2016 status indicator	Final CY 2016 APC
74177	Ct abd & pelv w/contrast	Q3	5572	5571	Disagree	Q3	5572
70544	Mr angiography head w/o dye	Q3	5581	5583	Disagree	Q3	5581
70547	Mr angiography neck w/o dye	Q3	5581	5583	Disagree	Q3	5581
70545	Mr angiography head w/dye	Q3	5582	5583	Disagree	Q3	5582
70546	Mr angiograph head w/o & w/dye	Q3	5582	5583	Disagree	Q3	5582
70548	Mr angiography neck w/dye	Q3	5582	5583	Disagree	Q3	5582
70549	Mr angiograph neck w/o & w/dye	Q3	5582	5583	Disagree	Q3	5582
C8902	Mra w/o fol w/cont, abd	Q3	5582	5583	Disagree	Q3	5582
C8911	Mra w/o fol w/cont, chest	Q3	5582	5583	Disagree	Q3	5582
C8914	Mra w/o fol w/cont, lwr ext	Q3	5582	5583	Disagree	Q3	5582
C8920	Mra w/o fol w/cont, pelvis	Q3	5582	5583	Disagree	Q3	5582
C8933	Mra, w/o & w/dye, spinal canal	Q3	5582	5583	Disagree	Q3	5582
C8936	Mra, w/o & w/dye, upper extr	Q3	5582	5583	Disagree	Q3	5582
93979	Vascular study	Q1	5531	5532	Agree	Q1	5532
76513	Echo exam of eye water bath	Q1	5531	5532	Agree	Q1	5532
76536	Us exam of head and neck	Q1	5531	5532	Agree	Q1	5532
76815	Ob us limited fetus(s)	Q1	5531	5532	Agree	Q1	5532
76775	Us exam abdo back wall lim	Q1	5531	5532	Agree	Q1	5532
76870	Us exam scrotum	Q1	5531	5532	Agree	Q1	5532
76817	Transvaginal us obstetric	Q1	5531	5532	Agree	Q1	5532
93890	Tcd vasoreactivity study	Q1	5531	5532	Agree	Q1	5532
76705	Echo exam of abdomen	Q3	5532	5531	Disagree	Q3	5532
76801	Ob us <14 wks single fetus	S	5532	5531	Disagree	S	5532
76830	Transvaginal us non-ob	S	5532	5531	Disagree	S	5532
76872	Us transrectal	S	5532	5531	Disagree	S	5532
76881	Us xtr non-vasc complete	S	5532	5531	Disagree	S	5532
93888	Intracranial limited study	S	5532	5531	Disagree	S	5532
93931	Upper extremity study	S	5532	5531	Disagree	S	5532
70559	Mri brain w/o & w/dye	S	5582	5526	Agree	S	5526
74261	Ct colonography dx	Q3	5521	5570	Agree	Q3	5570
75572	Ct hrt w/3d image	S	5523	5571	Agree	S	5571
75559	Cardiac mri w/stress img	Q3	5581	5592	Agree	Q3	5592
75557	Cardiac mri for morph	Q3	5581	5593	Disagree	Q3	5581
50430	Njx px nfrosgrm &/urtrgrm	Q2	5524	5373	Disagree	Q2	5372
50431	Njx px nfrosgrm &/urtrgrm	Q2	5524	5372	Agree	Q2	5372
50434	Convert nephrostomy catheter	T	5392	5372	Agree	T	5372
50435	Exchange nephrostomy cath	T	5392	5372	Agree	T	5372
73503	X-ray exam hip uni 4/> views	Q1	5521	5522	Agree	Q1	5522
73522	X-ray exam hips bi 3–4 views	Q1	5522	5523	Disagree	Q1	5522
73523	X-ray exam hips bi 5/> views	S	5522	5523	Agree	S	5523
72083	X-ray exam entire spi 4/5 vw	S	5522	5523	Agree	S	5523
72084	X-ray exam entire spi 6/> vw	S	5522	5524	Disagree	S	5523
78266	Gastric emptying imag study	S	5591	5592	Agree	S	5592
47532	Injection for cholangiogram	Q2	5525	5351	Agree	Q2	5351
47535	Conversion ext bil drg cath	T	5392	5351	Agree	T	5351
47536	Exchange biliary drg cath	T	5392	5351	Agree	T	5351
47537	Removal biliary drg cath	Q2	5391	5351	Disagree	Q2	5391
75563	Card mri w/stress img & dye	S	5592	5593	Agree	S	5593
75571	Ct hrt w/o dye w/ca test	Q1	5731	5570	Disagree	Q1	5731

We disagree with the commenters who requested that the procedures described by CPT codes 70370 (Radiologic examination; pharynx or larynx, including fluoroscopy and/or magnification technique), 71030 (Radiologic examination, chest, complete, minimum of 4 views), and 76496 be elevated from proposed APC 5521 to APC 5522 based on resource and clinical homogeneity. The procedure described by CPT code 70370 has a geometric mean unit cost of approximately $81 and the geometric mean cost of APC 5521 is approximately $64. Because the procedure described by CPT code 70370 is a low-volume procedure (49 single claims out of 66 total claims) in APC 5521, it is unnecessary to reassign the procedure describing CPT code 70370 to APC 5522, which has a geometric mean unit cost of approximately $105. The procedure described by CPT code 71030 is appropriately assigned to APC 5521 because of the similarity of clinical characteristics and resource use with other chest x-ray procedures assigned to APC 5521. CPT code 76496 is an unlisted fluoroscopic procedure code, and under our established policy, unlisted codes are assigned to the lowest level APC within a clinical family.

We disagree with the commenters who requested that CPT codes 72050, 72110, 72074, 77074, 74240, 72052, 74246, 76120, 74270, 74241, 70371, 77075, 74247, 49465, and 73092 that were proposed to be assigned to proposed APC 5522 (Level 2 X-Ray and Related Services) be reassigned to APC

5523 (Level 3 X-Ray and Related Services) to improve resource homogeneity. The geometric mean cost of these codes range from approximately $129 to approximately $176, and the geometric mean cost of APC 5522 is approximately $105. The geometric mean cost of APC 5523 is approximately $201. We believe that, given the geometric mean cost of APC 5522 and the clinical similarity of the procedures described by these codes compared to other procedures assigned to APC 5522, these codes are appropriately assigned to APC 5522.

We disagree with the commenters who requested that CPT codes 74430 (Cystography, minimum of 3 views, radiological supervision and interpretation) and 74450 (Urethrocystography, retrograde, radiological supervision and interpretation) that were proposed to be assigned to proposed APC 5523 (Level 3 X-Ray and Related Services) be reassigned to APC 5524 (Level 4 X-Ray and related Services). The geometric mean cost of CPT code 74430 is approximately $265. The geometric mean cost of CPT code 74450 is approximately $277. The geometric mean cost of APC 5523 is approximately $201. The geometric mean cost of APC 5524 is approximately $368. We believe that, given the geometric mean costs of APC 5523 and APC 5524, APC 5523 is a more appropriate APC assignment for the procedures described by CPT codes 74430 and 74450.

We disagree with the commenter who requested that the procedures described by CPT codes G0120 (Colorectal cancer screening) and 74445 (X-Ray exam of penis) that were proposed to be assigned to proposed APC 5524 (Level 4 X-Ray and Related Services) be reassigned to APC 5525 (Level 5 X-Ray and Related Services). The geometric mean cost of the procedure described by CPT code G0120 is approximately $330. The geometric mean cost of the procedure described by CPT code 74445 is approximately $532. The geometric mean cost of APC 5524 is approximately $368. The geometric mean cost of APC 5525 is approximately $700. We believe that, given the geometric mean costs of APC 5524 and APC 5525, APC 5524 is the more appropriate APC assignment for the procedures described by CPT codes G0120 and 74445.

We disagree with the commenter who requested that the procedure described by CPT code 78456 (Acute venous thrombosis imaging, peptide) that was proposed to be assigned to proposed APC 5525 (Level 5 X-Ray and Related Services) be reassigned to APC 5526 (Level 6 X-Ray and Related Services). Because the procedure described by CPT code 78456 is a nuclear medicine test, we are assigning it to APC 5593. We also disagree with the commenter who requested that CPT code 74210 and CPT code 72040 that were proposed to be assigned to APC 5522 (Level 2 X-Ray and Related Services) be reassigned to APC 5521 (Level 1 X-Ray and Related Services). The geometric mean cost of each of the CPT codes is approximately $90. The geometric mean cost of APC 5522 is approximately $105. The geometric mean cost of APC 5521 is approximately $64. We believe that, given the geometric mean cost of APCs 5521 and 5522, APC 5522 is the more appropriate assignment for the procedures described by CPT codes 74210 and 72040, based on similarity in resource use in relation to other procedures in these APCs.

We disagree with the commenters who requested that CPT code 75872 (Venography, epidural, radiological supervision and interpretation), which was proposed to be assigned to APC 5526, be reassigned to APC 5525. This procedure is a very low volume procedure and is assigned to APC 5526 based on similarity of the clinical test described by CPT code 75872 to other clinical tests assigned to the APC.

We disagree with the commenters who requested that CPT codes 70470; 70482; 70488; 70492; 70496; 70498; 71275; 72127; 72130; 72133; 72191; 72194; 73202; 73206; 73702; 73706; 74170; 74175; 75574; and 75635, which were proposed to be assigned to APC 5571 (Level 1 Computed Tomography with Contrast and Computed Tomography Angiography) be reassigned to APC 5572 (Level 2 Computed Tomography with Contrast and Computed Tomography Angiography). The geometric mean cost for these codes ranges from approximately $250 to approximately $284. The geometric mean cost of APC 5571 is approximately $248. The geometric mean cost of APC 5572 is approximately $364. We believe that, given the geometric mean cost of APC 5571 and 5572, APC 5571 is the more appropriate APC assignment for the procedures described by these codes.

We disagree with the commenters who requested that CPT codes 72126, 73201, and 74177, which were proposed to be assigned to APC 5572, be reassigned to APC 5571. The geometric mean cost for these codes range from approximately $325 to approximately $353. The geometric mean cost of APC 5572 is approximately $364. The geometric mean cost of APC 5571 is approximately $248. We believe that, given the geometric mean cost of APCs 5571 and 5572, APC 5572 is the more appropriate assignment for the procedures described by these codes.

We disagree with the commenters who requested that CPT codes 70544 (Magnetic resonance angiography) and 70547 (Magnetic resonance angiography, neck; without contrast material(s)), which were proposed to be assigned to APC 5581 (Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast), be reassigned to a requested new APC 5583 (Magnetic Resonance Imaging and Magnetic Resonance Angiography Without Contrast Followed by With Contrast). We do not believe that there is sufficient clinical or resource dissimilarity in the proposed APC groupings to warrant the creation of a third level.

We disagree with the commenters who requested that CPT codes 70545, 70546, 70548, 70549, C8902, C8911, C8914, C8920, C8933, and C8936, which were proposed to be assigned to APC 5582, be reassigned to a requested new APC 5583 (Magnetic Resonance Angiography [MRA] Without Contrast Followed by With Contrast). We do not believe it is necessary to separate MRA imaging services from MRI imaging services by creating an additional APC within this clinical family. The aforementioned MRA CPT codes do not represent clinically distinct imaging services from MRI CPT codes assigned to APC 5582 because MRA scans are often included with a MRI scan. Further, the resource costs of the aforementioned MRA CPT codes are not significantly different, but are very much in line with the resource costs of non-MRA imaging services.

We disagree with the commenters who requested that CPT codes 76705, 76801, 76830, 76872, 76881, 93888, and 93931, which were proposed to be assigned to APC 5532 (Level 2 Ultrasound and Related Services), be reassigned to APC 5531 (Level 1 Ultrasound and Related Services). The geometric mean cost of the procedures described by these codes ranges from approximately $122 to approximately $134. The geometric mean cost of APC 5532 is approximately $161. The geometric mean cost of 5531 is approximately $96. We believe that, given the geometric mean cost of APC 5531 and APC 5532, APC 5532 is the more appropriate assignment for the procedures described by these codes.

We disagree with the commenters who requested that CPT code 75557 (Cardiac magnetic resonance imaging for morphology and function without contrast material), which was proposed to be assigned to APC 5581 (Magnetic

Resonance Imaging and Magnetic Resonance Angiography without Contrast), be reassigned to APC 5592 (Level 2 Nuclear Medicine and Related Services). The geometric mean cost for the procedure described by CPT code 75557 is approximately $283. The geometric mean cost for APC 5581 is approximately $286. The geometric mean cost for APC 5592 is approximately $462. Based on the geometric mean costs of APC 5581 and APC 5592, we believe APC 5581 is the more appropriate assignment for the procedure described by CPT code 75557. We also disagree with the commenters regarding their requests for APC reassignment of CPT codes 78457 and 78458. These two codes describe nuclear medicine tests and therefore are being assigned to APCs in that series.

We disagree with the commenters who requested that we reassign the following new CY 2016 codes as indicated:

- CPT code 50430, which was proposed to be assigned to APC 5524 and requested by the commenters to be reassigned to APC 5372;
- CPT code 73522, which was proposed to be assigned to APC 5522 and requested by the commenters to be reassigned to APC 5523;
- CPT code 72084, which was proposed to be assigned to APC 5522 and requested by the commenters to be reassigned to APC 5524; and
- CPT code 47537, which was proposed to be assigned to APC 5391 and requested by the commenters to be reassigned to APC 5351.

Under our established policy, for new codes, we determine APC assignment based on clinical and resource similarities to existing codes. Because the procedures for these codes are not reflected in available CY 2014 claims data because of their newness, we believe that the proposed APCs are appropriate. We will consider reassignment of these codes as claims data become available.

Comment: One commenter requested that CMS reassign the procedure described by CPT code 91200 (Liver elastography, mechanically induced shear wave (*e.g.,* vibration), without imaging, with interpretation and report) from proposed APC 5531 (Level 1 Ultrasound and Related Services) to proposed APC 5532 (Level II Ultrasound and Related Services). The commenter stated that the procedure described by this code is assigned to APC 0266 (Level II Diagnostic and Screening Ultrasound) for CY 2015. The commenter acknowledged that the CPT code is new for CY 2015 and that cost information is not reflected in our CY 2014 claims data. Therefore, the commenter believed that, in the absence of claims data for CPT code 91200, it is inappropriate for CMS to propose assignment to a lower paying APC in CY 2016. In addition, the commenter requested that CMS change the proposed assigned status indicator of ''Q1'' to ''S'' because this procedure is not typically performed with other procedures of status indicator ''S,'' ''T,'' or ''V'' and therefore should be a separately payable service.

Response: We agree with the commenter. Therefore, for CY 2016, we are reassigning the procedure described by CPT code 91200 to APC 5532 (Level II Ultrasound and Related Services) with status indicator ''S.''

Comment: One commenter requested that CMS reassign CPT code 75571 (Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium) from proposed APC 5731 (Level 1 Minor Procedures) to proposed APC 5570 (Computed Tomography without Contrast) because the commenter believed that the procedure described by CPT code 75571 is similar to the procedure described by CPT code 71250, which was proposed to be assigned to APC 5570.

Response: Based on the latest available CY 2014 hospital claims data, the geometric mean cost of the procedure described by CPT code 75571 is approximately $13, based on 4,225 single claims. Therefore, we believe that the procedure described by CPT code 75571 is appropriately assigned to APC 5731.

After consideration of the public comments we received, we are finalizing our proposal, with modification, to reconfigure the imaging-related procedures into 26 APCs. Table 32 below lists the final CY 2016 APCs that result from the consolidation and restructuring of the current radiology and nuclear medicine services APCs. The final payment rates for the specific CPT imaging-related services are included in Addendum B to this final rule with comment period. The final payment rates for the specific APCs to which we are assigning the imaging-related services are included in Addendum A to this final rule with comment period. Both OPPS Addenda A and B are available via the Internet on the CMS Web site.

TABLE 32—CY 2016 IMAGING-RELATED PROCEDURES APCS

CY 2016 APC	CY 2016 APC group title
5521	Level 1 X-Ray and Related Services.
5522	Level 2 X-Ray and Related Services.
5523	Level 3 X-Ray and Related Services.
5524	Level 4 X-Ray and Related Services.
5525	Level 5 X-Ray and Related Services.
5526	Level 6 X-Ray and Related Services.
5531	Level 1 Ultrasound and Related Services.
5532	Level 2 Ultrasound and Related Services.
5533	Level 3 Ultrasound and Related Services.
5534	Level 4 Ultrasound and Related Services.
5561	Level 1 Echocardiogram with Contrast.
5562	Level 2 Echocardiogram with Contrast.
5570	Computed Tomography without Contrast.
5571	Level 1 Computed Tomography with Contrast and Computed Tomography Angiography.
5572	Level 2 Computed Tomography with Contrast and Computed Tomography Angiography.
5581	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast.
5582	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast.
5591	Level 1 Nuclear Medicine and Related Services.
5592	Level 2 Nuclear Medicine and Related Services.
5593	Level 3 Nuclear Medicine and Related Services.
5594	Level 4 Nuclear Medicine and Related Services.
8004	Ultrasound Composite.
8005	CT and CTA without Contrast Composite.
8006	CT and CTA with Contrast Composite.
8007	MRI and MRA without Contrast Composite.
8008	MRI and MRA with Contrast Composite.

9. Orthopedic Procedures

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we examined the APCs that contain orthopedic-related procedures. For CY 2016, we proposed to restructure the OPPS APC groupings for orthopedic surgery procedures to more appropriately reflect similar costs and clinical characteristics of the procedures within each APC grouping

in the context of the OPPS. The current APCs for orthopedic-related procedures are primarily divided according to anatomy and the type of musculoskeletal procedure. After reviewing these APCs, we believe that the current APC structure is based on clinical categories that do not necessarily reflect significant differences in the delivery of these services in the HOPD. The current level of granularity for these APCs results in groupings that are unnecessarily narrow for the purposes of a prospective payment system. For example, we see no reason for purposes of OPPS payment to continue to separate musculoskeletal procedures that do not involve the hand or foot from procedures that do include the hand or foot.

Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39262), for CY 2016, we proposed to restructure and consolidate the APCs for orthopedic surgery procedures. We stated in the proposed rule that we believe that this proposed restructuring and consolidation would result in APC groupings that would more appropriately reflect a prospective payment system that is based on payment for clinically consistent APC groupings and not code-specific payment rates while maintaining clinical and resource homogeneity. Table 29 of the proposed rule listed the current CY 2015 APCs that contain orthopedic-related procedures, and Table 30 of the proposed rule listed the proposed CY 2016 APCs that would result from the proposed restructuring and consolidation of the current orthopedic-related procedures APCs. We invited public comments on this proposal.

Comment: Some commenters generally concurred with the consolidation and reconfiguration of the orthopedic-related procedures APCs. However, many commenters expressed concern that the ranges of geometric mean costs for procedures assigned to the proposed orthopedic-related procedures APCs are too broad, resulting in payment misalignments for certain procedures. Many other commenters opposed the proposed restructuring of these APCs and asserted that the proposed revised reconfiguration is neither clinically homogeneous nor resource use homogeneous. Several of these commenters recommended that CMS either delay reconfiguration of the orthopedic-related procedures or maintain larger groupings based on anatomical region.

Response: In our effort to improve the similarity in resource use and clinical characteristics within the orthopedic-related APC groupings, we proposed to revise the existing orthopedic-related procedures APCs for CY 2016. We believe that the proposed revised orthopedic-related procedures APCs more appropriately reflect the resource costs and clinical characteristics of the procedures within each APC. We do not agree that creating orthopedic-related procedures APCs based on the specific anatomical region treated by the procedure is necessary or appropriate. For example, an orthopedic surgeon might perform a 1-hour procedure on a patient's leg and then perform a 1-hour procedure using similar instruments and supplies, among others, on a different patient's arm, and the hospital resources consumed in both cases would be very similar, which would support assignment of these procedures in the same APC. There is no purpose to group the leg procedure in an APC dedicated to leg procedures and the arm procedure in an APC dedicated to arm procedures if they are both orthopedic surgeries that consume similar hospital resources. Likewise, we do not agree that it is either necessary or appropriate to create an APC for high-cost, very low volume orthopedic-related procedures. We believe that establishing more inclusive categories of the orthopedic-related procedures is more appropriate for future ratesetting under the OPPS because the restructured APCs have more clinically appropriate groupings, while improving resource similarity. However, we agree with the commenters who were concerned that the proposed four levels of musculoskeletal APCs resulted in extremely wide geometric mean cost ranges, and in response to their comments, we have added a fifth level to the musculoskeletal APC grouping. Several procedures that were proposed to be assigned to APC 5123 (Level 3 Musculoskeletal Procedures) are now reassigned APC 5124 (Level 4 Musculoskeletal Procedures) for CY 2016. Similarly, several procedures that were proposed to be assigned to APC 5124 (Level 4 Musculoskeletal Procedures) are now reassigned to new APC 5125 (Level 5 Musculoskeletal Procedures) for CY 2016.

Comment: One commenter expressed concern with the proposed payment for the services described by CPT code 27279 (Sacroiliac join stabilization for arthrodesis, percutaneous or minimally invasive (indirect visualization), includes obtaining and applying autograft or allograft (structural or morselized) when performed, includes image guidance when performed (*e.g.,* CT or fluoroscopic), which the commenter considered would result in an underpayment. The commenter stated that CPT code 27279 became effective January 1, 2015 and is the successor code to CPT code 0334T (Sacroiliac join stabilization for arthrodesis, percutaneous or minimally invasive (indirect visualization), includes obtaining and applying autograft or allograft (structural or morselized) when performed, includes image guidance when performed (*e.g.,* CT or fluoroscopic)), and that the CY 2014 claims data for services described by CPT code 0334T is appropriate to use to set the CY 2016 payment rate for procedures described by CPT code 27279. The commenter stated that the proposed payment rate for procedures assigned to APC 5124 (Level 4 Musculoskeletal Procedures) is approximately $9,266, which is a rate that does not cover the cost of the procedure described by CPT code 27279, which had a proposed geometric mean cost of approximately $16, 816. The commenter requested that CMS reassign the procedure described by CPT code 27279 to an APC that has a payment rate that is comparable to the actual cost of the procedure.

Response: As previously mentioned in response to commenters' concerns regarding the wide range of costs associated with the musculoskeletal procedures APC group, we revised the musculoskeletal procedures APC grouping by adding a fifth level, APC 5125 (Level 5 Musculoskeletal Procedures). With the addition of APC 5125, we reassigned certain procedures from Level 4 (APC 5124) in the proposed rule to new Level 5 based on the geometric mean costs of the procedures. Therefore, in this final rule with comment period, for CY 2015, we are revising the APC assignment for the procedure described by CPT 27279 from APC 5124 to APC 5125. The geometric mean cost of APC 5125 is approximately $11,027, which is higher than the proposed geometric mean cost of APC 5124 of approximately $9,789.

Comment: A few commenters disagreed with the proposed APC assignment for kyphoplasty CPT code 22513 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (*e.g.,* kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic) and CPT code 22514 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included

when performed) using mechanical device (*e.g.,* kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar) to APC 5123 (Level 3 Musculoskeletal Procedures). Specifically, the commenters stated that these two kyphoplasty procedure codes are not clinically homogenous with the other procedures assigned to APC 5123 and that the proposed APC payment would underpay facilities for these procedures, thus negatively affecting beneficiary access.

Response: We appreciate the stakeholders' concern that the proposed assignment of the procedures described by CPT codes 22513 and 22514 to APC 5123 will cause outpatient facilities to stop offering minimally invasive outpatient procedures for patients with vertebral compression fractures, forcing these patients toward more expensive alternatives. Because CPT codes 22513 and 22514 were established January 1, 2015, our CY 2014 hospital claims data do not include costs for these procedures. Therefore, we proposed the APC assignment for these two codes based on similarities in resource cost to former kyphoplasty CPT codes 22523 through 22525. However, as discussed above, in this final rule with comment period, we are adding a fifth level to the musculoskeletal APC groupings (APC 5215) for CY 2016, and are reassigning the procedures described by CPT codes 22513 and 22514 from proposed APC 5124 (Level 4 Musculoskeletal Procedures) to APC 5125. We believe that this reassignment will improve resource and clinically homogeneity. However, we will continue to monitor service utilization trends in the HOPD for kyphoplasty and other minimally invasive procedures for patients with vertebral compression and consider APC reassignment in future rulemaking.

Comment: A few commenters believed that CMS used inaccurate CY 2014 claims data for the following auditory osseointegrated system implant codes:

- CPT code 69714 (Auditory osseointegrated device implantation with attachment to sound processor, without mastoidectomy);
- CPT code 69715 (Auditory osseointegrated device implantation with attachment to sound processor, with mastoidectomy);
- CPT code 69717 (Removal and replacement of existing osseointegrated implant, with attachment to sound processor, without mastoidectomy); and
- CPT code 69718 (Removal and replacement of existing osseointegrated implant, with attachment to sound processor, with mastoidectomy).

Specifically, the commenters expressed skepticism about the low volume of claims that reported the above codes and the underreporting of the device cost described by CPT code L8690 (Auditory osseointegrated device). The commenters recommended that CMS not reduce the APC payment for these procedures because of incorrectly coded claims.

Response: As we described in section II.A. of this final rule with comment period on the OPPS ratesetting methodology, ''Beyond our standard OPPS trimming methodology . . . that we apply to those claims that have passed various types of claims processing edits, it is not our general policy to judge the accuracy of hospital coding and charging for purposes of ratesetting'' (75 FR 71838). We use the latest available hospital claims data for these procedures to assign these procedures to APCs. Based on that data, we are assigning the procedure described by CPT code 69714 (which has a geometric mean cost of approximately $9,483) and by CPT code 69715 (which has a geometric mean cost of approximately $11,337) to APC 5125 (which has a geometric mean cost of approximately $11,027). We are assigning the procedure described by CPT code 69717 (which has a geometric mean cost of approximately $5,923) to APC 5123 (which has a geometric mean cost of approximately $5,200). We are assigning the procedure described by CPT code 69718 (which has a geometric mean cost of approximately $6,858) to APC 5124 (which has a geometric mean cost of approximately $7,392).

Comment: One commenter requested the reassignment of the procedure described by CPT code 23397 (Muscle transfer, any type, shoulder or upper arm; multiple) from proposed APC 5122 (Level 2 Musculoskeletal Procedures) to proposed APC 5123 (Level 3 Musculoskeletal Procedures) because of clinical and resource use homogeneity with the procedure described by CPT code 23395 (Muscle transfer, any type, shoulder or upper arm; single) that is assigned to APC 5123.

Response: We believe that the procedure described by CPT code 23397 is appropriately assigned to APC 5122 based on clinical and resource use homogeneity with other procedures in the APC. We disagree with the commenter's recommendation to reassign CPT code 23397 from APC 5122 to APC 5123. The geometric mean cost of the procedure described by CPT code 22397 is approximately $3,598 based on only one single claim (out of two total claims) and is higher than the APC geometric mean cost of APC 5122, which is approximately $2,507. However, the APC geometric mean cost for APC 5123 is approximately $5,200. Because of the very low claims volume for CPT code 23397, it is not appropriate at this time to reassign the procedure code to a higher paying APC.

Comment: Several commenters requested that CMS reassign the services described by CPT codes 29580 (Strapping; Unna boot), 29581 (Application of multi-layer compression system; leg (below knee), including ankle and foot), and 29450 (Application of clubfoot cast with molding or manipulation, long or short leg from proposed APC 5102 (Level 2 Strapping and Cast Application) to proposed APC 5101 (Level 1 Strapping and Cast Application) because the services described by these codes are neither clinically consistent nor similar in cost to other procedures assigned to APC 5102.

Response: Based on our review of the clinical characteristics and resource costs of the services described by CPT codes 29580, 29581, and 29450 that are reflected in the latest claims data, we agree with the commenters that it would be more appropriate to group the procedures described by these codes with similar procedures assigned to APC 5101. Therefore, we are reassigning the services described by CPT codes 29580, 29581, and 29450 from proposed APC 5102 to APC 5101 for CY 2016.

After consideration of the public comments we received, we are finalizing our proposal, with the modification of adding a Level 5 Musculoskeletal APC, to reconfigure the orthopedic-related procedures into 10 APCs. Table 33 below lists the final CY 2016 APCs that result from the restructuring and consolidation of the current orthopedic-related procedures APCs. The final payment rates for the specific CPT orthopedic-related procedure codes are included in Addendum B to this final rule with comment period. The final payment rates for the specific APCs to which we are assigning the orthopedic-related procedures codes are included in Addendum A to this final rule with comment period. Both OPPS Addenda A and B are available via the Internet on the CMS Web site.

TABLE 33—CY 2016 ORTHOPEDIC-RELATED PROCEDURES APCS

CY 2016 APC	CY 2016 APC group title
5101	Level 1 Strapping and Cast Application.

TABLE 33—CY 2016 ORTHOPEDIC-RELATED PROCEDURES APCS—Continued

CY 2016 APC	CY 2016 APC group title
5102	Level 2 Strapping and Cast Application.
5111	Level 1 Closed Treatment Fracture and Related Services.
5112	Level 2 Closed Treatment Fracture and Related Services.
5113	Level 3 Closed Treatment Fracture and Related Services.
5121	Level 1 Musculoskeletal Procedures.
5122	Level 2 Musculoskeletal Procedures.
5123	Level 3 Musculoskeletal Procedures.
5124	Level 4 Musculoskeletal Procedures.
5125	Level 5 Musculoskeletal Procedures.

10. Pathology Services

For CY 2016, we proposed to assign pathology services to one of the following APCs: APCs 5671, 5672, 5673, and 5674 (Levels 1 through 4 Pathology, respectively); APC 5681 (Transfusion Laboratory Procedures); and APCs 5731, 5732, 5733, and 5734 (Levels 1 through 4 Minor Procedures, respectively). The packaging of payment for pathology services is discussed in section II.A.3. of this final rule with comment period.

Comment: One commenter requested that CMS reassign the following CPT codes (that were new in CY 2015 and currently do not have available associated claims data) to APC 5673 (Level 3 Pathology):

- CPT code 88344 (Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure);
- CPT code 88366 (In situ hybridization (*e.g.,* fish), per specimen; each multiplex probe stain procedure);
- CPT code 88374 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure); and
- CPT code 88377 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure).

The commenter believed that these CPT codes should be assigned to the Level 3 Pathology APC (APC 5673) because these are multiplex codes and are inherently more resource intensive than the corresponding single antibody/single probe procedures, for example, CPT code 88342, which are currently assigned to APC 5673.

Response: We agree with the commenters. Therefore, for CY 2016, we are reassigning CPT codes 88344, 88366, 88374, and 88377 to APC 5673.

Comment: One commenter requested that CMS reassign CPT code 88121 (Cytopathology, in situ hybridization (*e.g.,* fish), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; using computer-assisted technology) from APC 5672 to APC 5673 because related CPT code 88120 (Cytopathology, in situ hybridization (*e.g.,* fish), urinary tract specimen with morphometric analysis, 3–5 molecular probes, each specimen; manual) is assigned to APC 5673, the Level 3 Pathology APC. The commenter asserted that, because the resources used for services described by CPT code 88121 are similar to the resources used for services described by CPT 88120, both of these two CPT codes should be assigned to APC 5673.

Response: Analysis of the latest CY 2014 claims data used for this final rule with comment period shows the geometric mean cost of services described by CPT code 88121 is approximately $132, and the geometric mean cost of services described by CPT code 88120 is approximately $154. Calculation of the geometric mean costs for the services described by these codes resulted in CPT code 88121 being assigned to APC 5672 (Level 2 Pathology) and CPT code 88120 being assigned to APC 5673 (Level 3 Pathology). The geometric cost of CPT code 88121 is at the top of the range of costs services assigned to APC 5672, and the geometric cost of CPT code 88120 is at the bottom of the range costs of services assigned to APC 5673. This situation sometimes occurs even for somewhat similar services because APC groupings by definition have boundaries that divide the levels within an APC series such as the four levels for pathology services. We believe that the services described by CPT code 88121 are appropriately assigned to APC 5672. Therefore, for CY 2016, we are not reassigning the services described by CPT code 88121 from APC 5672 to APC 5673 as the commenter requested.

Comment: Some commenters urged CMS to maintain the existing, separately payable status indicators (that is, ''S'' or ''T'') for a number of codes within the proposed nine reconfigured APC families instead of assigning them to a conditional packaging status indicator (that is, ''Q1'' or ''Q2''). One commenter provided a list of 70 codes and requested that CMS assign them to separately payable status indicators. Among the list of 70 codes provided by the commenter were 14 pathology services codes that, as a result of the APC restructuring policy, were proposed for CY 2016 to be assigned to either APC 5681 (Transfusion Laboratory Procedures) or to APC 5732 (Level 2 Minor Procedures) or APC 5733 (Level 3 Minor Procedures).

Response: Prior to our proposal, we reviewed all of the services associated with the proposed nine families. We believe that the procedures and services that we proposed to assign to a conditional packaging status indicator are ancillary and dependent in relation to the other procedures within the same family groupings with which they are most commonly furnished. Based on our review and input from CMS clinical staff, we believe that the codes that we proposed to conditionally package are appropriate. In addition, the APC to which we proposed to assign most of the 14 pathology services codes for CY 2016, APC 5681 (Transfusion Laboratory Procedures), is the successor APC to CY 2015 APC 0345 (Level I Transfusion Laboratory Procedures). APC 0345 was designated in CY 2015 as an APC for conditionally packaged ancillary services (79 FR 66822). In the proposed rule, 3 of the 14 pathology codes in question were proposed to be assigned to either APC 5732 (Level 2 Minor Procedures) or APC 5733 (Level 3 Minor Procedures). These APCs are the successor APCs to the CY 2015 APCs 0340 (Level II Minor Procedures) and 0420 (Level III Minor Procedures), which were also designated in CY 2015 as APCs for conditionally packaged ancillary services (79 FR 66822). Therefore, we believe that the services assigned to APCs 5681, 5732, and 5733 are appropriately assigned a conditionally packaged status indicator. Further, based on the clinical nature of the services and our understanding of the procedures, we believe that assigning them to a conditional packaging status indicator will create incentives for hospitals and their physician partners to work together to establish appropriate protocols that will eliminate unnecessary services where they exist and institutionalize approaches to providing necessary services more efficiently. Therefore, after consideration of the public comments we received, we are finalizing our proposal to assign the 14 pathology services codes in question status indicator ''Q1'' for CY 2016.

11. Radiology Oncology Procedures and Services

a. Therapeutic Radiation Treatment Preparation

(1) Teletherapy Planning

For CY 2016, we proposed the following four-level configuration for the Therapeutic Radiation Treatment Preparation APCs:

- APC 5611 (Level 1 Therapeutic Radiation Treatment Preparation);
- APC 5612 (Level 2 Therapeutic Radiation Treatment Preparation);
- APC 5613 (Level 3 Therapeutic Radiation Treatment Preparation); and
- APC 5614 (Level 4 Therapeutic Radiation Treatment Preparation).

Procedures described by CPT codes 77306 (Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s)) and 77307 (Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s)) were considered new codes for CY 2015 and assigned to APC 0304 (Level I Therapeutic Radiation Treatment Preparation) in the CY 2015 OPPS/ASC final rule with comment period. In the CY 2016 OPPS/ASC proposed rule, we proposed to reassign procedures described by CPT codes 77306 and 77307 to proposed new APC 5611.

Comment: One commenter who responded to the CY 2015 OPPS/ASC final rule with comment period and the CY 2016 OPPS/ASC proposed rule requested that CMS reassign procedures described by CPT codes 77306 and 77307 to a higher level APC within the group of Therapeutic Radiation Treatment Preparation APCs. The commenter stated that the procedures described by these new codes have greater resource intensity than their predecessor codes because these procedures now include services that were formerly separately reportable.

Response: We agree with the commenter. We also believe that it is likely that the procedures described by the complex code, CPT code 77307, requires more resources than the procedures described by CPT code 77306. Therefore, for CY 2016, we are modifying our proposal and assigning the procedures described by CPT code 77306 to new APC 5612 and the procedures described by CPT code 77307 to new APC 5613 for CY 2016.

(2) Intensity Modulated Radiotherapy (IMRT) Planning

In the CY 2016 OPPS/ASC proposed rule, we proposed to assign procedures described by CPT code 77301 (Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications) was assigned to new APC 5614. We proposed new APC 5614 as the highest level APC in the group of Therapeutic Radiation Treatment Preparation APCs.

Since 2008, CMS has provided coding guidance for claims reporting CPT code 77301 in the Medicare Claims Processing Manual, Chapter 4, Section 200.3.2, which states the following: ''Payment for the services identified by CPT codes 77014, 77280–77295, 77305–77321, 77331, 77336, and 77370 is included in the APC payment for IMRT planning when these services are performed as part of developing an IMRT plan that is reported using CPT code 77301. Under those circumstances, these codes should not be billed in addition to CPT code 77301 for IMRT planning.''

In addition to this CMS Manual guidance, there is National Correct Coding Initiative (NCCI) guidance in the NCCI Policy Manual for Medicare Services, Chapter 9, page IX–17, which states the following: ''12. Intensity modulated radiotherapy (IMRT) plan (CPT code 77301) includes therapeutic radiology simulation-aided field settings. Simulation field settings for IMRT should not be reported separately with CPT codes 77280 through 77295. Although procedure-to-procedure edits based on this principle exist in NCCI for procedures performed on the same date of service, these edits should not be circumvented by performing the two procedures described by a code pair edit on different dates of service.''

Comment: A few commenters requested that CMS clarify its coding guidance on reporting services involving IMRT planning on claims. Several commenters stated that the service described by CPT code 77290 (Therapeutic radiology simulation-aided field setting; complex) should be separately reported from the services described by CPT code 77301 for patients receiving IMRT planning. These commenters believed that the services described by CPT code 77290 are never performed as part of IMRT planning services and, therefore, should be allowed to be reported separately from the services described by CPT 77301. Another commenter stated that recent coding guidance issued by the American Society for Radiation Oncology (ASTRO) also has caused confusion for hospitals and requested that CMS clarify its reporting guidance for IMRT planning in light of the recent ASTRO coding guidance. The commenter referred to the ASTRO Coding Guidance Articles, Process of Care: Treatment Preparation, which is available on the ASTRO Web site at: *https://www.astro.org/Practice-Management/Radiation-Oncology-Coding/Coding-Guidance/Articles/Process-of-Care—Treatment-Preparation.aspx*. The ASTRO guidance states in part that ''[I]f IMRT is the chosen modality for treating the patient, a simulation code (*e.g.,* CPT code 77290) cannot be reported separately prior to completion of the IMRT treatment plan, even if the two services are performed on separate days.'' The commenter further believed that ASTRO's guidance should only apply to physician billing and not to hospital outpatient billing.

Response: We disagree with these commenters. We believe that the types of services included in IMRT treatment planning include simulation. Although the commenter believed that simulation is never included as part of IMRT planning services, we believe CMS' longstanding Manual and coding guidance issued in CY 2008 has been precise in conveying its policy and instructions regarding coding for IMRT services and that, generally, IMRT services have been properly reported by hospitals.

It is our policy that payments for the services identified by CPT codes 77280 through 77295 are included in the APC payment for IMRT planning services, and that the services described by these CPT codes should not be reported separately from services described by CPT code 77301, regardless of when the various services that comprise CPT code 77301 are performed. If a hospital submits a claim that separately reports services described by one of these simulation CPT codes in addition to separately reporting IMRT planning services that are performed, we would consider this reporting to constitute unbundling of the APC payment, which is prohibited. We will revise and update the Medicare Claims Processing Manual and coding guidance in the near future to ensure that this policy is more directly stated. The clarified coding guidance will state the following:

''Payment for the services identified by CPT codes 77014, 77280 through 77295, 77305 through 77321, 77331, and 77370 is included in the APC payment for CPT code 77301 (IMRT planning). These codes should not be reported in addition to CPT code 77301 (on either the same or a different date of service)

unless these services are being performed in support of a separate and distinct non-IMRT radiation therapy for a different tumor.''

Comment: One commenter requested that CMS reassign the services described by CPT code 77301 to a higher level APC to reflect the additional resource utilization involved with CT simulation, in addition to the resource-intensive IMRT planning services included as services described by CPT code 77301.

Response: We proposed to assign the service described by CPT code 77301 to new proposed APC 5614, which is the highest level APC in the Therapeutic Radiation Treatment Preparation APC group. We believe that the service described by CPT code 77301 is a therapeutic radiation treatment preparation service and that it clinically aligns with other services within in the Therapeutic Radiation Treatment Preparation APC group. The final geometric mean cost of the services described by CPT code 77301 is approximately $1,125 based on 51,301 single claims (out of 52,016 total claims), which is comparable to the final geometric mean cost of approximately $1,074 for new APC 5614. We also believe that, given the close proximity of the geometric mean cost of services described by CPT code 77301 to the geometric mean cost of new APC 5614, this APC assignment is appropriate for CPT code 77301. As we do with all codes annually, next year we will examine the cost information on claims reporting services described by CPT code 77301 and determine if a change to the APC assignment is warranted. In addition, if the clarification of our coding guidance for IMRT planning services results in a significant change in the geometric mean cost of services described by CPT code 77301 in future years, we will consider an alternative APC assignment for the code other than APC 5614.

b. Radiation Therapy (Including Brachytherapy)

In the CY 2016 OPPS/ASC proposed rule, we proposed the following five levels for the Radiation Therapy APC group:

- APC 5621 (Level 1 Radiation Therapy);
- APC 5622 (Level 2 Radiation Therapy);
- APC 5623 (Level 3 Radiation Therapy);
- APC 5624 (Level 4 Radiation Therapy); and
- APC 5625 (Level 5 Radiation Therapy).

We also proposed to create two new APCs for CY 2016: APC 5631 (Single Session Cranial Stereotactic Radiosurgery) and APC 5641 (Brachytherapy). All of these proposed APCs describe various types of radiation therapy or radiation delivery.

Comment: One commenter requested that CMS reassign the procedure described by CPT code 0394T (High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when Performed) from proposed APC 5622 to proposed APC 5623, and the procedure described by CPT code 0395T (High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed) from proposed APC 5641 to proposed APC 5624. The commenter believed that these codes should be assigned to these higher paying APCs because the procedures described by these new codes include procedures such as dosimetry that were formerly separately payable under the OPPS.

Response: CPT codes 0394T and 0395T are new codes for CY 2016. The procedures described by these new codes were mapped to new proposed APCs 5622 and 5641 based on our best estimate of the likely resource costs for these procedures. We anticipate that we will have claims data for the procedures describing these new CPT codes for the CY 2018 OPPS rulemaking. At this time, we do not believe that we have sufficient information to support reassigning CPT codes 0394T and 0395T to the next higher level radiation therapy APC. Therefore, we are finalizing, as proposed, the APC assignments for procedures described by CPT codes 0394T and 0395T.

Comment: A few commenters requested that CMS reassign the procedure described by CPT code 77762 (Intracavitary radiation source application; intermediate) from proposed new APC 5622 to proposed new 5623 because related CPT codes 77761 (Intracavitary radiation source application; simple) and 77763 (Intracavitary radiation source application; complex) were both proposed to be assigned to new proposed APC 5623 in the CY 2016 OPPS/ASC proposed rule. The commenters stated that, although CMS may lack sufficient claims data for the procedure described by CPT code 77762, the procedure (the intermediate level of this code series) is similar in terms of clinical characteristics and resource use to the procedures described by CPT codes 77761 and 77763 and, therefore, the procedure described by CPT code 77762 should be assigned to the same APC as these other codes in the intracavitary radiation source application APC group.

Response: We agree with the commenters that the procedure involving intermediate intracavitary radiation source application should not be assigned to a lower level APC than the simple version of this procedure. After examining claims data for the CPT codes in this APC group that reported intracavitary radiation source application, we found that, although the number of claims is relatively small, the geometric mean cost of the procedure described by CPT code 77763 is more similar to the geometric mean costs of procedures assigned to new APC 5624 than that of the procedures assigned to new APC 5623. Therefore, we are modifying our proposal and reassigning the procedure described by CPT code 77762 from proposed APC 5622 to APC 5623, and the procedure described by CPT code 77763 (the complex code) from new APC 5623 to APC 5624 for CY 2016. We also believe that it is appropriate, for consistency and easy comprehension, to revise the title of some of the radiation therapy APCs. Depicted in Table 34 below is a listing of the finalized titles of the radiation therapy APCs. The revisions to the titles of these APCs do not affect the APC assignment of any of the codes.

TABLE 34—FINAL RADIATION THERAPY APC TITLES FOR CY 2016

Proposed CY 2016 APC No.	Proposed CY 2016 APC title	Final CY 2016 APC No.	Final CY 2016 APC title
5621	Level 1—Radiation Therapy	5621	Level 1—Radiation Therapy.
5622	Level 2—Radiation Therapy	5622	Level 2—Radiation Therapy.
5623	Level 3—Radiation Therapy	5623	Level 3—Radiation Therapy.
5641	Brachytherapy	5624	Level 4—Radiation Therapy.
5624	Level 4—Radiation Therapy	5625	Level 5—Radiation Therapy.
5625	Level 5—Radiation Therapy	5626	Level 6—Radiation Therapy.

TABLE 34—FINAL RADIATION THERAPY APC TITLES FOR CY 2016—Continued

Proposed CY 2016 APC No.	Proposed CY 2016 APC title	Final CY 2016 APC No.	Final CY 2016 APC title
5631	Single Session Cranial Stereotactic Radiosurgery	5627	Level 7—Radiation Therapy.

In summary, for CY 2016, the simple and intermediate intracavitary radiation source application codes, CPT codes 77761 and 77762, are assigned to new APC 5623, and the complex intracavitary radiation source application code, CPT code 77763, is assigned to APC 5624.

Comment: Several commenters requested that CMS estimate costs for the new CY 2016 high dose rate (HDR) brachytherapy codes (CPT codes 77767 through 77772) to include the cost of the dose calculation, which is now a part of the services described by the HDR brachytherapy codes. The commenters believed that if CMS included these additional costs, the calculations would result in increased payment rates for the APCs to which the HDR brachytherapy codes are assigned.

Response: We believe that these commenters may have misunderstood our ratesetting methodology as it applies to new codes. We generally do not model costs for new codes and incorporate modeled cost data into our payment rate calculations. Instead, we make an initial APC assignment for new codes based on predecessor code APC assignments and other information that allows for a suitable APC assignment until claims data is available for the new codes. We do not believe the commenters' suggested approach is appropriate under our established ratesetting methodology for new codes.

c. Fractionated Stereotactic Radiosurgery (SRS)

For CY 2016, we proposed to reassign the services described by CPT code 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions) from APC 0066 (Level V Radiation) to APC 5625 (Level 5 Radiation Therapy), with a proposed payment rate of approximately $1,699.

Comment: Several commenters disagreed with the proposed APC assignment of the services described by CPT code 77373 to APC 5625. In particular, the commenters were concerned that the proposed payment rate for the services described by CPT code 77373 equates to a reduction of 11 percent in payment when compared to the payment rate for CY 2015. The commenters believed that the proposed payment is not reflective of the actual costs of providing fractionated SRS services. The commenters also expressed concerns about the accuracy of the hospital cost data on fractionated SRS services used to set the proposed payment rate. They believed that hospitals have miscoded the service by reporting CPT code 77372 (Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based) for the first fraction, and instead have reported the services described by CPT code 77373. Several commenters requested that CMS increase the proposed payment rate of approximately $1,699 for APC 5625 by at least $630 to more accurately capture the costs of providing this therapy, or alternatively, assign services described by CPT code 77373 to a stable APC, such as a new technology APC, for a period of 3 years to allow for the reporting of appropriate claims data to use to calculate a more appropriate payment. One commenter recommended that CMS reassign CPT code 77373 to New Technology—Level 25 ($3,500-$4,000), with a payment rate of approximately $3,750.

Response: We believe that we have adequate claims data for services described by CPT code 77373 because fractionated/multi-session SRS is not a new technology. For the CY 2016 ratesetting, there are 59,853 single claims (out of 64,629 total claims) for the services described by CPT code 77373, which is an adequate volume for ratesetting purposes. Although CPT code 77373 was not recognized under the OPPS until January 1, 2014, the code has been in existence since January 1, 2007. Hospital outpatient facilities have been reporting the SRS CPT codes to other payers since the codes were established in 2007. We believe that hospital outpatient facilities have had sufficient time to educate themselves on how to appropriately report the services described by CPT code 77373. We do not agree that assigning the services described by CPT code 77373 to a New Technology APC is appropriate, given the robust claims data we have from CY 2014. Miscoding of procedures and services by hospitals is generally not an area that we investigate or attempt to remedy by substituting other payment rates for the payment rate calculated from the claims data according to our standard methodology.

We note that (as discussed above) the APC number and title for APC 5625, the APC to which the services described by CPT code 77373 are assigned, have been changed to APC 5626 (Level 6 Radiation Therapy). In addition, as discussed in section III.D.15.b. of this final rule with comment period, because the procedure codes describing MRgFUS treatment are being reassigned to other APCs, CPT code 77373 is the only procedure code assigned to APC 5626.

In summary, after consideration of the public comments we received, we are modifying our proposal and assigning the services described by CPT code 77373 to APC 5626 for CY 2016. The final CY 2016 payment rate for the services described by CPT code 77373 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

12. Skin Procedures

As a part of our CY 2016 comprehensive review of the structure of the APCs and procedure code assignments, we examined the APCs that describe skin procedures. Based on our evaluation of the hospital outpatient claims data available for the CY 2016 OPP/ASC proposed rule, we proposed to restructure all of the APCs for skin-related procedures by combining the debridement and skin procedures APCs to more appropriately reflect the resource costs and clinical characteristics of the procedures assigned to each APC. Clinically, the services assigned to the current debridement APC grouping are similar to the services assigned to the current skin procedures APCs. Therefore, we believe that the services assigned to these two APC groupings would be more appropriately represented by combining the services into a single APC grouping described as skin procedures and related services. We believe that the proposed consolidation and restructuring of these APCs more appropriately categorizes all of the skin procedures and related services with different resource use, such that the services within each proposed newly configured APC are comparable based on the homogeneity of clinical characteristics and resource costs.

Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39262 through 39263), for CY 2016, we proposed to consolidate and restructure the skin and debridement APCs into a single APC grouping. Table 31 of the proposed rule listed the current CY 2015 APCs that contain skin and debridement procedures, and Table 32 of the proposed rule listed the proposed CY 2016 APCs that would result from the proposed consolidation and restructuring of the current skin procedures and related services APCs into a single APC grouping. We invited public comments on this proposal.

We received several public comments related to the proposed APC assignments for certain skin-related services and procedures and one comment specifically relating to the proposed restructuring of the skin procedures APCs. A summary of the public comments and our responses are below.

Comment: Some commenters expressed concern with CMS' proposal to consolidate the skin substitute and skin debridement APCs, and stated that the proposed reconfiguration reduces the clinical cohesiveness of the procedures assigned to the APC grouping and could negatively impact payments for these services. One commenter stated that the proposed reconfigured APC 5051 (Level 1 Skin Procedures) and APC 5053 (Level 3 Skin Procedures) combine simple and complex procedures under the APCs that make no distinctions in the clinical characteristics and resource costs for certain procedures. The commenter requested that CMS reconsider its proposal and work with clinical experts to refine the structure of these APCs that reflects the clinical cohesiveness and resource use associated with these services. Another commenter disagreed with CMS' rationale that the proposed restructuring and consolidation of these APCs would more appropriately reflect the comparable costs and clinical characteristics of the procedures assigned to each APC and stated that combining the debridement and skin procedure APCs produces broad categories with wide payment variations, which creates inappropriate resource distinctions for certain procedures.

Response: We disagree with the commenters. We believe that the reconfigured skin procedure APCs all include clinically similar procedures with similar resource costs. We also believe that the range of procedure costs in each of the skin procedure APCs is appropriate, and there are no violations of the 2 times rule within these APCs. The CY 2015 APC structure separated skin procedures from debridement and destruction procedures, which resulted in procedures that were otherwise similar skin procedures being assigned to different APCs (if the procedures also were debridement and destruction procedures). The CY 2015 structure resulted in similar procedures involving the skin procedure being assigned to different APCs based on a procedure being labelled either debridement/destruction or a skin procedure. Debridement of skin is a skin procedure; therefore, assignment to a skin procedure APC is appropriate. We do not believe this distinction is the most appropriate way to distinguish procedures involving the skin because debridement of skin is a skin procedure. Therefore, we believe that the services assigned to these two APC groups are more appropriately classified as skin procedures and related services in a single APC group. We believe that the proposed consolidation and restructuring of these APCs more appropriately categorizes all of the similar skin procedures and related services with different resource use, such that the services within each proposed newly configured APC are comparable based on the homogeneity of clinical characteristics and resource costs. We also believe that restructuring the APC groupings decreases overlapping cost ranges among APCs in a series and, consequently, allows CMS to pay for these procedures and services through a skin procedures APC series that is more clinically homogeneous and that contain procedures with similar costs.

Comment: One commenter stated that the proposed payment rate for APC 5053 would result in substantial underpayment for procedures and services involving the low-cost skin substitute products compared to procedures and services involving the high-cost skin substitute products. Specifically, the commenter indicated that facilities using the low-cost skin substitute products would experience a reduction in payment between approximately $274 and $290 per treatment session. The commenter believed that the potential underpayment associated with the use of low-cost skin substitute products would ultimately incentivize the use of the high-cost skin products, and result in greater overall expenditures to the Medicare program. Therefore, the commenter recommended that CMS create a new APC level in addition to the APC Level 3 and APC Level 4 for the skin procedures and related services APC grouping to eliminate this perceived incentive and discrepancy.

Response: We again reviewed all of the skin procedures and related services and the APC assignments for this final rule with comment period. Based on our evaluation of the latest hospital outpatient claims data used for this final rule with comment period, we are revising the proposed APC assignments for several skin procedures within the Skin Procedures APC grouping. Specifically, we are modifying our proposal by reassigning certain procedures from proposed APC 5053 to APC 5052 (Level 2 Skin Procedures) to more appropriately reflect the homogeneity of the resource costs associated with the other procedures assigned to APC 5052. In light of this modification, we do not believe that creating a new level within the skin procedures and related services APC groupings is necessary. We believe that the reassignment of certain procedures results in improved clinical homogeneity and resource costs for all of the skin procedures within the skin procedures groups.

Comment: Some commenters urged CMS to maintain the existing, separately payable status indicator assignments (that is, status indicators ''S'' or ''T'') for several procedure codes included within the proposed nine reconfigured APC grouping, instead of assigning these procedures to a status indicator that would generate a conditionally packaged payment (that is, either status indicator ''Q1'' or ''Q2''). One commenter provided a list of 70 procedure codes and requested that CMS reassign the listed procedures to status indicators that would generate separate payment for the services described by those procedure codes. Among the listed 70 procedure codes in the commenter's request, 36 describe skin procedures that, as a result of the proposed APC restructuring and consolidation, were proposed for CY 2016 to be reassigned to APC 5051.

Response: Prior to developing our proposal, we reviewed all of the procedures and services associated with the proposed reconfigured nine APCs skin procedures and related services groupings. Based on our review and input from CMS clinical staff, we believe that the proposed assignment of the procedures and services to a status indicator that indicates them as conditionally packaged is appropriate because these services are considered ancillary and dependent in relation to the other procedures with which they are most commonly furnished. In addition, the APC to which the 36 procedure codes listed by the

commenter were proposed to be assigned for CY 2016, APC 5051, is the successor APC to the CY 2015 APC 0012 (Level I Debridement & Destruction). APC 0012 was designated in CY 2015 as an APC containing procedures that are considered ancillary services for which payment is conditionally packaged. Therefore, we believe that the procedures and services proposed to be reassigned to APC 5051 also should be appropriately assigned to a status indicator that conditionally packages payment for these services. Further, based on the clinical nature of the services and our understanding of the procedures, we believe that the proposed assignments for these procedures and services to a status indicator indicating conditional packaging will create incentives for hospitals and their physician partners to work together to establish appropriate protocols that will eliminate providing unnecessary services where these instances exist and institutionalize approaches to providing necessary services more efficiently. Therefore, in this final rule with comment period, we are assigning status indicator ''Q1'' to the 36 skin procedure codes identified by the commenter in the nine reconfigured APC groupings for CY 2016.

After consideration of the public comments we received, we are finalizing our proposal to restructure and consolidate the skin procedures and related services APCs, with one modification. We are revising the APC assignment for several procedures, which are listed in Addendum B to this final rule with comment period, by reassigning them from APC 5053 to APC 5052 to appropriately reflect the resource costs associated with the procedures. We also are assigning the 36 procedure codes describing skin procedure and related services identified by the commenter to status indicator ''Q1'' for CY 2016.

a. Negative Pressure Wound Therapy (NPWT) Services

As listed in Addendum B to the CY 2016 OPPS/ASC proposed rule, we proposed to reassign the NPWT services to two separate APCs. Specifically, as listed in Table 35 below, we proposed to reassign the durable medical equipment (DME)-related NPWT CPT codes 97605 and 97606 from APC 0012 (Level I Debridement & Destruction) and APC 0015 (Level II Debridement & Destruction), respectively, to proposed APC 5051 (Level 1 Skin Procedures), with a proposed payment rate of approximately $120, and the disposable NPWT CPT codes 97607 and 97608 from APC 0015 to proposed APC 5052 (Level 2 Skin Procedures), with a proposed payment rate of approximately $166.

TABLE 35—PROPOSED APC ASSIGNMENT FOR THE NPWT SERVICES FOR CY 2016

CY 2015 CPT/HCPCS code	Long descriptor	CY 2015 OPPS status indicator	CY 2015 OPPS APC	Proposed CY 2016 OPPS status indicator	Proposed CY 2016 OPPS APC
97605	Negative pressure wound therapy (*e.g.,* vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.	Q1	0012	Q1	5051
97606	Negative pressure wound therapy (*e.g.,* vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.	T	0015	Q1	5051
97607	Negative pressure wound therapy, (*e.g.,* vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.	T	0015	T	5052
97608	Negative pressure wound therapy, (*e.g.,* vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.	T	0015	T	5052

We note that the DME-related NPWT CPT codes 97605 and 97606 were effective January 1, 2005. The disposable NPWT CPT codes 97607 and 97608 were effective January 1, 2015. However, the predecessor codes for the CY 2015 disposable NPWT procedure codes, specifically HCPCS codes G0456 and G0457, became effective January 1, 2013, and were deleted on December 31, 2014, when the NWPT replacement CPT codes became effective.

Comment: Some commenters disagreed with CMS' proposal to assign the procedures described by DME-related NPWT CPT codes 97605 and 97606 to OPPS status indicator ''Q1.'' The commenters believed that these procedures should be treated as independent clinical procedures and not ancillary services, and requested that CMS not finalize its proposal to assign these procedures to OPPS status indicator ''Q1.''

Response: We believe that the commenters may have misunderstood the meaning of OPPS status indicator ''Q1.'' Assigning a procedure to OPPS status indicator ''Q1'' indicates that payment for the service is conditionally packaged under the OPPS. A criterion under the conditional packaging policy is that payment for a service is packaged when it is provided in combination with a significant procedure on the same date of service, but the service is separately paid when it is reported on the claim without a significant procedure. Below is an excerpt from Addendum D1 to the CY 2016 OPPS/ASC proposed rule that shows the definition of status indicator ''Q1.''

ADDENDUM D1—PROPOSED OPPS PAYMENT STATUS INDICATORS FOR CY 2016

Status indicator	Item/code/service	OPPS payment status
Q1	STV-Packaged Codes	Paid under OPPS; Addendum B displays APC assignments when services are separately payable. (1) Packaged APC payment if billed on the same date of service as a HCPCS code assigned status indicator "S," "T," or "V." (2) In other circumstances, payment is made through a separate APC payment.

In the case of the procedures described by CPT codes 97605 and 97606, payment for these procedures is included in the payment for the significant procedure when these procedures are reported in combination with HCPCS codes that are assigned to either status indicators ''S,'' ''T,'' or ''V.'' Alternatively, the procedures are separately paid when performed alone, or when they are reported in combination with HCPCS codes that described procedures assigned to a status indicator other than ''S,'' ''T,'' or ''V.'' We believe that ''Q1'' is the most appropriate status indicator assignment for the DME-related NPWT CPT codes 97605 and 97606 because the services described by these codes are often provided in combination with other wound treatments and procedures.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to assign DME-related NPWT CPT codes 97605 and 97606 to OPPS status indicator ''Q1'' for CY 2016. The complete list of the OPPS payment status indicators and their definitions for CY 2016 is displayed in Addendum D1 to this final rule with comment period, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*. In addition, we are finalizing our proposal, without modification, to reassign the DME-related NWPT CPT codes 97605 and 97606 from CY 2015 APCs 0012 and 0015, respectively, to APC 5051 for CY 2016. The final CY 2016 payment rate for the procedures described by CPT codes 97605 and 97605 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

Comment: Several commenters opposed CMS' proposal to reassign the disposable NWPT procedures, specifically the procedures described by the disposable NWPT CPT codes 97607 and 97608 from CY 2015 APC 0015 to APC 5052 for CY 2016. The commenters believed that the claims data used to set the payment rates for these two procedures are flawed and do not reflect the actual costs incurred by hospitals for providing this treatment. The commenters opined that, because of the confusion related to the accurate coding of the procedures described by the predecessor HCPCS G-codes (HCPCS codes G0456 and G0457), hospitals have continuously miscoded this service in CY 2013 and CY 2014 by reporting charges for the DME-related NPWT CPT codes 97605 and 97606 instead of charges for the disposable NWPT CPT codes 97607 and 97608 when these services were actually provided. Some commenters stated that the resource costs associated with the disposable NPWT procedures, which require the use of disposable NPWT supplies, is significantly higher than the resource costs associated with the DME-related NPWT service, which requires the use of a device that is not paid for under the OPPS, but rather is paid based on the DMEPOS fee schedule. One commenter indicated that, based on its internal analysis, the costs of disposable NPWT devices may be as low as $200 and as high as over $800. Another commenter noted that if an average acquisition cost is approximately $194 for a particular disposable NPWT device, a provider may incur costs ranging from approximately $312 to $358 to provide this treatment. The commenters believed that the proposed payment rate for APC 5052 does not reflect the cost of the disposable NWPT supplies used in furnishing the service. Therefore, the commenters urged CMS not to finalize the proposed reassignment of these procedures to APC 5052 and, instead, reassign the procedures to APC 5053 (Level 3 Skin Procedures), which the commenters believed more appropriately compare to the actual resource costs associated with providing the service. Another commenter requested that CMS reassign the disposable NWPT CPT codes to an appropriate APC based on an estimated payment rate of $305.10 for the procedure. One commenter suggested that, if the alternative of reassigning the disposable NWPT CPT codes to APC 5053 was not achievable, CMS consider creating a sixth skin procedures APC that would be comprised of clinically homogenous wound care services proposed for reassignment to APCs 5052 and 5053. The commenter believed that creating this new APC would eliminate any potential violations of the 2 times rule within proposed APC 5052 or APC 5053.

Response: As reflected in Table 16 of the CY 2016 OPPS/ASC proposed rule (80 FR 39258), there are no violations of the 2 times rule within APC 5052. For CY 2016, our analysis of the CY 2014 claims data available for the proposed rule did not show any violations of the 2 times rule within APC 5052 (which included the proposed reassigned disposable NPWT procedures) because the lowest cost of a procedure described by a CPT code with significant claims data assigned to APC 5052 was approximately $158 (for CPT code 36471), while the highest cost of a procedure described by a CPT code with significant claims data was approximately $277 (for CPT code 96913). We note that the geometric mean cost for the procedure described by HCPCS code G0456 (which became CPT code 97607, effective January 1, 2015) was approximately $176 based on 6,655 single claims (out of 8,826 total claims) and approximately $203 for the procedure described by HCPCS G0457 (which became CPT code 97608, effective January 1, 2015) based on 409 single claims (out of 779 total claims). The CY 2016 OPPS/ASC proposed rule claims data was based on claims submitted between January 1, 2014, through December 31, 2014, and processed on or before December 31, 2014.

For this final rule with comment period, the claims data is based on the same CY 2014 claims data updated to include those claims that were processed on or before June 30, 2015. Our analysis of the final rule claims data initially showed a violation of the 2 times rule within APC 5053. To eliminate the violation of the 2 times rule, we reassigned some of the

procedures at the lower end of the cost range of APC 5053 to APC 5052. After modifying the proposed reassignment of a few codes from APC 5053 to 5052, the disposable NPWT procedures remain appropriately assigned to APC 5052 based on the comparability of the geometric mean costs. Specifically, our final rule claims data show a geometric mean cost of approximately $174 for procedures described by HCPCS code G0456 based on 7,301 single claims (out of 9,699 total claims) and approximately $216 for procedures described by HCPCS code G0457 based on 449 single claims (out of 858 total claims). The lowest cost of a procedure described by a CPT code with significant claims data assigned to APC 5052 is approximately $163 (for CPT code 36471), while the highest cost of a procedure described by a CPT code with significant claims data is approximately $299 (for CPT code 10120). The geometric mean costs of approximately $174 (for HCPCS code G0456) and $216 (for HCPCS code G0457) fall within this range without creating any violations of the 2 times rule. However, if we modify our proposal and reassign the procedures described by HCPCS codes G0456 and G0457 to APC 5053, a violation of the 2 times rule would exist. In addition, we do not believe that it is appropriate or necessary to create a sixth level within the skin procedures APC groupings. The geometric mean cost of APC 5052 is approximately $236 and the geometric mean cost of APC 5053 is approximately $449. We believe that these levels represent a meaningful separation between geometric mean costs without creating a wider range of costs between adjacent levels in an APC series.

Regarding the commenters' assertions that hospitals are miscoding claims or are not appropriately charging for disposable NPWT services and supplies and their requests that we disregard the claims data, we repeat our general policy: ''Beyond our standard OPPS trimming methodology . . . that we apply to those claims that have passed various types of claims processing edits, *it is not our general policy to judge the accuracy of hospital coding and charging for purposes of ratesetting''* (75 FR 71838). Therefore, because we do not judge the accuracy of hospital coding and charging, we will not disregard any claims data for services involving disposable NPWT procedures and supplies in calculating the payment rate for these procedures. In addition, it is not our policy to use any information (such as invoices, statements from companies who sell the medical devices used in the procedure, various reports from consultants, among others) other than hospital claims data for determining payment rates. As we do every year, we will reevaluate the APC assignment for the procedures involving disposable NPWT services and supplies in preparation for the CY 2017 rulemaking cycle. We remind hospitals that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

After consideration of the public comments we received, we are finalizing our proposal, without modification. Specifically, we are reassigning the disposable NWPT CPT codes 97607 and 97608 to APC 5052 for CY 2016. Table 36 below lists the final OPPS status indicator and APC assignments for CPT codes 97605, 97606, 97607, and 97608 for CY 2016. The final CY 2016 payment rates for these codes can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 36—FINAL APC ASSIGNMENT FOR THE NPWT SERVICES FOR CY 2016

CY 2016 CPT/HCPCS code	Long descriptor	Proposed CY 2016 OPPS status indicator	Proposed CY 2016 OPPS APC	Final CY 2016 OPPS status indicator	Final CY 2016 OPPS APC
97605	Negative pressure wound therapy (*e.g.,* vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.	Q1	5051	Q1	5051
97606	Negative pressure wound therapy (*e.g.,* vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.	Q1	5051	Q1	5051
97607	Negative pressure wound therapy, (*e.g.,* vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.	T	5052	T	5052
97608	Negative pressure wound therapy, (*e.g.,* vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.	T	5052	T	5052

b. Platelet Rich Plasma (PRP)

As listed in Addendum B to the CY 2016 OPPS/ASC proposed rule, we proposed to assign HCPCS code G0460 (Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment) to APC 5053 (Level 3 Skin Procedure), with a proposed payment rate of approximately $305.

Comment: Some commenters disagreed with CMS' proposed assignment of HCPCS code G0460 to APC 5053 and recommended that CMS consider assigning the code to either APC 1511 (New Technology—Level 11 ($900–$1000)) or 1548 (New Technology—Level 11 ($900–$1000)), with a proposed payment rate of approximately $950. One commenter stated that the proposed payment rate for APC 5053 is inadequate and does not

take into account the full components of providing the service described by HCPCS code G0460 and the Coverage with Evidence Development (CED) complexity associated with HCPCS code G0460. In addition, the commenter believed that a violation of the 2 times rule exists within APC 5053 when HCPCS code G0460 is assigned to this APC and, therefore, urged CMS to consider assigning HCPCS code G0460 to New Technology APC 1511 rather than APC 5053. Further, the commenter opined that the repeated payment adjustment for this service is causing significant confusion in the market place and hampering the success of Medicare's CED protocol. The commenter stated that assigning HCPCS code G0460 to either APC 1511 or APC 1548 would provide participating hospitals and sponsored sites predictability in payment levels for the service described by HCPCS code G0460.

Response: Table 16 of the CY 2016 OPPS/ASC proposed rule (80 FR 39255) listed the three APCs that violated the 2 times rule for ratesetting and which we proposed to except from the 2 times rule for CY 2016. APC 5053 does not appear on that list. For CY 2016, our analysis of the CY 2014 claims data available for the proposed rule showed that no violations of the 2 times rule existed within APC 5053 because the geometric mean cost for the service described by HCPCS code G0460 did not fall outside of the acceptable significant costs range. For purposes of identifying significant HCPCS codes for examination under the 2 times rule, we consider those codes that have more than 1,000 single major claims, or codes that have both greater than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC geometric mean cost to be significant. This longstanding policy of when a HCPCS code is considered significant for purposes of the 2 times rule was based on the premise that we believe a subset of 1,000 claims is negligible within the set of approximately 120 million single procedure or single session claims we use for establishing geometric mean costs. Similarly, procedures described by a HCPCS code for which there are fewer than 99 single claims or which comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC geometric mean cost.

Based on our analysis of the claims data used for the proposed rule, there was no violation of the 2 times rule within APC 5053 when HCPCS code G0460 was assigned to this APC. Specifically, our data revealed that the lowest cost procedure with significant claims data ($305 for CPT code 11042) and the highest cost procedure with significant claims data ($595 for HCPCS code C5271) met the 2 times rule for APC 5053 whose geometric mean cost was approximately $322.

Section 1833(t)(9) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. Consistent with the requirements set forth in section 1833(t)(9), we annually review all the items and services within an APC group to determine, with respect to comparability of the use of resources, if the geometric mean cost of the highest cost item or service within an APC group is more than 2 times greater than the geometric mean cost of the lowest cost item or service within that same group. In making this determination, we review our claims data and determine whether we need to make changes to the current APC assignments for the following year.

We acknowledge the commenters' concerns. However, based on our analysis of the claims data available for this final rule with comment period, we believe that the services described by HCPCS code G0460 more appropriately align with the other services assigned to APC 5054 (Level 4 Skin Procedures) than services assigned either to APC 1511 or APC 1548. We note that the proposed rule claims data was based on claims submitted between January 1, 2014, through December 31, 2014, and processed on or before December 31, 2014. However, for this final rule with comment period, the cost data also includes claims that were processed on or before June 30, 2015. Specifically, our claims data show a geometric mean cost of approximately $1,579 based on 35 single claims (out of 52 total claims) for HCPCS code G0460. We believe that the geometric mean cost of the service described by HCPCS code G0460 (approximately $1,579) is comparable to the geometric mean cost of APC 5054.

Therefore, after consideration of the public comments we received, we are finalizing our proposal to assign the service described by HCPCS code G0460 to one of the reconfigured skin procedure APCs, with one modification. We are assigning the service described by HCPCS code G0460 to APC 5054 (rather than proposed APC 5053) for CY 2016. The final CY 2016 payment rate for HCPCS code G0460 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site). We remind the commenters that, as we do every year, we will again review the APC assignment for all items, procedures, and services, for the CY 2017 rulemaking cycle.

In summary, after consideration of the public comments we received, we are finalizing our proposed APC reconfiguration for the skin procedures and related services APCs, with the modifications described earlier. Table 37 below lists the final CY 2016 APCs that result from the consolidation and restructuring of the current skin procedures and related services APCs into a single APC grouping. The final payment rates for the specific CPT or Level II HCPCS skin procedure codes can be found in Addendum B to this final rule with comment period, while the final payment rates for the specific APCs to which the skin procedures and related services are assigned can be found in Addendum A to this final rule with comment period. Both OPPS Addenda A and B are available via the Internet on the CMS Web site.

TABLE 37—CY 2016 APCS ASSIGNMENT FOR SKIN PROCEDURES

CY 2016 APC	CY 2016 APC title
5051	Level 1 Skin Procedures.
5052	Level 2 Skin Procedures.
5053	Level 3 Skin Procedures.
5054	Level 4 Skin Procedures.
5055	Level 5 Skin Procedures.

13. Urology and Related Services

In the CY 2016 OPPS/ASC proposed rule (80 FR 39263), for the CY 2016 OPPS update, based on our evaluation of the latest hospital outpatient claims data used for the proposed rule, we proposed to revise all of the APCs for urology and related services APCs to more appropriately reflect the resource costs and clinical characteristics of the procedures assigned to each APC. Currently, several of the urology and related services APCs are differentiated based on resource costs of the procedures and services rather than the clinical similarity when compared to the other procedures and services assigned to the APC. We believe that establishing more inclusive categories of the urology and related services is more appropriate for future ratesetting under the OPPS because the proposed restructured APCs have a more clinically appropriate granularity, while improving the balance of resource similarities for all of the procedures

assigned to these APCs. In addition, we believe that this proposed revision and consolidation of APCs would more appropriately categorize all of the urology and related services within an APC grouping such that the services and procedures assigned to each proposed newly configured APC are most appropriately comparable with respect to clinical characteristics and resource use. Therefore, for CY 2016, we proposed to restructure and consolidate the urology and related services APCs into a single APC grouping. Table 33 of the proposed rule listed the CY 2015 urology and related services APCs and status indicator assignments, and Table 34 of the proposed rule listed the CY 2016 APCs that would result from the proposed consolidation and restructuring of the current urology and related services APCs into a single APC grouping. We invited public comments on this proposal.

Comment: Some commenters supported the proposed consolidation and reconfiguration of the urology and related services APCs, but expressed concern that the significant differences between the APC payment rates for the procedures and related services assigned to the proposed APCs are too broad, which could result in payment misalignments for certain procedures and services that utilize expensive supplies and equipment. Many other commenters disagreed with the proposed consolidation because they believed that the proposed APC reconfigurations and procedure reassignments are neither clinically or resource homogeneous. Several commenters stated that, although the existing urology APC 0163 (Level IV Cystourethroscopy and Other Genitourinary Procedures) is also diverse, similar to the proposed revised urology APCs, the procedures are based on expensive technology and single disease treatments. In addition, several commenters expressed concern with the proposed payment for the shockwave lithotripsy procedure described by CPT code 50590 (Lithotripsy, extracorporeal shock wave). The commenters stated that shockwave lithotripsy is grouped in APC 5374 (Level 4 Urology and Related Services) with other procedures that are non-lithotripsy related and do not have the same capital expenditures. The commenters believed that assigning the shockwave lithotripsy procedure to the proposed reconfigured urology and related services APC 5374 would significantly underpay providers for the cost of the procedure and noted that the resources used to perform shockwave lithotripsy procedures are significantly greater than the resources used to perform many of the other procedures assigned to APC 5374. The commenters explained that the shockwave lithotripsy procedure involves the use of highly specialized capital equipment that cost approximately $50,000 with an additional $80,000 to $100,000 per year contract maintenance, as well as the assistance of a certified technician. The commenters suggested that CMS consider modifying its proposal for restructuring and reconfiguring the urology and related services APCs by assigning the shockwave lithotripsy procedure to its own APC, separating APC 5374 into two APCs and grouping the APCs based on disease process (for example, BPH and stone extraction, among others). The commenters believed that these changes would simplify the APC groupings and create an APC structure that is more rational. Another commenter recommended separating APC 5374 into two APCs: One APC that has lower cost/resource use, with a payment rate of approximately $2,150; and the other APC with higher cost/resource use, with a payment rate of approximately $3,091. The commenter believed that such a change to the structure and configuration of APC 5374 would improve the distribution of the urology and related services procedures assigned to this APC and reduce overpayments and underpayments for the services and procedures that are currently proposed to be assigned to the proposed APCs.

Response: As part of our overall effort to improve the homogeneity of resource costs and clinical characteristic within the APC groupings, we proposed to revise the existing urology and related services APCs for CY 2016. We believe that the proposed restructuring and reconfiguration of the urology and related services APCs more appropriately reflect the homogeneity of resource costs and clinical characteristics of the procedures assigned within each APC.

Although we do not agree with the commenters' suggestion that creating urology and related services APCs based on the specific disease treated by the procedure is necessary or appropriate, we understand some of the commenters' concerns. We continue to believe that establishing more inclusive categories of urology and related services is more appropriate for future ratesetting under the OPPS because the restructured APCs are comprised of more clinically appropriate groupings, while improving the balance of resource similarities for all of the procedures assigned to these APCs. However, in response to the concerns raised by the commenters, we are modifying our proposal by reassigning some of the procedures to APC 5374 to APC 5373 (Level 3 Urology and Related Services) and APC 5375 (Level 5 Urology and Related Services) rather than reassigning them to APC 5374. Specifically, the procedures that are being reassigned to APC 5375 are assigned status indicator ''J1'' because APC 5375 is a C–APC, and one of the procedures reassigned to APC 5375 is the shockwave lithotripsy procedure (described by CPT code 50590).

Based on the commenters' feedback and our analysis of the latest hospital outpatient claims data used for this final rule with comment period, we believe that the procedure described by CPT code 50590 is more appropriately assigned to APC 5375 than APC 5374. The geometric mean cost for the procedure described by CPT code 50590 is approximately $3,243 based on 44,088 single claims (out of 44,403 total claims), which is comparable to the geometric mean cost of approximately $3,551 for APC 5375. Because we have modified our proposal and are reassigning certain procedures from APC 5374 to APCs 5373 and 5375, we do not believe that it is necessary or appropriate to divide APC 5374 into two separate APCs. We believe that the modifications to our proposal to restructure and reconfigure APCs 5373, 5374, and 5375 appropriately group the urology and related services based on the homogeneity of the clinical characteristics and resource use.

Comment: One commenter requested that CMS reassign the following two laser vaporization procedures used to treat benign prostatic hyperplasia from APC 5374 to APC 5375:

- CPT code 52647 (Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed); and
- CPT code 52648 (Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)).

The commenter believed that these two procedures are similar to the procedure described by CPT code 52649 (Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration

and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)), which was proposed to be reassigned to APC 5375.

Response: Based on input from our clinical advisors and analysis of the latest hospital outpatient claims data used for this final rule with comment period, we agree with the commenter that the procedures described by CPT codes 52647 and 52648 would be more appropriately reassigned to APC 5375. Our claims data show that the geometric mean cost of the procedure described by CPT code 52647 is approximately $3,296 based on 392 single claims (out of 393 total claims), and the geometric mean cost of the procedure described by CPT code 52648 is approximately $3,696 based on 20,813 single claims (out of 21,015 total claims). Based on our latest review, we believe that the geometric mean costs for procedures described by CPT codes 52647 and 52648 are similar to the geometric mean cost of other procedures assigned to APC 5375, whose geometric mean cost is approximately $3,551.

Therefore, after consideration of the public comments received, we are finalizing our proposal, with modification, to reassign CPT codes 52647 and 52648 to APC 5375. The final CY 2016 payment rates for the procedures described by CPT codes 52647, 52648, and 52649 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

Comment: One commenter noted that, although the proposed reconfiguration of the urology and related services APCs would increase the payment rates for some services, the proposed reconfiguration would also decrease the payment rates for other procedures. In particular, the commenter expressed concern that the proposed reassignment would result in underpayment for the following CPT codes:

- 51741 (Complex uroflowmetry (*e.g.*, calibrated electronic equipment));
- 55700 (Biopsy, prostate; needle or punch, single or multiple, any approach); and
- 52000 (Cystourethroscopy (separate procedure)).

The commenter stated that the proposed restructuring would decrease the payment rate for the procedure described by CPT code 51741 by 18 percent within a single year. The commenter added that, similarly, payment rates for the procedures described by CPT codes 55700 and 52000 would experience a decrease of 8 percent and 5 percent, respectively. The commenter expressed concern with the instability in payment rates, which the commenter suggested would hinder a hospital's ability to negotiate with suppliers and manufacturers on the purchase price of certain devices and services. Specifically, the commenter stated that, in order for hospitals to be able to forecast for the future and invest in technologies that are essential for providing high quality care, they need to be able to rely on stable and predictable payment rates.

Response: We appreciate the commenter's input. Based on our review of the latest hospital outpatient claims data used for this final rule with comment period, we believe that reassigning CPT code 51741 to APC 5721 (Level 1 Diagnostic Tests and Related Services) improves the homogeneity of resource use and clinical characteristics of the procedures in this APC. In addition, we believe that the proposed APC assignments for the procedures described by CPT codes 55700 and 52000 are optimal. Our claims data reveal that CPT code 55700 has a geometric mean cost of approximately $1,475, which is comparable to the geometric mean cost of approximately $1,576 for APC 5373 (Level 3 Urology and Related Services). We also believe that the procedure described by CPT code 55700 is appropriately grouped in APC 5373 with clinically similar procedures. Further, we believe that CPT code 52000, whose geometric mean cost is approximately $574, is more appropriately assigned to APC 5372 (Level 2 Urology and Related Services), whose geometric mean cost is approximately $549. We do not believe that we should assign CPT code 52000 to the next higher level in the urology and related services APC, which is APC 5373 (Level 3 Urology and Related Services) and has a geometric mean cost of approximately $1,576, as this would result in a significant overpayment for the procedure. Moreover, reassigning CPT code 52000 from APC 5372 to APC 5373 would create a violation of the 2 times rule within APC 5373.

Overall, we believe that the proposed restructuring and reconfiguration of the urology and related services APCs appropriately reflect the similar resource costs and clinical characteristics of the procedures within each APC. We also believe that establishing broader categories of urology and related services APCs (as compared to CY 2015) is more appropriate for future ratesetting under the OPPS because the restructured APCs support greater similarities in clinical characteristic and resource use of procedures assigned to APCs, while improving the homogeneity of the APC structure.

In addition, section 1833(t)(9) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. Consistent with the requirements set forth in section 1833(t)(9) of the Act, we annually review all the items and services within an APC group to determine, with respect to comparability of the use of resources, if the geometric mean cost of the highest cost item or service within an APC group is more than 2 times greater than the geometric mean cost of the lowest cost item or service within that same group. In making this determination, we review our claims data and determine whether we need to make changes to the current APC assignments for the following year. Consequently, as we do every year for all services and procedures under the OPPS, we will again review the claims data for the procedures described by CPT codes 51741, 52000, and 55700 for the CY 2017 rulemaking cycle.

Therefore, after consideration of the public comments received, we are finalizing our proposal for CPT codes 55700 and 52000 to APC 5373 and 5372, respectively. However, we are finalizing our proposal for CPT code 51741 with modification by reassigning this procedure from APC 5734 to APC 5721 based on clinical and resource homogeneity within APC 5721. The final CY 2016 payment rate for CPT codes 51741, 55700, and 52000 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

Comment: One commenter expressed concern with the volume of procedures proposed to be reassigned to proposed APC 5374. In addition, the commenter was concerned that the proposed payment rates would result in underpayments for the following three CPT codes:

- 50590 (Lithotripsy, extracorporeal shock wave);
- 52601 (Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included); and
- 52648 (Laser vaporization of prostate, including control of

postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed).

Response: As we discussed above, we are modifying our proposed APC assignments for the procedures described by CPT codes 50590 and 52648 by reassigning the procedures from APC 5374 to APC 5375 for CY 2016, based on our evaluation of the latest hospital outpatient claims data used for this final rule with comment period. Similarly, we examined our latest claims data for CPT code 52601 and found that its geometric mean cost is comparable to that of APC 5375. Specifically, our claims data revealed that the procedure described by CPT code 52601 has a geometric mean cost of approximately $3,529 based on 27,568 single claims (out of 27,864 total claims), which is comparable to the geometric mean cost of approximately $3,551 for APC 5375.

Therefore, after consideration of the public comments received, we are finalizing our proposal, with modification, by reassigning the procedures described by CPT codes 50590, 52601, and 52648 to APC 5375 for CY 2016. The final CY 2016 payment rate for CPT codes 50590, 52601, and 52648 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

We are finalizing our proposal, with modification, to reconfigure the urology and related services into seven APCs. Table 38 below lists the final CY 2016 APCs that result from the consolidation and restructuring of the current urology procedures APCs into a single APC grouping. The final payment rates for the specific CPT or Level II HCPCS urology and related services codes are included in Addendum B to this final rule with comment period. The final payment rates for the specific APCs to which we are reassigning the urology and related services codes are included in Addendum A to this final rule with comment period. Both OPPS Addenda A and B are available via the Internet on the CMS Web site.

TABLE 38—CY 2016 APCs ASSIGNED TO UROLOGY AND RELATED SERVICES

CY 2016 APC	CY 2016 APC title
5371	Level 1 Urology and Related Services.
5372	Level 2 Urology and Related Services.
5373	Level 3 Urology and Related Services.
5374	Level 4 Urology and Related Services.
5375	Level 5 Urology and Related Services.
5376	Level 6 Urology and Related Services.
5377	Level 7 Urology and Related Services.

14. Vascular Procedures (Excluding Endovascular Procedures)

In the CY 2016 OPPS/ASC proposed rule (80 FR 39263 through 39264), for the CY 2016 OPPS update, based on our evaluation of the latest hospital outpatient claims data available for the proposed rule, we proposed to restructure all of the vascular procedure-related APCs (excluding endovascular procedures) to more appropriately reflect the costs and clinical characteristics of the procedures within each APC. We stated in the proposed rule that we believe that this proposed restructuring of APCs for vascular procedures more accurately categorizes all of the vascular procedures within an APC group, such that the services within each proposed newly configured APC are more comparable clinically and with respect to resource use. Table 35 of the CY 2016 OPPS/ASC proposed rule (80 FR 39263) lists the vascular procedures APCs for CY 2015, and Table 36 of the CY 2016 OPPS proposed rule (80 FR 39264) lists the proposed vascular procedures APCs for CY 2016. We invited public comments on this proposal.

Comment: One commenter noted that CPT code 93503 (Insertion and placement of flow directed catheter (*e.g.,* Swan-Ganz) for monitoring purposes) and CPT code 93505 (Endomyocardial biopsy) are proposed to be assigned to APC 5181 (Level 1 Vascular Procedures), and stated that the codes are not clinically homogenous. The commenter believed that the APC assignment for these two codes could destabilize the APC and recommended a delay in implementation of these restructured APCs. In addition, the commenter stated that the procedures described by CPT codes 36818 (Arteriovenous anastomosis, open; by upper arm cephalic vein transposition), 36821 (direct, any site (*e.g.,* Cimino type) (separate procedure)) and 36831 (Thrombectomy, open, arteriovenous fistula without revision, autogenous or nonautogenous dialysis graft (separate procedure)) are proposed to be assigned to APC 5182 (Level 2 Vascular Procedures) but all of the procedures described by these codes have a significant volume of claims (that is, greater than 1,000) and would be substantially underpaid under their APC assignment relative to their geometric mean costs. For these codes, the commenter suggested a delay in implementation or reassignment to APC 5183 (Level 3 Vascular Procedures). Another commenter recommended that four cardiac procedures that were proposed to be assigned to APC 5181, specifically CPT 33215 (Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode), CPT 33226 (Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement with existing generator)), CPT 93503, and CPT 93505, instead be assigned to APC 5188 (Diagnostic Cardiac Catheterization). The commenter also recommended the reassignment of the following CPT codes to APC 5183: CPT code 36222 (Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral extracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed); CPT code 36223 (Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed); and CPT code 36225 (Selective catheter placement, subclavian or innominate artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed). The commenter believed that these procedures, which were proposed to be assigned to APC 5526 (Level 6 X-Ray and Related Services), would better align with the procedures assigned to APC 5183 because they are similar procedures with similar clinical characteristics.

Another commenter suggested that the procedures described by CPT 37799

(Unlisted procedure, vascular surgery), and CPT 93505 be reassigned from APC 5181 to 5182; that the procedure described by CPT 37501 (Unlisted vascular endoscopy procedure) be reassigned from APC 5181 to APC 5183; and that the procedure described by CPT 36566 (Insertion of tunneled centrally inserted central venous access device, requiring 2 catheters via 2 separate venous access sites; with subcutaneous port(s)) and CPT 36861 (External cannula declotting (separate procedure; with balloon catheter) be reassigned from APC 5182 to APC 5183. The commenter believed that these suggested revisions would be more appropriate clinically and with respect to resource use.

Response: We agree with some of the comments on the APC assignment change requests and disagree with others. Table 39 below lists all codes that were commented on and our decision on the final APC assignment.

TABLE 39—VASCULAR PROCEDURES WITH SPECIFIC COMMENTER RECOMMENDATIONS, FINAL CMS DECISIONS, FINAL APC ASSIGNMENT AND FINAL STATUS INDICATORS

CPT/HCPCS code	Short descriptor	Proposed CY 2016 OPPS status indicator	Proposed CY 2016 OPPS APC	Commenter requested APC	CMS decision	Final CY 2016 OPPS status indicator	Final CY 2016 OPPS APC
33215	Reposition pacing-defib lead	T	5181	5188	Disagree	T	5181
36222	Place cath carotid/inom art	Q2	5526	5183	Disagree	Q2	5526
33226	Reposition l ventric lead	T	5181	5188	Disagree	T	5182
36223	Place cath carotid/inom art	T	5526	5183	Agree	Q2	5183
36225	Place cath subclavian art	Q2	5526	5183	Disagree	Q2	5526
36566	Insert tunneled cv cath	T	5182	5183	Agree	T	5183
36818	Av fuse uppr arm cephalic	T	5182	5183	Disagree	T	5182
36821	Av fusion direct any site	T	5182	5183	Disagree	T	5182
36831	Open thrombect av fistula	T	5182	5183	Disagree	T	5182
36861	Cannula declotting	T	5182	5183	Agree	T	5183
37501	Vascular endoscopy procedure	T	5181	5183	Disagree	T	5181
37799	Vascular surgery procedure	T	5181	5182	Disagree	T	5181
93503	Insert/place heart catheter	T	5181	5188	Disagree	T	5181
93505	Biopsy of heart lining	T	5181	5182 or 5188	Agree with 5182.	T	5182

All of the APCs proposed for the codes listed in Table 39 above and all of the APCs suggested by commenters contain procedures involving the vascular system. For the codes with which we agree with the commenters, there is greater resource similarity between the procedure in question and the procedures in the APC requested by the commenter than the procedures in the proposed APC. In most cases where we disagree with the commenter in Table 39 above, the opposite is true, and resource similarity is greater for the proposed APC. By greater resource similarity, we mean that the geometric mean cost of the procedure is closer to the geometric mean cost of the APC to which we are assigning the code than it is to the APC to which the commenter requested assignment of the code.

For CPT code 33215, we do not agree that the code should be reassigned from APC 5181to 5188. The final geometric mean cost of the procedure described by CPT code 33215 is approximately $1,575 and the final geometric mean cost of APC 5181 is approximately $903. The final geometric mean cost of APC 5188 is approximately $2,668. We believe that, given the significant resource dissimilarity between CPT code 33215 and APC 5188, APC 5188 is not an appropriate APC assignment.

For the procedure described by CPT code 36222, we do not agree that the procedure code should be reassigned from proposed APC 5526 to APC 5183. The final geometric mean cost of the procedure described by CPT code 36222 is approximately $2,677, and the final geometric mean cost of APC 5526 is approximately $2,845. The final geometric mean cost of APC 5183 is approximately $3,971. We believe that, given the significant resource dissimilarity between CPT code 36222 and APC 5183, APC 5183 is not an appropriate APC assignment.

For the procedure described by CPT code 33226, we do not agree that the procedure should be reassigned from proposed APC 5181 to APC 5188. The final geometric mean cost of the procedure described by CPT code 33226 is approximately $2,190 and the final geometric mean cost of APC 5181 is approximately $903. The final geometric mean cost of APC 5188 is approximately $2,667. Upon further evaluation, based on resource use and clinical similarity to other assigned procedures, we believe that the appropriate APC assignment for CPT code 33226 is APC 5182, which has a final geometric mean cost of approximately $2,352.

For the procedure described by CPT code 36225, we do not agree that it should be reassigned from proposed APC 5526 to APC 5183. The final geometric mean cost of the procedure described by CPT code 36225 is approximately $2,717 and the final geometric mean cost of APC 5526 is approximately $2,845. The final geometric mean cost of APC 5183 is approximately $3,971. We believe that, given the significant resource dissimilarity between the procedure described by CPT code 36225 and the procedures assigned to APC 5183, APC 5183 is not an appropriate APC assignment.

For the procedure described by CPT code 36818, we do not agree that it should be reassigned from proposed APC 5182 to APC 5183. The final geometric mean cost of the procedure described by CPT code 36818 is approximately $2,960 and the final geometric mean cost of APC 5182 is approximately $2,352. The final geometric mean cost of APC 5183 is approximately $3,971. We believe that, given the significant resource dissimilarity between the procedure described by CPT code 36818 and the procedures assigned to APC 5183, APC 5183 is not an appropriate APC assignment.

For the procedure described by CPT code 36821, we do not agree that it should be reassigned from proposed APC 5182 to APC 5183. The final

geometric mean cost of the procedure described by CPT code 36821 is approximately $2,880 and the final geometric mean cost of APC 5182 is approximately $2,352. The final geometric mean cost of APC 5183 is approximately $3,971. We believe that, given the significant resource dissimilarity between the procedure described by CPT code 36821 and the procedures assigned to APC 5183, APC 5183 is not an appropriate APC assignment.

For the procedure described by CPT code 36831, we do not agree that it should be reassigned from proposed APC 5182 to APC 5183. The final geometric mean cost of the procedure described by CPT code 36831 is approximately $2,961 and the final geometric mean cost of APC 5182 is approximately $2,352. The final geometric mean cost of APC 5183 is approximately $3,971. We believe that, given the significant resource dissimilarity between the procedure described by CPT code 36831and the procedures assigned to APC 5183, APC 5183 is not an appropriate APC assignment.

Regarding CPT codes 37799 and 37501, these are unlisted procedure codes, and according to our established policy, these codes are always assigned to the lowest level APC within a group.

For the procedure described by CPT code 93503, we do not agree that it should be reassigned from proposed APC 5181 to APC 5188. The final geometric mean cost of the procedure described by CPT code 93503 is approximately $1,460 and the final geometric mean cost of APC 5181 is approximately $903. The final geometric mean cost of APC 5188 is approximately $2,667. We believe that, given the significant resource dissimilarity between the procedure described by CPT code 93503 and the procedures assigned to APC 5188, APC 5188 is not an appropriate APC assignment.

After considering the public comments we received on the reorganization and restructuring of the vascular procedures APC family, we are finalizing the proposed APC structure depicted in Table 40 below and the proposed code assignments with the exception of those codes noted in Table 40 for which we are finalizing APC assignments that differ from the proposed rule in response to public comments. The final payment rates for the vascular procedure codes are included in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 40—CY 2016 VASCULAR PROCEDURES APCS

CY 2016 APC	CY 2016 APC group title
5181	Level 1 Vascular Procedures.
5182	Level 2 Vascular Procedures.
5183	Level 3 Vascular Procedures.

15. Other Procedures and Services

a. Ear, Nose, Throat (ENT) Procedures

For CY 2016, as a part of our review, restructuring, and reorganization of the OPPS APCs, we proposed to consolidate the APCs for ear, nose, and throat (ENT) procedures from seven levels in CY 2015 to six levels for CY 2016.

Comment: One commenter believed that the proposed consolidation of the ENT procedure APCs into six levels results in APC groups that contain a volume of procedures that is too large. The commenter requested that CMS add an APC grouping between proposed Level 4 and Level 5. The commenter did not provide any discussion regarding any problem caused by our proposed consolidation of the ENT APCs.

Response: We disagree with the commenter that the ENT APC groups are too large. The cost ranges for the procedures within this APC series are within the 2 times rule limit. Moreover, many of the services assigned to these APC groups are low-volume services. Therefore, we do not believe that it is necessary to create a seventh level in the ENT procedures APC group for a small number of low-volume procedures. We will continue to monitor this APC grouping, and we will consider any adjustments as the need arises in the future.

b. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS)

In the CY 2016 OPPS/ASC proposed rule, we proposed to assign new CY 2016 CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to APC 5625 (Level 5 Radiation Therapy), with a proposed payment of approximately $1,699. We also assigned CPT code 0398T to comment indicator ''NP'' in Addendum B to indicate that the code is new for CY 2016 with a proposed APC assignment and that public comments would be accepted on the proposed APC assignment for the new code. The procedure described by CPT code 0398T involves treatment of an essential tremor using an MRgFUS procedure. We note that CPT code 0398T will be effective January 1, 2016. However, this code was listed as 03XXA (the 5-digit CMS placeholder code) in Addendum B, O, and Q2 of the CY 2016 OPPS/ASC proposed rule. We invited public comments on our proposed APC assignment for CY 2016.

In addition to proposing to assign the procedure described by CPT code 0398T to APC 5625, we also proposed to reassign the existing MRgFUS procedures to APC 5625, specifically the procedures described by following CPT/HCPCS codes:

- CPT code 0071T (Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue);
- CPT code 0072T (Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue); and
- HCPCS code C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance).

Comment: Commenters disagreed with the proposed assignment of the procedure described by CPT code 0398T to APC 5625, and requested that CMS not finalize the proposed APC assignment. The commenters believed that the resources associated with the procedure described by CPT code 0398T are significantly different from the resources associated with MRgFUS procedures that are also being proposed for reassignment to APC 5625. Specifically, the commenters stated that the resource costs associated with MRgFUS procedures for the treatment of essential tremor are significantly greater than the resource costs for the treatment of uterine fibroids (described by CPT codes 0071T and 0072T) or pain palliation for metastatic bone cancer (described by HCPCS code C9734) because procedures involving MRgFUS treatment for essential tremor requires additional unique resources that are not required with either uterine fibroids or pain palliation MRgFUS treatments. The commenters further explained that, while MRgFUS has been approved by the FDA for the treatment of uterine fibroids and pain palliation for metastatic bone cancer, it has not been approved for the treatment of essential tremor. The commenters also indicated that MRgFUS treatment for essential tremor is still in the clinical trial stage. Therefore, the commenters believed that it would be inappropriate to assign CPT code 0398T to APC 5626, which is the same APC that the existing MRgFUS

procedures are being proposed to be reassigned.

Furthermore, the commenters believed that CMS' proposal to assign the procedure described by CPT code 0398T to an APC without any available claims data could undervalue the payment for the procedure and ultimately prevent hospitals from furnishing the procedure to Medicare beneficiaries once it becomes FDA-approved. Another commenter noted that approval of the equipment associated with the MRgFUS procedure for the treatment of an essential tremor would not be approved by the FDA until the end of 2016. Therefore, the commenter stated that it would be unlikely that any Medicare beneficiaries would be eligible for the MRgFUS treatment for essential tremor before CY 2017. To ensure an accurate APC assignment, the commenters requested that CMS not finalize an APC assignment for the procedure described by CPT code 0398T, and instead wait until additional data become available for ratesetting purposes Another commenter stated that assigning the procedure described by CPT code 0398T to APC 5625 is inappropriate because the APC's title, ''Level 5 Radiation Therapy'' indicates that procedures assigned to this APC describe procedures involving radiation therapies, and that MRgFUS procedures, including the procedure described by CPT code 0398T, do not involve the delivery of radiation or radiation therapy and, therefore, cannot be considered ''radiation therapies.''

Response: We acknowledge that the FDA-approved indication for use and approval of the necessary equipment used in association with the procedure described by CPT code 0398T may not be granted during CY 2016, and that there are no claims data available for ratesetting purposes. Therefore, we agree with the commenters that it would be more appropriate to not finalize the APC assignment for the procedure described by CPT code 0398T at this time. As a result, this procedure code will be assigned to OPPS status indicator ''E,'' effective January 1, 2016, to indicate that the service is not paid by Medicare under the OPPS. Once the procedure and associated equipment involved with the MRgFUS treatment for essential tremor has received FDA approval and we have available claims data to use for ratesetting purposes, we will reevaluate the APC assignment for CPT code 0398T.

Comment: One commenter believed that, based on the APC title, APC 5625 describes procedures involving the delivery of radiation or radiation therapies, which does not adequately describe the procedures described by CPT codes 0071T and 0072T and HCPCS code C9734. Consequently, the commenter requested that CMS reassign CPT codes 0071T and 0072T to C–APC 5376 (Level 6 Urology and Related Services) and HCPCS code C9734 to C–APC 5124 (Level 4 Musculoskeletal Procedures). The commenter indicated that it performed its own internal analysis of the associated cost of providing these services and, based on its findings, believed that the resource use associated with these procedures (CPT codes 0071T and 0072T and HCPCS code C9734) is similar to the resource use associated with the procedures assigned to APC 5376 and APC 5124.

Response: CPT codes 0071T and 0072T became effective January 1, 2005, and HCPCS code C9734 became effective April 1, 2013. Based on our analysis of the latest hospital outpatient claims data used for this final rule with comment period, which are claims submitted between January 1, 2014, and December 31, 2014, and processed on or before June 30, 2015, we do not have any single claims that reported any of the three MRgFUS procedures. Therefore, we agree with the commenter that APC 5625 is not the most appropriate APC assignment for these three MRgFUS procedures based on clinical characteristics because these three MRgFUS procedures do not involve the delivery of radiation or radiation therapy. In addition, given the lack of single claims data for the procedures described by CPT codes 0071T and 0072T and HCPCS code C9734, we do not agree with the commenters' suggested APC assignments for these procedures. We believe that the clinical characteristics of the three MRgFUS procedures are significantly similar to the clinical characteristics of the procedures assigned to APCs 5414 (Level 4 Gynecologic Procedures) and 5122 (Level 2 Musculoskeletal Procedures). Therefore, we are reassigning the procedures described by CPT codes 0071T and 0072T to APC 5414, and the procedures described by HCPCS code C9734 to APC 5122.

After consideration of the public comments we received, we are modifying our proposals and reassigning the procedures described by CPT codes 0071T and 0072T to APC 5414 and the procedures described by HCPCS code C9734 to APC 5122. In addition, we are not finalizing our proposed APC assignment for the procedure described by CPT code 0398T because the equipment associated with the performance of the procedure has not received FDA approval. As we previously stated, CPT code 0398T is assigned to OPPS status indicator ''E'' (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type), effective January 1, 2016, to indicate that the service is not paid by Medicare under the OPPS. Once the procedure involving MRgFUS treatment for essential tremor receives FDA approval and we have available claims data for ratesetting purposes, we will reevaluate the APC assignment for CPT code 0398T. The final CY 2016 payment rate for CPT codes 0071Tand 0072T and HCPCS code C9734 can be found in Addendum B to this final rule with comment period (which is available via the Internet on the CMS Web site).

c. Stem Cell Transplant

For CY 2016, we proposed to continue to pay for stem cell transplant procedures as we have done for many years through APCs 5271 (Blood Product Exchange) and 5281 (Apheresis and Stem Cell Procedures). Specifically, we proposed to assign the procedure described by CPT code 38240 (Hematopoietic progenitor cell (HPC); allogenic transplantation per donor) to APC 5281 (Apheresis/Stem Cell and Related Services), for which we proposed a CY 2016 geometric mean cost of approximately $3,217.

Comment: Commenters opposed the proposed payment rate for the procedure described by CPT code 38240. The commenters stated that the current CY 2015 outpatient payment rate does not provide adequate payment for the total cost of an hematopoietic cell transplants (HCT), particularly donor cell acquisition costs. Commenters asked that CMS consider changing its payment methodology for donor cell acquisition costs and made the following specific requests of CMS to: (1) Create a separate, dedicated cost center line for HCT, similar to how it established the cost center line for Implantable Devices, MRIs, CT Scans, and Cardiac Catheterizations; (2) work with the NUBC to release a new, dedicated revenue code for providers to use when reporting their HCT donor search and cell acquisition charges; (3) create payment parity for the donor search and cell acquisition component of HCT between the inpatient and outpatient settings; (4) recognize the search and procurement costs associated with HCT transplant and develop a reasonable cost basis solution for HCT that mimics the acquisition cost procedures for solid organ transplantation; (5) if CMS chooses not to consider number (4) request, find a

way to incorporate the donor search and cell acquisition charges reported through revenue code 819 into the overall outpatient transplant APC rate (The commenters suggested that CMS could incorporate this suggested change by creating a Composite APC whereby it identifies the allogenic transplant CPT code and a revenue code 0819 and creates an appropriate payment rate, or that CMS could study applying the C–APC concept to HCT.); (6) require transplant centers to submit their actual cost information on the UB–04s for patients receiving both allogeneic related and unrelated transplants; and (7) instruct providers to report their actual cost on the revenue code 0819 claim line item in order for CMS to apply a default CCR of 1.0 for claims reporting outpatient allogeneic HCT procedures (This would be defined by the presence of an outpatient allogeneic CPT procedure code.). In addition, one commenter asked that CMS describe clearly in the preamble to the final rule that it is incumbent on hospitals to report their entire donor search and cell acquisition charges on the recipient's transplant claim.

Response: We continue to believe that the procedure described by CPT code 38240 is appropriately assigned to APC 5281 because its geometric mean cost and clinical characteristics are similar to other procedures assigned to APC 5281. We note the commenters' concerns that donor acquisition cost is not appropriately captured in the current payment methodology for HCT procedures. As we have previously stated, allogeneic harvesting procedures, which are performed not on the beneficiary but on a donor, cannot be paid separately under the OPPS because hospitals may bill and receive payment only for services provided to the Medicare beneficiary who is the recipient of the HCT procedure, and whose illness is being treated with the transplant. We stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60575) and in section 231.11 of Chapter 4 of the Medicare Claims Processing Manual (Pub. 100–04) that payment for allogeneic stem cell acquisition services (such as harvesting procedures and donor evaluation) is packaged into the payment for the transplant procedure (either the Medicare Severity Diagnosis Related Group (MS–DRG) when the transplant is performed on an inpatient basis, or the APC when the transplant is performed on an outpatient basis). Hospitals should report all allogeneic outpatient HCT procedure acquisition charges on the recipient's outpatient claim as uncoded charges under revenue code 0819.

In response to comments concerning the creation of a dedicated cost center and/or revenue code for HCT procedures, payment parity for the donor search and cell acquisition component of HCT procedures between the inpatient and outpatient settings, requiring transplant centers to submit their actual cost information on the UB–04s for both allogeneic related and unrelated transplant patients, and applying a default CCR of 1.0 for outpatient allogeneic HCT claims, we note that we did not make any such proposals in the CY 2016 OPPS/ASC proposed rule. Therefore, we consider these comments outside the scope of the proposed rule and are not responding to them in this final rule with comment period. We will take these suggestions into consideration for future rulemaking.

While converting the outpatient stem cell transplant APCs to composite APCs or C–APCs would reduce to a small degree the differential between the OPPS payment rate and the costs as represented in the public comment we received, it would only provide a relatively modest increase in payment, consistent with our previous data studies on this issue. We believe that we need to further examine the costs associated with outpatient stem cell transplant services and how their costs could best be captured for ratesetting purposes in the OPPS. These transplant services remain low-volume in the HOPD. However, we will continue to monitor this issue and the volume of outpatient allogeneic transplant services.

After consideration of the public comments we received, we are finalizing our CY 2016 proposal, and continuing to assign the services described by CPT code 38240 to APC 5281, for which the final CY 2016 geometric mean cost is approximately $3,155.

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices

a. Background

Section 1833(t)(6)(B)(iii) of the Act sets forth the period for which a device category eligible for transitional pass-through payments under the OPPS may be in effect. The implementing regulation at 42 CFR 419.66(g) provides that this pass-through payment eligibility period begins on the date CMS establishes a particular transitional pass-through category of devices. The eligibility period is for at least 2 years but no more than 3 years. We may establish a new device category for pass-through payment in any quarter. Under our established policy, we base the pass-through status expiration date for a device category on the date on which pass-through payment is effective for the category; that is, the date CMS establishes a particular category of devices eligible for transitional pass-through payments. We propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update.

We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763). Brachytherapy sources, which are now separately paid in accordance with section 1833(t)(2)(H) of the Act, are an exception to this established policy.

b. CY 2016 Policy

As stated earlier, section 1833(t)(6)(B)(iii) requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. There currently are four device categories eligible for pass-through payment: HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) was established effective October 1, 2013. HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components) was established effective January 1, 2015. HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) was established effective April 1, 2015. HCPCS code C2613 (Lung biopsy plug with delivery system) was established effective July 1, 2015. The pass-through payment status of the device category for HCPCS code C1841 will end on December 31, 2015. Therefore, in accordance with our established policy, in the CY 2016 OPPS/ASC proposed rule (80 FR 39264), we proposed, beginning with CY 2016, to package the costs of the HCPCS code C1841 devices into the costs related to the procedures with which the device is reported in the hospital claims data.

We stated in the proposed rule that if we create any new device categories for pass-through payment status during the remainder of CY 2015 or during CY 2016, we will propose future expiration dates in accordance with § 419.66(g).

We did not receive any public comments on this proposal. Therefore,

we are finalizing our proposal to expire device pass-through payments for the device described by HCPCS code C1841, effective January 1, 2016.

2. Annual Rulemaking Process in Conjunction With Quarterly Review Process for Device Pass-Through Payment Applications

a. Background

Section 1833(t)(6)(B) of the Act requires payment to be made on a ''pass-through'' basis for designated medical devices. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations might be most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at 42 CFR 419.66(b)(1) through (b)(3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria: (1) If required by FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or another appropriate FDA exemption; (2) the device must be determined reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as provided under section 1862(a)(1)(A) of the Act; and (3) the device must be an integral part of the service, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, whether or not it remains with the patient when the patient is released from the hospital. A device is not eligible if it is any of the following, as specified at § 419.66(b)(4): Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a category of devices should be established. The device to be included in the category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 416.66(d); and
- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

More details on the requirements for device pass-through payment applications are included on the CMS Web site in the application form itself at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*, in the ''Downloads'' section.

The current OPPS process for applying for a new device category for transitional pass-through payment is subregulatory; that is, device or implantable biological or skin substitute manufacturers, hospitals, or other interested parties may apply to the agency through an application process available online. The application determination process is handled outside of rulemaking. Applications are accepted by CMS on a rolling basis and determinations are made on a quarterly basis. Decisions by CMS to approve an application for a device for pass-through payment under the OPPS are announced quarterly through a subregulatory process via program transmittal and are communicated directly to the applicant. Approvals are then referenced in our annual rulemaking as a means to establish payment periods. Currently, denials of applications for devices for pass-through payment status under the OPPS are communicated directly to the applicant and not announced publicly through rulemaking, program transmittal, or other public forum. Applicants for pass-through payment for a device whose application is denied may submit a reconsideration request to CMS. The applicant must send a written letter that explains the reasons for the request for reconsideration of CMS' decision, along with any additional information or evidence that may not have been included with the original application that may further support the reconsideration request. Currently, reconsiderations of denials of devices for pass-through payment under the OPPS are handled similarly to previous denials through direct communication with the applicant.

Over the years, stakeholders have opined that the current OPPS device pass-through payment application process lacks transparency and consistent approval standards. That is, stakeholders have suggested that the unavailability to the public of specific information about application decisions makes it difficult to determine if there are consistent approval standards because there is no public knowledge regarding which applications are rejected and which criteria are not met. Likewise, for approved applications, there is a lack of the specific information available to the public that led to approval of the application. Some stakeholders have requested that CMS increase transparency in the device pass-through payment application process by notifying the public, through rulemaking, of the number of applications received each year in aggregate and, for each application, include in rulemaking the preliminary decision, any additional details included in follow-up with the applicant, and the final decision, including the rationale for the approval or denial of the application. Stakeholders also have requested that CMS consult with industry and other stakeholders during the application review process.

We agree with stakeholders that the current OPPS device pass-through payment application process could benefit from increased transparency and stakeholder input. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39265), for CY 2016, we proposed changes to the OPPS device pass-through payment application process to help achieve the goals of increased transparency and stakeholder input. We proposed to align a portion of the OPPS device pass-through payment application process with the already established Hospital Inpatient Prospective Payment System (IPPS) application process for new medical services and new technology add-on payments. (We refer readers to sections 1886(d)(5)(K) and (d)(5)(L) of the Act and 42 CFR 412.87 and 412.88 for additional information on the IPPS process for approval of new medical

services and technologies for new technology add-on payment under the IPPS.) Frequently, an applicant will apply for both device pass-through payments under the OPPS and for new technology add-on payments under the IPPS. Both the OPPS and the IPPS require that the applicant demonstrate that the technology represents a substantial clinical improvement relative to existing technologies. Approvals and denials of applications for new technology add-on payments under the IPPS are finalized through annual rulemaking. We discuss the specific changes that we proposed for the transitional medical device pass-through payment application process under the OPPS in the section below.

b. Revisions to the Application Process for Device Pass-Through Payments

In the CY 2016 OPPS/ASC proposed rule (80 FR 39265), we proposed, beginning in CY 2016, to add a rulemaking component to the current quarterly device pass-through payment application process. That is, we proposed to supplement the quarterly process by including a description of applications received (whether they are approved or denied) as well as our rationale for approving or denying the application in the next applicable OPPS proposed rule. This proposed revised process would include providing information related to the establishment of the new device category, the cost thresholds, and the substantial clinical improvement criterion. For applications that are approved during the quarterly review process, based on public comments received in response to proposed rulemaking, we proposed that we would either continue to maintain device pass-through payment status or finalize a policy to discontinue pass-through payment status. In the rare case in which an applicant is approved during the quarterly process and then a decision is made in rulemaking to reverse the approval, the applicant could reapply with new information, in advance of the following year's proposed rule, assuming that the device would still be considered new, as described in the section below. A summary description of the application would be included in the proposed rule, along with a proposal to approve or deny device pass-through payment status and a final decision would be provided in the final rule after consideration of public comments. The information requested in the device pass-through payment application itself would not change as a result of the proposed process changes.

For applications that we deny during the quarterly review process, we proposed to include the same type of information that we include for approved devices in the next applicable OPPS proposed rule and, after consideration of public comments received, could revisit our decision and either uphold the original decision of denial or approve the application based on additional evidence submitted through the rulemaking process. The final decision would be published in the appropriate final rule. In lieu of the informal reconsideration process that has been in place prior to CY 2016 for denied applications, we would only provide opportunity to reconsider applications that are denied through the rulemaking process. We proposed to allow applicants whose applications are denied through the quarterly review process to withdraw their applications if they do not wish to go through the rulemaking process. If such a decision is made, the quarterly review decision to deny device pass-through payment for the application would be considered final and there would be no further reconsideration process available. By providing an opportunity for public comment, we believe that we would not only make the device pass-through payment application and review process more transparent, but also would assure that applicants have the benefit of public input on the ultimate decision to approve or deny an application for device pass-through payments under the OPPS.

Currently, the deadline for device pass-through payment application submission is the first business day in March, June, September, and December of a year for consideration for the next quarter (at the earliest) of the calendar year. For example, under our proposal, CMS' decision on an application that is submitted by the first business day in March would likely be presented in that calendar year's OPPS proposed rule (assuming the application that is submitted is complete). Decisions on applications received after the first business day in March would be included in the OPPS proposed rule for the following calendar year.

In response to requests for more transparency and public input on the device pass-through payment application process, we considered moving entirely to a yearly process through rulemaking and eliminating quarterly submissions. However, in an effort to maintain flexibility under the OPPS process for device pass-through payment applications, we believe that maintaining the quarterly process in addition to adding the annual rulemaking process may be beneficial because applications approved on a quarterly basis would be granted access to pass-through payments as soon as possible for approved devices. In addition, all applications would be considered through the rulemaking process, which would provide increased transparency and allow public input that would be considered in making a final determination. We invited public comments on this proposed approach as well as on whether moving to a rulemaking process entirely would be more helpful to further increase transparency and further align the review of applications submitted under both the IPPS and the OPPS.

Comment: Commenters generally supported the addition of an annual rulemaking process, while maintaining a quarterly submission process. The commenters, in particular, supported the increased transparency and stakeholder input that would occur with an annual rulemaking component because it would increase both equity and predictability in the process. In addition, the commenters supported providing the industry with necessary information regarding approval standards and the opportunity for Medicare beneficiaries to have access to this important information.

Response: We appreciate the commenters' support. We agree that our proposal to add a rulemaking element to the device pass-through process will increase transparency and stakeholder input in the device pass-through process. We also believe that seeking public comment through rulemaking on pass-through applications will allow for a more rigorous review of applications and will enable prospective applicants to gain insights to help with the development of their applications.

Comment: Some commenters suggested that CMS publicize all final decisions and their rationale on a quarterly basis, in addition to the yearly rulemaking process.

Response: Under our current quarterly review process, we include information about proper coding for applications that are approved for pass-through payment in the quarterly transmittals called ''change requests'' (CRs). We do not currently publish any information about applications that are not approved. We do not believe it is necessary to notify the public of submitted applications and our decisions outside of the annual rulemaking process. That is, we believe that notifying the public annually of applications under review for rulemaking and, ultimately our decisions on pass-through payment

status in the final rule, provides sufficient transparency and is consistent with most other payment determinations. However, we will continue to publish coding information for applications approved on a quarterly basis through our quarterly CRs. In addition, we are finalizing in this final rule with comment period a policy that applicants whose applications are not approved through the quarterly review process may elect to withdraw their application from consideration in the next applicable rulemaking cycle.

Comment: Several commenters expressed concern that, under the proposed process with respect to applications that are denied upon quarterly review, the ability of submitters to have their applications reconsidered in a timely manner is limited. In addition, the commenters believed that having a reconsideration process moved to annual rulemaking (instead of having opportunity on a quarterly basis) would lead to lengthy gaps between receipt of a denial and the ability to submit additional documentation. The commenters were particularly concerned about timeliness in light of the proposal to more strictly define ''newness'' for device pass-through applications. One commenter also believed that there was potential for a backlog of applications by moving to an annual decision-making process. One commenter suggested that CMS evaluate reconsiderations quarterly for cases in which new data became available and allow for a 60-day public comment period through a separate **Federal Register** publication process, outside of the annual rulemaking process.

Response: We are sensitive to the commenters' concern about the timeliness of review of denied quarterly applicants. However, we do not believe that a quarterly reconsideration process with a 60-day comment period in addition to notice-and-comment rulemaking is necessary. As noted earlier, the public has been supportive of the benefits of having device pass-through payment applications go through a public rulemaking process. While we appreciate the comment about a potential backlog of applications, we do not anticipate a backlog based on the prior and current volume of applications received.

In response to the commenters' concerns about applications that are denied upon quarterly review not having the ability to be reconsidered on a quarterly basis, we note that, as described in the section below, the proposed newness period only applies to the date upon which an application must be submitted through the quarterly application process. Therefore, a quarterly denial should not impact the ability of an application from being considered through the next applicable annual rulemaking cycle, so long as the quarterly application was submitted within 3 years of the initial FDA approval or clearance. Nonetheless, in response to comments articulating concerns about applications that receive a denial upon quarterly review, we are modifying our proposal in this final rule with comment period. Specifically, rather than denying an application based on quarterly review, for applications that we do not approve based upon the evidence available during the quarterly review process, we will instead seek public comment on the application in the next applicable rulemaking cycle. No special reconsideration process would be necessary, as no decision would be made until the rulemaking process is complete. Applicants could submit new data, such as clinical trial results published in a peer-reviewed journal, for consideration in advance of the following year's proposed rule and during the public comment period under the rulemaking process.

Comment: Several commenters expressed concern about the possibility of quarterly approvals being reversed through the rulemaking process. The commenters emphasized that there should be a high bar to reversing quarterly approved applications and believed that such a reversal would cause disruption for Medicare beneficiaries who may anticipate utilizing the device. One commenter suggested that, if a quarterly approved device pass-through applicant is denied in the final rule, CMS should consider any subsequent reapplication for that application on a quarterly basis.

Response: As we stated in our proposed rule, we expect that it would be a rare case where an application that was approved for device pass-through payment under the quarterly review process is reversed in the annual rulemaking process. However, we will consider all public comments on each application, including clinical evidence that may not have been available upon the quarterly review of the application. Individuals, including the manufacturers of devices under review for device pass-through payment, also would be able to submit public comments demonstrating how the device meets the device pass-through payment criteria. As stated previously in this section, we do not believe that a quarterly reconsideration process in addition to notice-and-comment rulemaking is necessary. We note that, in the case in which an applicant is approved during the quarterly process and then a decision is made in rulemaking to reverse the approval, the applicant could reapply with a new quarterly application that provides new information, in advance of the following year's proposed rule, assuming that the device is still new, which would be the case if the new quarterly application is submitted within 3 years of the initial FDA approval or clearance.

After consideration of the public comments we received, we are finalizing our proposal for processing applications for new device pass-through payments with one modification. Specifically, beginning in CY 2016, we are adopting a policy that all device pass-through payment applications submitted through the quarterly subregulatory process will be subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. However, rather than denying an application based on quarterly review, for applications that we do not approve based upon the evidence available during the quarterly review process, we will instead seek public comment on the application in the next applicable annual rulemaking cycle. Under this final policy, all applications that are approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration entirely. No special reconsideration process would be necessary, as no denial decision would be made except through the annual rulemaking process. Applicants will be able to submit new data, such as clinical trial results published in a peer-reviewed journal, for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications.

c. Criterion for Newness

Since the inception of transitional pass-through payments for medical devices on April 7, 2000, we have not had any specific criteria to evaluate the newness of the device for purposes of determining eligibility and receiving

device pass-through payment under the OPPS. We believe that one consideration in determining whether a new category is warranted should be whether or not the device seeking such new category status is itself new. We believe that transitional pass-through payments for devices under the OPPS are intended as an interim measure to allow for adequate payment for new innovative technology while we collect the necessary data to incorporate the costs for these devices into the base APC rate (66 FR 55861). Typically, there is a lag of 2 to 3 years from the point when a new device is first introduced on the U.S. market (generally on the date that the device receives FDA approval) until it is reflected in our claims data.

Existing regulations at § 419.66(b)(1) specify that, if required by the FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of the regulations), or meet another appropriate FDA exemption. This existing regulatory provision does not address the issue of how dated these device approvals, clearances, or exemptions may be. As a result, a device that has received FDA approval, clearance, or exemption, and has been available on the U.S. market for several years, could apply for and possibly be approved for pass-through payments for a new device category if the device is not described by any of the existing (either currently active or expired) categories established for transitional device pass-through payments. Over the years, we have received applications for device pass-through payment for devices that have been on the U.S. market for several years. We do not believe that this is consistent with the intent of the regulation. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39266), we proposed to modify the medical device eligibility requirement at § 419.66(b)(1) to provide that, not only must a device, if required, receive FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of the regulations) or meet another appropriate FDA exemption from premarket approval or clearance, but also that, beginning with applications submitted on or after January 1, 2016, CMS will consider only applications for a medical device submitted within 3 years from the date of the initial FDA approval or clearance. That is, we proposed to add a requirement to ensure that medical devices falling under § 419.66(b)(1) and seeking device pass-through payment must be ''new.'' This proposed adjustment also would further align the OPPS device pass-through process with the IPPS process for new medical services and new technology add-on payments (42 CFR 412.87(b)(2) and 78 FR 50570) by adding the requirement that the device be new. Specifically, we proposed to reflect in § 419.66(b)(1) that, beginning with applications submitted on or after January 1, 2016, a device will only be eligible for transitional pass-through payment under the OPPS if, in cases where the device requires FDA approval, clearance, or exemption, the device meets the newness criterion; that is, the date of original or initial FDA approval or clearance and U.S. market availability is within 3 years from the date of the application for transitional pass-through payment. We invited public comments on this proposal.

Comment: Some commenters supported the proposed newness criterion. They believed that the proposed newness criterion would provide greater certainty for applicants and that it would more closely align with the IPPS new technology add-on criteria.

Response: We appreciate the commenters' support. We agree that this criterion will provide additional clarity for device pass-through applicants.

Comment: Several commenters opposed the proposed addition of the newness criterion. They believed that the criterion was unnecessary. Other commenters offered alternative proposals for defining newness that mirror the FDA approval processes. Specifically, some commenters suggested that any application that was approved by the FDA under the 510(k) or PMA process should be considered new, and some commenters suggested that any technology, for which the FDA establishes a new product code, be considered ''new'' for purposes of device pass-through payments. In addition, the commenters who opposed the newness criterion stated that it may have unforeseen and unintended consequences that could result in limiting beneficiary access to beneficial new technologies, with specific concern about delay in availability on the U.S. market or to limited sales that would prevent generation of adequate claims data.

Response: We believe that the payment adjustment for transitional pass-through payments for devices under the OPPS is intended as an interim measure to allow for adequate payment of a new innovative technology while we collect the necessary data to incorporate the costs for these devices into the base APC rate (66 FR 55861). We believe that instituting a newness criterion will help to ensure that only those devices that are truly new and that could not have already been sufficiently reflected in our claims data are eligible to receive these enhanced payments. In our experience, we have received applications for devices that received FDA approval several years prior to the submission of the pass-through payment application. Sometimes these devices have not been well-adopted by the medical community due to issues such as changes in device ownership or difficulties with coding and payment. However, we believe that the primary intent of transitional pass-through payments is to address dissemination of new technology. We believe that adopting a newness criterion will help ensure that applications that represent devices newly available on the market that have not had time to be incorporated into the OPPS claims data will be considered for the additional pass-through payments.

In response to suggestions to use the FDA definitions for newness, although FDA approval or clearance is required for a device pass-through payment application to be considered (unless the device is exempt, as described in § 419.66(b)(1)), we do not believe that a new product code from the FDA, which is used by FDA to classify and track a medical device, is relevant in CMS' consideration of whether the device is new for the purposes of device pass-through payment. A new device, as designated by the FDA, may be substantially similar to an existing technology. That is, even if a technology receives a new FDA approval, it may not be necessarily considered ''new'' for purposes of device pass-through payments under the OPPS because a substantially similar product has been approved by the FDA and has been on the U.S. market for more than 2 to 3 years. Given the length of time that a substantially similar product has been on the U.S. market, its costs would already be incorporated into the base APC rate. Lastly, we note that the newness criterion only applies to the 3-year window in which an applicant can apply for device pass-through payments and does not affect the amount of time that a new device would be eligible for pass-through payments should it be approved.

Comment: One commenter suggested that, similar to the IPPS new technology add-on payment process, CMS should follow a timeline for FDA approval of a device by a date that coincides with the ability to include the application in the proposed rule. Specifically, the commenter suggested that applicants be required to have received FDA approval by no later than the first business day in June, in order to be considered in that calendar year rulemaking process.

Response: We proposed to supplement the quarterly device pass-through review process by adding a yearly rulemaking process. Under this proposed policy, which we are finalizing in this final rule with comment period, all applicants will have already undergone a quarterly review process prior to consideration in the annual rulemaking. Under existing policy, devices are already required to have FDA approval or clearance, with exceptions as noted at § 419.66(b)(1), before a review can be completed. Therefore, we do not believe that FDA approval or clearance by a June 1 date is necessary for the annual rulemaking process.

We wish to clarify that we specified ''initial'' FDA clearance or approval in § 419.66(b)(1) because, in some cases, the FDA will provide supplemental approvals or clearances for a device after the initial approval or clearance. We intended to convey that the 3-year timeframe for submitting a device pass-through payment application would be triggered by the FDA initial approval or clearance, and not by any subsequent FDA approvals or clearances.

Comment: Some commenters noted that new products frequently experience delays in approval by FDA before these technologies are available on the U.S. market and recommended that the period of newness begin with the date of first sale. One commenter opposed the proposed newness criterion but requested that, if the agency finalized the proposal, CMS develop necessary exceptions to the newness criterion for situations in which the 3-year newness window would be ''unreasonable.''

Response: We understand the commenters' concerns about delays in approved devices being available on the U.S. market. We also note that the IPPS new technology add-on process recognizes a date later than the FDA approval as the appropriate starting date for ''newness'' if there is a documented delay in market availability (69 FR 49002 through 49003). For the OPPS, we believe that the payment adjustment for transitional pass-through payments for devices is intended as an interim measure to allow for adequate payment of new innovative technology while we collect the necessary data to incorporate the costs for these devices into the base APC rate (66 FR 55861). Typically, there is a lag of 2 to 3 years from the point when a new device is first introduced on the U.S. market (generally on the date that the device receives FDA approval) until it is reflected in our claims data. However, we recognize that, in some cases, FDA approval or clearance may not correspond to the date upon which the device becomes available on the U.S. market. That is, we recognize that there may be cases where the product initially is unavailable to Medicare beneficiaries following FDA approval, such as in cases of a delay in bringing the product to the U.S. market (for instance, manufacturing issues or other Federal regulatory issues, such as a national coverage determination of noncoverage in the Medicare population). Therefore, we are modifying our proposal and will consider newness to begin on the later of initial FDA approval or clearance date or U.S. market availability if there is a documented, verifiable delay in market availability.

Comment: One commenter suggested that CMS delay the newness criterion until CY 2017 rulemaking to allow for more information and clarity.

Response: We believe that we have received useful stakeholder input on this proposal, and we are modifying our proposal in response to concerns raised by a number of commenters. We do not agree that there is a need for delay in implementation.

After consideration of the public comments we received, we are finalizing our proposal to add a newness criterion (under the regulations at § 419.66(b)(1)) for CY 2016 for approval of new device pass-through payments, with a modification that newness will begin on the later of the initial FDA approval or clearance date or U.S. market availability if there is a documented, verifiable delay in market availability.

3. Provisions for Reducing Transitional Pass-Through Payments To Offset Costs Packaged Into APC Groups

a. Background

Section 1833(t)(6)(D)(ii) of the Act sets the amount of additional pass-through payment for an eligible device as the amount by which the hospital's charges for a device, adjusted to cost (the cost of the device), exceeds the portion of the otherwise applicable Medicare outpatient department fee schedule amount (the APC payment amount) associated with the device. We have an established policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of the associated devices that are eligible for pass-through payments (66 FR 59904) for purposes of estimating the portion of the otherwise applicable APC payment amount associated with pass-through devices. For eligible device categories, we deduct an amount that reflects the portion of the APC payment amount that we determine is associated with the cost of the device, defined as the device APC offset amount, from the charges adjusted to cost for the device, as provided by section 1833(t)(6)(D)(ii) of the Act, to determine the pass-through payment amount for the eligible device. We have consistently used an established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC rates (72 FR 66751 through 66752). We establish and update the applicable device APC offset amounts for eligible pass-through device categories through the transmittals that implement the quarterly OPPS updates. In the unusual case where the device offset amount exceeds the device pass-through payment amount, the regular APC rate would be paid.

We published a list of all procedural APCs with the CY 2015 portions (both percentages and dollar amounts) of the APC payment amounts that we determined are associated with the cost of devices on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The dollar amounts are used as the device APC offset amounts. In addition, in accordance with our established practice, the device APC offset amounts in a related APC are used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices, as specified in our regulations at § 419.66(d).

Beginning January 1, 2010, we include packaged costs related to implantable biologicals in the device offset calculations in accordance with our policy that the pass-through evaluation process and payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-

through process and payment methodology only (74 FR 60476). Beginning January 1, 2015, skin substitutes are evaluated for pass-through status and payment using the device pass-through evaluation process (79 FR 66888).

b. CY 2016 Policy

In the CY 2016 OPPS/ASC proposed rule (80 FR 39267), we proposed to continue, for CY 2016, our established methodology to estimate the portion of each APC payment rate that could reasonably be attributed to (that is, reflect) the cost of an associated device eligible for pass-through payment, using claims data from the period used for the most recent recalibration of the APC payment rates. We also proposed to continue our established policies for calculating and setting the device APC offset amounts for each device category eligible for pass-through payment. In addition, we proposed to continue to review each new device category on a case-by-case basis to determine whether device costs associated with the new category are already packaged into the existing APC structure. If device costs that are packaged into the existing APC structure are associated with the new category, we proposed to deduct the device APC offset amount from the pass-through payment for the device category. As stated earlier, these device APC offset amounts also would be used in order to evaluate whether the cost of a device in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices (§ 419.66(d)).

In addition, we proposed to update the list of all procedural APCs with the final CY 2016 portions of the APC payment amounts that we determine are associated with the cost of devices on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html* so that this information is available for use by the public in developing potential CY 2016 device pass-through payment applications and by CMS in reviewing those applications.

In response to the CY 2016 OPPS/ASC proposed rule, we received a few public comments that related to aspects of the pass-through device policy on which we did not propose changes. The comments addressed highly technical and operational matters and pertained to matters that are addressed in subregulatory guidance. Therefore, we believe these public comments are outside of the scope of the proposed rule, and we are not addressing them in this final rule with comment period. We note that the public may contact us via other means to discuss these types of issues.

In this final rule with comment period, we are finalizing the proposed pass-through device policy for reducing transitional pass-through payments to offset costs packaged into APC groups, without modification.

B. Device-Intensive Procedures

1. Background

Under the OPPS, device-intensive APCs are defined as those APCs with a device offset greater than 40 percent (79 FR 66795). In assigning device-intensive status to an APC, the device costs of all of the procedures within the APC are calculated and the geometric mean device offset of all of the procedures must exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilize devices, and the device costs for the associated HCPCS codes exceed the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs and is discussed in detail in section IV.B.3. of this final rule with comment period. A related device policy is the requirement that procedures assigned to certain (formerly device-dependent) APCs require the reporting of a device code on the claim (79 FR 66795).

2. Changes to the Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed below in Table 41 (the formerly device-dependent APCs) is reported on the claim.

TABLE 41—APCS THAT REQUIRE A DEVICE CODE TO BE REPORTED ON A CLAIM WHEN A PROCEDURE ASSIGNED TO ONE OF THESE APCS IS REPORTED FOR CY 2015

CY 2015 APC	CY 2015 APC title
0039	Level III Neurostimulator.
0061	Level II Neurostimulator.
0083	Level I Endovascular.
0084	Level I EP.
0085	Level II EP.
0086	Level III EP.
0089	Level III Pacemaker.
0090	Level II Pacemaker.
0107	Level I ICD.

TABLE 41—APCS THAT REQUIRE A DEVICE CODE TO BE REPORTED ON A CLAIM WHEN A PROCEDURE ASSIGNED TO ONE OF THESE APCS IS REPORTED FOR CY 2015—Continued

CY 2015 APC	CY 2015 APC title
0108	Level II ICD.
0202	Level V Gynecologic Procedures.
0227	Implantation of Drug Infusion.
0229	Level II Endovascular.
0259	Level VII ENT Procedures.
0293	Level IV Intraocular.
0318	Level IV Neurostimulator.
0319	Level III Endovascular.
0384	GI Procedures with Stents.
0385	Level I Urogenital.
0386	Level II Urogenital.
0425	Level V Musculoskeletal.
0427	Level II Tube/Catheter.
0622	Level II Vascular Access.
0648	Level IV Breast Surgery.
0652	Insertion of IP/PI. Cath.
0655	Level IV Pacemaker.

There are 10 APCs listed in Table 41 that are not device-intensive APCs; that is, their device offsets do not exceed 40 percent. As discussed in the CY 2016 OPPS/ASC proposed rule (80 FR 39267), we do not believe that we should continue to require device codes on claims for procedures that are not assigned to device-intensive APCs because the relative device costs do not exceed the device-intensive threshold of 40 percent. Unlike with device-intensive APCs, we believe it is not necessary to require the reporting of a device code for reporting device charges on a claim because the relative device costs are much less significant than those associated with device-intensive APCs. We believe that device code reporting requirements should only apply to the device-intensive APCs because these APCs have significant device costs that are associated with particular devices. We noted that, in CY 2015 (79 FR 66794 through 66795), we applied the device code reporting requirements to those formerly device-dependent APCs that also met the device-intensive APC definition. However, as stated in the CY 2016 OPPS/ASC proposed rule (80 FR 39268), after further consideration, we no longer believe it is appropriate to restrict the application of this policy to only the subset of device-intensive APCs that were formerly device-dependent and now believe the device code reporting requirements should apply to all device-intensive APCs, regardless of whether or not the APC was formerly device-dependent. We believe that the device coding requirement should apply to

procedures assigned to all device-intensive APCs because these are the APCs with significant device costs. Therefore, for CY 2016, we proposed that only the procedures that require the implantation of a device that are assigned to a device-intensive APC would require a device code on the claim. The list of device-intensive APCs was listed in Table 38 of the CY 2016 OPPS/ASC proposed rule (80 FR 39268).

In the CY 2016 OPPS/ASC proposed rule, we proposed that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to an APC listed in Table 38 of the proposed rule (80 FR 39268), would satisfy the edit. Claims submitted with a procedure code requiring a device assigned to an APC listed in Table 38 of the proposed rule, but without any device code reported on the claim, would be returned to the provider.

Comment: A number of commenters supported CMS' proposal to apply device code reporting requirements to procedures that require the implantation of a device and that are assigned to a device-intensive APC. One commenter who supported the proposal recommended that CMS continue to monitor claims to evaluate the need to reinstate all device edits. Other commenters urged CMS to reinstate device-to-procedure edits. One commenter expressed concern that removal of procedure-to-device code edits could potentially cause device-to-procedure code mismatches in the CY 2015 claims data, which, ultimately, could result in incorrect APC payment rates. One commenter requested that CMS require device coding for any procedure that has a device offset of greater than 40 percent, regardless of whether the procedure is assigned to a device-intensive APC. A few commenters requested that CMS remove APC 5221 from the ''device intensive'' APC list because the procedures described by the HCPCS codes assigned to APC 5221 represent procedures for device removal, revision, and repair, which do not require or include the device itself.

Response: We appreciate the commenters' support. We will continue to monitor the claims data to ensure that hospitals continue reporting appropriate device codes on the claims for device-intensive APCs. We continue to believe that the elimination of device-to-procedure edits and procedure-to-device edits is appropriate due to the experience hospitals now have in coding and reporting these claims fully. For the more costly devices, we believe the C–APCs will reliably reflect the cost of the device if charges for the device are included anywhere on the claim. We remind the commenters that, under our proposed policy, hospitals would still be expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. We also remind the commenters that, as with all other items and services recognized under the OPPS, we expect hospitals to code and report their device costs appropriately, regardless of whether there are claims processing edits in place. We do not believe that our proposed policy will result in device-to-procedure code mismatches, which would require miscoding by hospitals. We continue to expect hospitals to use an appropriate device code consistent with correct coding in order to ensure that device costs are always reported on the claim and that costs are appropriately captured in claims that CMS uses for ratesetting.

In response to the commenter's request that CMS require device coding for any procedure that has a device offset of greater than 40 percent, regardless of whether the procedure is assigned to a device-intensive APC, we note that we did not propose such a policy change. However, we will take this comment into consideration for future rulemaking. We also note that APC 5221 does not have a final device offset of greater than 40 percent. Therefore, we are not finalizing it as a device-intensive APC for CY 2016.

After consideration of the public comments we received, we are finalizing our proposal, without modification, that, beginning in CY 2016, only the procedures that require the implantation of a device that are assigned to a device-intensive APC will require a device code on the claim. We also are finalizing, without modification, our proposal that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to an APC listed in Table 42 below will satisfy the edit.

Table 42 below lists the CY 2016 device-intensive APCs.

TABLE 42—CY 2016 DEVICE-INTENSIVE APCS

Renumbered CY 2016 APC	CY 2016 APC title
1565	New Technology—Level 28 ($5,000–$5,500).
1599	New Technology—Level 48 ($90,000–$100,000).
5125	Level 5 Musculoskeletal Procedures.
5166	Level 6 ENT Procedures.
5192	Level 2 Endovascular Procedures.
5193	Level 3 Endovascular Procedures.
5222	Level 2 Pacemaker and Similar Procedures.
5223	Level 3 Pacemaker and Similar Procedures.
5224	Level 4 Pacemaker and Similar Procedures.
5231	Level 1 ICD and Similar Procedures.
5232	Level 2 ICD and Similar Procedures.
5377	Level 7 Urology and Related Services.
5462	Level 2 Neurostimulator and Related Procedures.
5463	Level 3 Neurostimulator and Related Procedures.
5464	Level 4 Neurostimulator and Related Procedures.
5471	Implantation of Drug Infusion Device.
5493	Level 3 Intraocular Procedures.
5494	Level 4 Intraocular Procedures.

3. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals are instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals are instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the

device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim. For CY 2015, we continued our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873).

b. Policy for CY 2016

For CY 2016 and subsequent years, in the CY 2016 OPPS/ASC proposed rule (80 FR 39268), we proposed to continue our existing policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Specifically, for CY 2016, we proposed to continue to reduce the OPPS payment, for the device-intensive APCs listed in Table 38 of the proposed rule (80 FR 39268), by the full or partial credit a provider receives for a replaced device. Under this proposed policy, hospitals would continue to be required to report on the claim the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. In CY 2015 and prior years, we specified a list of costly devices to which this APC payment adjustment would apply. As discussed in the CY 2016 OPPS/ASC proposed rule (80 FR 39269), upon further consideration of our existing value code ''FD'' APC payment adjustment policy and the ability to deduct the actual amount of the device credit from the OPPS payment, regardless of the cost of the individual device, instead of a percentage of the device offset, we no longer believe it is necessary to restrict the application of this policy to a specific list of costly devices (most recently listed in Table 27 of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66873)) as was necessary under the ''FB''/''FC'' modifier payment adjustment policy, which made APC payment adjustments as a percentage of the applicable device offset amount. Under the CY 2015 policy, the actual amount of the device credit can be appropriately reported in the amount portion of value code ''FD'' and deducted from the OPPS payment for all no cost/full credit and partial credit devices furnished in conjunction with a procedure assigned to a device-intensive APC. Therefore, for CY 2016 and subsequent years, we proposed to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply. Instead, we proposed to apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

For CY 2016 and subsequent years, in the CY 2016 OPPS/ASC proposed rule (80 FR 39269), we also proposed to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which our proposed CY 2016 policy would apply (71 FR 68072 through 68077). Specifically: (1) All procedures assigned to the selected APCs must involve implantable devices that would be reported if device insertion procedures were performed; (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and (3) the APC must be device-intensive; that is, the device offset amount must be significant, which is defined as exceeding 40 percent of the APC cost. We continue to believe these criteria are appropriate because no-cost devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the APC into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost. As noted earlier in this section, APCs with a device offset that exceed the 40-percent threshold are called device-intensive APCs.

Comment: A number of commenters supported CMS' proposed policy. One commenter recommended that CMS continue to provide lists of both the device-intensive APCs and the device HCPCS codes for which a credit would need to be reported.

Response: We appreciate the commenters' support. As stated in the proposed rule (80 FR 39269), we no longer believe it is necessary to restrict the application of this policy to a specific list of costly devices as was necessary under the ''FB''/''FC'' modifier payment adjustment policy. Therefore, we no longer believe it is necessary to specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to reduce the OPPS payment, for the device-intensive APCs (listed in Table 42 of this final rule with comment period), by the full or partial credit a provider receives for a replaced device. We also are finalizing our proposal, without modification, to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead, apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned

to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device. In addition, we are finalizing our proposal, without modification, to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply.

As discussed in the CY 2016 OPPS/ASC proposed rule (80 FR 39269), we examined the offset amounts calculated from the CY 2016 claims data and the clinical characteristics of the CY 2016 APCs to determine which APCs meet the criteria for CY 2016. The full list of device-intensive APCs to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2016 is included in Table 42 of this final rule with comment period.

4. Adjustment to OPPS Payment for Discontinued Device-Intensive Procedures

It has been our longstanding policy to instruct hospitals to use an appropriate modifier on a claim to report when a procedure is discontinued, partially reduced, or canceled. Specifically, when appropriate, hospitals are instructed to append modifiers ''73,'' ''74,'' and ''52'' to report and be paid for expenses incurred in preparing a patient for a procedure and scheduling a room for performing the procedure where the service is subsequently discontinued (Medicare Claims Processing Manual (Pub. 100–04, Chapter 4, Section 20.6.4). The circumstances identifying when it is appropriate to append modifier ''73,'' ''74,'' or ''52'' to a claim are detailed below.

Modifier ''73'' is used by the hospital to indicate that a procedure requiring anesthesia was terminated due to extenuating circumstances or to circumstances that threatened the well-being of the patient after the patient had been prepared for the procedure (including procedural pre-medication when provided), and been taken to the room where the procedure was to be performed, but prior to administration of anesthesia. For purposes of billing for services furnished in the HOPD, anesthesia is defined to include local, regional block(s), moderate sedation/analgesia (''conscious sedation''), deep sedation/analgesia, or general anesthesia. Modifier ''73'' was created so that the costs incurred by the hospital to prepare the patient for the procedure and the resources expended in the procedure room and recovery room (if needed) could be recognized for payment even though the procedure was discontinued. Modifier ''73'' results in a payment rate of 50 percent of the full OPPS payment for the procedure.

Modifier ''74'' is used by the hospital to indicate that a procedure requiring anesthesia was terminated after the induction of anesthesia or after the procedure was started (for example, the incision made, the intubation started, and the scope inserted) due to extenuating circumstances or to circumstances that threatened the well-being of the patient. This modifier may also be used to indicate that a planned surgical or diagnostic procedure was discontinued, partially reduced, or canceled at the physician's discretion after the administration of anesthesia. For purposes of billing for services furnished in the HOPD, anesthesia is defined to include local, regional block(s), moderate sedation/analgesia (''conscious sedation''), deep sedation/analgesia, or general anesthesia. Modifier ''74'' was created so that the costs incurred by the hospital to initiate the procedure (preparation of the patient, procedure room, and recovery room) could be recognized for payment even though the procedure was discontinued prior to completion. Modifier ''74'' results in a payment rate of 100 percent of the full OPPS payment for the procedure.

Modifier ''52'' was revised in CY 2012 and is used by the hospital to indicate partial reduction, cancellation, or discontinuation of services for which anesthesia is not planned. (We refer readers to the January 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS), Transmittal 2386, Change Request 7672, dated January 13, 2012.) The modifier provides a means for reporting reduced services without disturbing the identification of the basic service. Modifier ''52'' results in a payment rate of 50 percent of the full OPPS payment for the procedure.

When a procedure assigned to a device-intensive APC is discontinued either prior to administration of anesthesia or for a procedure that does not require anesthesia, we presume that, in the majority of cases, the device was not used and remains sterile such that it could be used for another case. In these circumstances, under current policy, hospitals could be paid twice by Medicare for the same device, once for the initial procedure that was discontinued and again when the device is actually used. Accordingly, for CY 2016, in the CY 2016 OPPS/ASC proposed rule (80 FR 39269 through 39270), we proposed that, for procedures involving implantable devices that are assigned to a device-intensive APC (defined as those APCs with a device offset greater than 40 percent), we would reduce the APC payment amount for discontinued device-intensive procedures, where anesthesia has not been administered to the patient or the procedure does not require anesthesia, by 100 percent of the device offset amount prior to applying the additional payment adjustments that apply when the procedure is discontinued. We proposed to restrict the policy to device-intensive APCs so that the adjustment would not be triggered by the use of an inexpensive device whose cost would not constitute a significant portion of the total payment rate for an APC. We did not propose to deduct the device offset amount from a procedure that was discontinued after anesthesia was administered (modifier ''74'') because we believe that it may be more likely that devices involved with such procedures may no longer be sterile, such that they could be restocked and used for another case. However, we solicited public comments on how often the device becomes ineligible for use in a subsequent case and whether we should deduct the device offset amount from claims with modifier ''74'' as well. In addition, we proposed to amend the existing regulations at 42 CFR 419.44(b) accordingly.

Comment: Commenters generally opposed the proposal. The commenters disagreed with CMS' assumption that devices involved in discontinued procedures were able to be used for another case. One commenter noted, for example, that a nurse may unpack and breach the sterility of implantable devices and other sterile supplies prior to the decision to proceed with the surgery and before the administration of anesthesia. The commenters also noted that companies do not routinely provide information on how to resterilize the devices after the packaging has been opened. The commenters urged CMS not to finalize the proposals, absent a study or evidence that showed that devices remain sterile in discontinued procedures.

Response: We note that the commenters did not provide a clinical reason for why an implantable device would need to be opened in advance of a procedure. Although we acknowledge that some hospitals may choose to open devices prior to the start of the surgery, we do not believe that this practice is necessary. We continue to believe that, in the majority of cases, supplies for a procedure can be arrayed in advance of the procedure, and that implantable devices that are assigned to a device-

intensive APC could be opened when ready for insertion. Further, in the case of a device that became unsterile but was not ultimately used in a procedure, in addition to information that is already available from the FDA about resterilizing reusable medical devices, we note that the manufacturer may provide information on how to ''resterilize'' such a device. We would expect that the hospital would take necessary steps to avoid having to throw away an unused device, especially in circumstances involving expensive devices.

Comment: Some commenters supported CMS' existing policy to reduce the APC payment for procedures that were discontinued, but requested that CMS not reduce any of the device cost associated with the procedure. Specifically, the commenters requested that CMS: (1) Reduce the full APC payment amount by the device offset; (2) apply the discontinued procedure reduction; and (3) add back to the full device offset amount the reduced payment rate to arrive a payment rate that incorporates the cost of the discarded device and supplies related to the procedure.

Response: We continue to believe that device costs are not incurred when the device remains unopened and sterile. While there may be some scenarios under which a device is opened prior to the decision to cancel the procedure, the OPPS is based on a system of averages, and we believe that, overall, those instances will be balanced by those cases where the device that would have been used is not opened prior to the decision to cancel the procedure. As discussed later in this section, we are not finalizing our proposal with respect to cases for which anesthesia is not planned (modifier ''52''). Accordingly, the device offset amount will not be deducted from device-intensive procedures involving modifier ''52.''

Comment: Several commenters urged CMS to review the use of revenue code 0278 for claims that included modifier ''52'' or ''73.'' One commenter noted that, because the OPPS is a system based on averages, if the number of discontinued procedures under Medicare is small, payment for device costs associated with such procedures where the device is opened but unused is likely to be balanced out by other cases involving the device.

Another commenter stated that, in the absence of a study or other evidence that demonstrated that devices remain sterile in procedures with modifiers ''52'' and ''73'' appended to the claim, it is inappropriate to implement the proposed payment reductions. Several commenters cited to an external analysis of 1,500 claims that had a device-intensive procedure code reporting either modifier ''52'' or ''73'' where approximately two-thirds of the time, these claims also contained a charge using revenue code 0278. Some commenters requested that CMS conduct a more detailed analysis of the proposed policy to better understand whether devices can be used for another case. One commenter requested that CMS provide information in the final rule on the number of claims for device-intensive procedures on which modifier ''52'' or ''73'' is appended.

Another commenter suggested that a hospital could apply a token charge for the device as a mechanism to note that the device was opened on a canceled procedure because the use of modifier ''52'' or ''73'' does not provide specific information on whether or not the device was opened. The commenter believed that the token charge would provide a mechanism for gathering information that would inform whether the use of these modifiers should reduce the overall APC payment by the full offset amount and the 50-percent reduction in payment.

Some commenters noted that, because the APC payment is based on the average cost of all cases, the APC weights should already reflect a reduced cost for the unused device based on the mechanics of CMS' costing methodology and, therefore, this policy may penalize the hospital twice.

Response: In response to commenters' request, we analyzed Medicare claims data from CY 2014. We found that, among those claims that contained modifier ''52'' or ''73,'' charges under revenue code 0278 (Implantable Device) for device-intensive procedures were rare. Specifically, we found that, for device-intensive procedures, there were 597 claims on which modifier ''52'' was appended, and 116 claims on which modifier ''73'' was appended. Based on a total of 527,138 device-intensive procedures performed in CY 2014, we determine that approximately 0.14 percent of device-intensive procedures are canceled prior to anesthesia or do not require anesthesia.

In response to the comments regarding use of revenue code 0278, we remind the commenters that a charge under revenue code 0278 should only be posted when the cost associated with an implantable device is incurred. With respect to the suggestion to require a token charge for devices that were compromised in canceled procedures, we note that we are already able to gather information regarding canceled procedures through the use of revenue code 0278 on claims that also contain modifier ''52,'' ''73,'' or ''74.'' Therefore, we disagree that there is a need to add a token charge for the purpose of identifying when a device was opened on a canceled procedure.

With respect to the comment that the APC relative weights already reflect the cost of canceled procedures, we note that, to the extent that a device is unused for the canceled procedure and is instead used on another case, the APC payment rate may be inappropriately inflated because the cost of the unused device may be included in the canceled procedure case (as evidenced by charges on the claim for the device). Therefore, we continue to believe that it is appropriate to deduct the device offset for discontinued procedures reported on claims to which modifier ''73'' is appended. As discussed below, we are not finalizing our proposal to deduct the device offset amount from the APC payment amount for device procedures for which modifier ''52'' is appended to the claim.

Comment: One commenter asked CMS to clarify the use of modifier ''52'' on claims for device-intensive procedures because the commenter believed it would be a rare occurrence that an implantable device would be used for a procedure for which anesthesia was not planned.

Response: Our analysis of CY 2014 Medicare claims data confirms that modifier ''52,'' which is used for procedures for which anesthesia was not planned, is rarely appended with a device-intensive procedure. We agree with the commenter that it would be rare that an implantable device would be used for procedures for which anesthesia was not planned because anesthesia is commonly used in procedures that involve surgically implanting a device. Accordingly, we are not finalizing our proposal to deduct the device offset amount from device-intensive APC payment amounts for discontinued procedures involving modifier ''52.''

Comment: Commenters supported CMS' decision not to include the use of modifier ''74'' under the proposed policy. The commenters stated that, in cases in which the device implantation is canceled after receipt of anesthesia, it was likely that sterile devices would have been opened and rendered useless for another patient and the facility will have incurred the full cost of the device.

Response: We appreciate the insights offered in response to our solicitation for comment on whether to deduct the device offset amount when a device procedure case is canceled after

administration of anesthesia (modifier ''74'').

After consideration of the public comments we received, we are finalizing our proposed policy, with modification, under the regulation at § 419.44(b). Specifically, for procedures involving implantable devices that are assigned to a device-intensive APC (defined as those APCs with a device offset greater than 40 percent), we will reduce the APC payment amount for discontinued device-intensive procedures, where anesthesia has not been administered to the patient (as evidenced by the presence of modifier ''73''), by 100 percent of the device offset amount prior to applying the additional payment adjustments that apply when the procedure is discontinued. As discussed earlier in this section, we are not finalizing this policy for procedures for which anesthesia is not planned and the procedure is discontinued (as evidenced by the presence of modifier ''52'').

V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout this final rule with comment period, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. ''Biological'' as used in this final rule with comment period includes (but is not necessarily limited to) ''biological product'' or ''biologic'' as defined in the Public Health Service Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this provision requires the Secretary to make additional payments to hospitals for: Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to drugs or biologicals that are outpatient hospital services under Medicare Part B for which payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. CY 2016 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this final rule with comment period, which are available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. If the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, the pass-through payment amount is determined by the Secretary to be equal to the average price for the drug or biological for all competitive acquisition areas and the year established under such section as calculated and adjusted by the Secretary. However, we note that the Part B drug competitive acquisition program (CAP) has been postponed since CY 2009, and such a program has not been reinstated for CY 2016.

This methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological. Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this final rule with comment period, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

The pass-through application and review process for drugs and biologicals is explained on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*.

2. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2015

In the CY 2016 OPPS/ASC proposed rule (80 FR 39270), we proposed that the pass-through status of 12 drugs and biologicals would expire on December 31, 2015, as listed in Table 39 of the proposed rule (80 FR 39271). All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2015. These drugs and biologicals were approved for pass-through status on or before January 1, 2014. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is $100 for CY 2016), as discussed further in section V.B.2. of the proposed rule and this final rule with comment period. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we proposed to package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we proposed to provide separate payment at the applicable relative ASP-based payment amount (which is ASP+6 percent for CY 2016, as discussed further in section V.B.3. of the proposed rule and this final rule with comment period).

Comment: A few commenters recommended that CMS continue pass-

through payment status for new drugs, specifically diagnostic radiopharmaceuticals and contrast agents, for a full 3 years. The commenters asserted that providing pass-through payment status for 3 years would help provide a more current and accurate data set on which to base payment amounts of the procedure when the diagnostic radiopharmaceutical or contrast agent is subsequently packaged. The commenters further recommended that CMS expire pass-through payment status for drugs and biologicals on a quarterly as opposed to an annual basis.

Response: We appreciate the commenters' recommendation that we authorize OPPS pass-through payment for new drugs, including contrast agents and diagnostic radiopharmaceuticals, for 3 full years and that we expire pass-through status on a quarterly basis. While we are not accepting this recommendation for CY 2016, we will take it under consideration as we review our OPPS pass-through payment policy for CY 2017.

However, for CY 2016, as we stated in the CYs 2012 through 2015 OPPS/ASC final rules with comment period (76 FR 74287; 77 FR 68363; 78 FR 75010; and 79 FR 66875, respectively), and as described in section V.A. of this final rule with comment period, section 1833(t)(6)(c)(i)(II) of the Act permits CMS to make pass-through payments for a period of at least 2 years, but not more than 3 years, after the product's first payment as a hospital outpatient service under the OPPS. We continue to believe that this period of payment appropriately facilitates dissemination of these new products into clinical practice and facilitates the collection of sufficient hospital claims data reflective of their costs for future OPPS ratesetting. Our longstanding practice has been to provide pass-through payment for a period of 2 to 3 years, with expiration of pass-through payment status proposed and finalized through the annual rulemaking process. Each year, when proposing to expire the pass-through payment status of certain drugs and biologicals, we examine our claims data for these products. We observe that hospitals typically have incorporated these products into their chargemasters based on the utilization and costs observed in our claims data. Under the existing pass-through payment policy, we begin pass-through payment on a quarterly basis, depending on when applications are submitted to us for consideration. We are confident that the period of time for which drugs, biologicals, contrast agents, and radiopharmaceuticals receive pass-through payment status, which is at least 2 but no more than 3 years, is appropriate for CMS to collect the sufficient amount of data to make a packaging determination.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to expire the pass-through payment status of the 12 drugs and biologicals listed in Table 43 below. Table 43 lists the drugs and biologicals for which pass-through payment status will expire on December 31, 2015, the status indicators, and the assigned APCs for CY 2016.

TABLE 43—DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2015

CY 2016 HCPCS code	CY 2016 long descriptor	Final CY 2016 status indicator	Final CY 2016 APC
A9520	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	N	N/A
C9132	Prothrombin complex concentrate (human), Kcentra, per i.u. of Factor IX activity	K	9132
J1556	Injection, immune globulin (Bivigam), 500 mg	K	9130
J3060	Injection, taliglucerase alfa, 10 units	K	9294
J7315	Mitomycin, ophthalmic, 0.2 mg	N	N/A
J7316	Injection, Ocriplasmin, 0.125mg	K	9298
J9047	Injection, carfilzomib, 1 mg	K	9295
J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	K	9297
J9354	Injection, ado-trastuzumab emtansine, 1 mg	K	9131
J9400	Injection, Ziv-Aflibercept, 1 mg	K	9296
Q4122	Dermacell, per square centimeter	N	N/A
Q4127	Talymed, per square centimeter	N	N/A

3. Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Payment Status in CY 2016

In the CY 2016 OPPS/ASC proposed rule (80 FR 39271), we proposed to continue pass-through payment status in CY 2016 for 32 drugs and biologicals. None of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2015. These drugs and biologicals, which were approved for pass-through status between January 1, 2013, and July 1, 2015, were listed in Table 40 of the proposed rule (80 FR 39272). The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through July 1, 2015 were assigned status indicator ''G'' in Addenda A and B to the proposed rule. Addenda A and B to the proposed rule are available via the Internet on the CMS Web site.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Payment for drugs and biologicals with pass-through status under the OPPS is currently made at the physician's office payment rate of ASP+6 percent. We stated in the proposed rule that we believe it is consistent with the statute to propose to continue to provide payment for drugs and biologicals with pass-through status at a proposed rate of ASP+6 percent in CY 2016, which is the amount that drugs and biologicals receive under section 1842(o) of the Act.

Therefore, for CY 2016, we proposed to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2016. We proposed that a $0.00 pass-through payment amount would be paid for most pass-through drugs and biologicals under the CY 2016 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which was proposed at ASP+6 percent, and the portion of the

otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which was proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: Contrast agents; diagnostic radiopharmaceuticals; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2016 because, if not for their pass-through status, payment for these products would be packaged into the associated procedure.

In addition, we proposed to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2016 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

In CY 2016, as is consistent with our CY 2015 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated above, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2016, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which was proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

Comment: Several commenters supported CMS' proposal to provide payment at ASP+6 percent for drugs, biologicals, contrast agents, and radiopharmaceuticals that are granted pass-through payment status. A few commenters requested that CMS provide an additional payment for radiopharmaceuticals that are granted pass-through payment status.

Response: As discussed above, the statute provides that mandated pass-through payment for pass-through drugs and biologicals for CY 2015 equals the amount determined under section 1842(o) of the Act minus the portion of the otherwise applicable APC payment that CMS determines is associated with the drug or biological. Therefore, the pass-through payment is determined by subtracting the otherwise applicable payment amount under the OPPS (ASP+6 percent for CY 2015) from the amount determined under section 1842(o) of the Act (ASP+6 percent).

Regarding the commenters' request that CMS provide an additional payment for radiopharmaceuticals that are granted pass-through payment status, we note that, for CY 2016, consistent with our CY 2015 payment policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals with pass-through payment status based on the ASP methodology. As stated above, the ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the WAC if the ASP is unavailable, and 95 percent of the radiopharmaceutical's most recent AWP if both the ASP and WAC are unavailable. For purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2016, we proposed to follow the standard ASP methodology to determine its pass-through payment rate under the OPPS to account for the acquisition and pharmacy overhead costs, including compounding costs. We continue to believe that a single payment is appropriate for diagnostic radiopharmaceuticals with pass-through payment status in CY 2016, and that the payment rate of ASP+6 percent (or WAC or AWP if ASP is not available) is appropriate to provide payment for both a radiopharmaceutical's acquisition cost and any associated nuclear medicine handling and compounding costs. We refer readers to section V.B.3. of this final rule with comment period for further discussion of payment for therapeutic radiopharmaceuticals based on ASP information submitted by manufacturers. We also refer readers to the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1633-P.html.*

After consideration of the public comments we received, we are finalizing our proposal to provide payment for drugs, biologicals, diagnostic and therapeutic radiopharmaceuticals, and contrast agents that are granted pass-through payment status based on the ASP methodology. If a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2016, we will follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we will provide pass-through payment at WAC+6 percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC information also is not available, we will provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

As discussed in more detail in section II.A.3. of the proposed rule and this final rule with comment period, we implemented a policy whereby payment for the following nonpass-through items is packaged into payment for the associated procedure: Policy-packaged drugs that include drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to contrast agents, stress agents, and diagnostic radiopharmaceuticals), anesthesia drugs; and drugs and biologicals that function as supplies when used in a surgical procedure (for example, skin substitutes). As stated earlier, pass-through payment is the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. Because payment for a drug that is policy-packaged would otherwise be packaged if the product did not have pass-through payment status, we believe the otherwise applicable OPPS payment amount would be equal to the policy-packaged drug APC offset amount for the associated clinical APC in which the drug or biological is utilized. The calculation of the policy-packaged drug APC offset amounts is described in more detail in section V.A.4. of this final rule with comment period. It follows that the copayment for the nonpass-through payment portion (the otherwise applicable fee schedule amount that we also would offset from payment for the

drug or biological if a payment offset applies) of the total OPPS payment for those drugs and biologicals, therefore, would be accounted for in the copayment for the associated clinical APC in which the drug or biological is used. Section 1833(t)(8)(E) of the Act provides that the amount of copayment associated with pass-through items is equal to the amount of copayment that would be applicable if the pass-through adjustment was not applied. Therefore, as we did in CY 2015, we proposed to continue to set the associated copayment amount to zero for CY 2016 for pass-through drugs and biologicals that would otherwise be packaged if the item did not have pass-through payment status. The 32 drugs and biologicals that we proposed to continue to have pass-through payment status for CY 2016 or have been granted pass-through payment status as of July 2015 were shown in Table 40 of the proposed rule (80 FR 39272).

Comment: Commenters supported the proposal to continue to set to zero the associated copayment amounts for pass-through diagnostic radiopharmaceuticals and contrast agents that would otherwise be packaged if the product did not have pass-through payment status for CY 2016. The commenters noted that this policy is consistent with statutory requirements and provides cost-saving benefits to Medicare beneficiaries.

Response: We appreciate the commenters' support. As discussed in the CY 2016 OPPS/ASC proposed rule (80 FR 39271 through 39272), we believe that, for drugs and biologicals that are ''policy-packaged,'' the copayment for the nonpass-through payment portion of the total OPPS payment for this subset of drugs and biologicals is accounted for in the copayment of the associated clinical APC in which the drug or biological is used. Section 1833(t)(8)(E) of the Act provides that the amount of copayment associated with pass-through items is equal to the amount of copayment that would be applicable if the pass-through adjustment was not applied. Therefore, we believe that the copayment amount should be zero for drugs and biologicals that are ''policy-packaged,'' including diagnostic radiopharmaceuticals and contrast agents. We also believe that the copayment amount should be zero for pass-through anesthesia drugs that would otherwise be packaged if the item did not have pass-through payment status.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to set the associated copayment amount for pass-through diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs that would otherwise be packaged if the item did not have pass-through payment status to zero for CY 2016 and for future years. The 38 drugs and biologicals that continue pass-through payment status for CY 2016 or have been granted pass-through payment status as of January 2016 are shown in Table 44 below.

TABLE 44—DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2016

CY 2015 HCPCS code	CY 2016 HCPCS code	CY 2016 long descriptor	CY 2016 status indicator	CY 2016 APC
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664
C9025	J9035	Injection, ramucirumab, 5 mg	G	1488
C9026	J3380	Injection, vedolizumab, 1 mg	G	1489
C9027	C9027	Injection, pembrolizumab, 1 mg	G	1490
C9349	C9349	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter	G	1657
C9442	J9032	Injection, belinostat, 10 mg	G	1658
C9443	J0875	Injection, dalbavancin, 5 mg	G	1659
C9444	J2407	Injection, oritavancin, 10 mg	G	1660
C9445	J0596	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445
C9446	J3090	Injection, tedizolid phosphate, 1 mg	G	1662
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663
C9449	J9039	Injection, blinatumomab, 1 mcg	G	9449
C9450	J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450
C9451	J2547	Injection, peramivir, 1 mg	G	9451
C9452	J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	9452
C9453	J9299	Injection, nivolumab, 1 mg	G	9453
C9454	J2502	Injection, pasireotide long acting, 1 mg	G	9454
C9455	J2860	Injection, siltuximab, 10 mg	G	9455
C9497	C9497	Loxapine, inhalation powder, 10 mg	G	9497
C9022	J1322	Injection, elosulfase alfa, 1mg	G	1480
Q9970	J1439	Injection, ferric carboxymaltose, 1 mg	G	9441
J1446	J1446	Injection, TBO-Filgrastim, 5 micrograms	G	1477
C9023	J3145	Injection, testosterone undecanoate, 1 mg	G	1487
C9134	J7181	Factor XIII (antihemophilic factor, recombinant), Tretten, per i.u	G	1746
C9133	J7200	Factor ix (antihemophilic factor, recombinant), Rixubus, per i.u	G	1467
C9135	J7201	Factor ix (antihemophilic factor, recombinant), Alprolix, per i.u	G	1486
J7508	J7508	Tacrolimus, Extended Release, Oral, 0.1 mg	G	1465
C9021	J9301	Injection, obinutuzumab, 10 mg	G	1476
J9371	J9371	Injection, Vincristine Sulfate Liposome, 1 mg	G	1466
Q4121	Q4121	Theraskin, per square centimeter	G	1479
Q9975	J7205	Injection, factor viii, fc fusion protein, (recombinant), per i.u	G	1656
Q9978	J8655	Netupitant (300mg) and palonosetron (0.5 mg)	G	9448
C9456	J1833	Injection, isavuconazonium sulfate, 1 mg	G	9456
C9457	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9457
N/A	C9458	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458
N/A	C9459	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459
N/A	C9460	Injection, cangrelor, 1 mg	G	9460
Q5101	Q5101	Injection, Filgrastim (G–CSF), Biosimilar, 1 microgram	G	1822

4. Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals To Offset Costs Packaged Into APC Groups

a. Background

Prior to CY 2008, diagnostic radiopharmaceuticals and contrast agents were paid separately under the OPPS if their mean per day costs were greater than the applicable year's drug packaging threshold. In CY 2008 (72 FR 66768), we began a policy of packaging payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents as ancillary and supportive items and services into their associated nuclear medicine and radiology procedures. Therefore, beginning in CY 2008, nonpass-through diagnostic radiopharmaceuticals and contrast agents were not subject to the annual OPPS drug packaging threshold to determine their packaged or separately payable payment status, and instead all non-pass-through diagnostic radiopharmaceuticals and contrast agents were packaged as a matter of policy.

Beginning in CY 2014, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), we finalized a policy to package nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. In addition, beginning in CY 2014, we finalized the packaging of all drugs and biologicals that function as supplies when used in a surgical procedure (including but not limited to skin substitutes and implantable biologicals). These packaging policies are codified at 42 CFR 419.2(b).

b. Payment Offset Policy for Diagnostic Radiopharmaceuticals

As previously noted, radiopharmaceuticals are considered to be drugs for OPPS pass-through payment purposes. As described above, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for diagnostic radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor radiopharmaceuticals in order to ensure no duplicate radiopharmaceutical payment is made.

In CY 2009, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals when considering a new diagnostic radiopharmaceutical for pass-through payment (73 FR 68638 through 68641). Specifically, we use the policy-packaged drug offset fraction for APCs containing nuclear medicine procedures, calculated as 1 minus the following: The cost from single procedure claims in the APC after removing the cost for policy-packaged drugs divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through diagnostic radiopharmaceuticals that takes into consideration the otherwise applicable OPPS payment amount, we multiply the policy-packaged drug offset fraction by the APC payment amount for the nuclear medicine procedure with which the pass-through diagnostic radiopharmaceutical is used and, accordingly, reduce the separate OPPS payment for the pass-through diagnostic radiopharmaceutical by this amount. For CY 2016, as we did in CY 2015, we proposed to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals. In the proposed rule, we indicated that, for CY 2016, there will be three diagnostic radiopharmaceuticals with pass-through payment status under the OPPS: (1) HCPCS code A9586 (Florbetapir f18, diagnostic, per study dose, up to 10 millicuries); (2) HCPCS code C9458 (Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries); and (3) HCPCS code C9459 (Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries). We currently apply the established radiopharmaceutical payment offset policy to pass-through payment for these products.

Table 41 of the proposed rule (80 FR 39273) displayed the proposed APCs to which nuclear medicine procedures would be assigned in CY 2016 and for which we expect that an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

We did not receive any public comments on our proposed policy. Therefore, we are finalizing our proposal, without modification, to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals. We will continue to reduce the payment amount for procedures in the APCs listed in Table 45 in this final rule with comment period by the full policy-packaged offset amount appropriate for diagnostic radiopharmaceuticals. Table 45 below displays the APCs to which nuclear medicine procedures are assigned in CY 2016 and for which an APC offset may be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

TABLE 45—APCS TO WHICH A DIAGNOSTIC RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2016

CY 2016 APC	CY 2016 APC title
5591	Level 1 Nuclear Medicine and Related Services.
5592	Level 2 Nuclear Medicine and Related Services.
5593	Level 3 Nuclear Medicine and Related Services.
5594	Level 4 Nuclear Medicine and Related Services.

c. Payment Offset Policy for Contrast Agents

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for contrast agents an amount reflecting the portion of the APC payment associated with predecessor contrast agents in order to ensure no duplicate contrast agent payment is made.

In CY 2010, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor contrast agents when considering new contrast agents for pass-through payment (74 FR 60482 through 60484). Specifically, we use the policy-packaged drug offset fraction for procedural APCs, calculated as 1 minus the following: The cost from single procedure claims in the APC after removing the cost for policy-packaged drugs divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through contrast agents that takes into consideration the otherwise applicable OPPS payment amount, in the CY 2016 OPPS/ASC proposed rule (80 FR 39273), we proposed to multiply the policy packaged drug offset fraction

by the APC payment amount for the procedure with which the pass-through contrast agent is used and, accordingly, reduce the separate OPPS payment for the pass-through contrast agent by this amount. For CY 2016, as we did in CY 2015, we proposed to continue to apply our standard contrast agents offset policy to payment for any pass-through contrast agents (we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66879) for the final CY 2015 policy and the CY 2016 OPPS/ASC proposed rule (80 FR 39273) for the proposed CY 2016 policy).

There is currently one contrast agent with pass-through payment status under the OPPS. HCPCS code Q9950 (Injection, sulfur hexafluoride lipid microsphere, per ml) was granted pass-through payment status beginning October 1, 2015. We currently apply the established pass-through payment offset policy to pass-through payment for this product. For CY 2016, we proposed to identify procedural APCs for which we expect a contrast offset could be applicable in the case of a pass-through contrast agent as any procedural APC with a policy-packaged drug amount greater than $20 that is not a nuclear medicine APC identified in Table 41 of the proposed rule, and these APCs were displayed in Table 42 of the proposed rule. The methodology used to determine a proposed threshold cost for application of a contrast agent offset policy is described in detail in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60483 through 60484). For CY 2016 and subsequent years, we proposed to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 42 of the proposed rule (80 FR 39273 through 39274), a specific offset based on the procedural APC would be applied to payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal for CY 2016 without modification. We will continue to recognize that when a contrast agent with pass-through payment status is billed with any procedural APC listed in Table 46 below, a specific offset based on the procedural APC will be applied to the payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

TABLE 46—APCS TO WHICH A CONTRAST AGENT PAYMENT OFFSET ARE APPLICABLE FOR CY 2016

CY 2016 APC	CY 2016 APC title
5181	Level 1 Vascular Procedures and Related Services.
5182	Level 2 Vascular Procedures and Related Services.
5183	Level 3 Vascular Procedures and Related Services.
5188	Diagnostic Cardiac Catheterization.
5191	Level 1 Endovascular Procedures.
5192	Level 2 Endovascular Procedures.
5193	Level 3 Endovascular Procedures.
5351	Level 1 Percutaneous Abdominal/Biliary Procedures and Related Services.
5352	Level 2 Percutaneous Abdominal/Biliary Procedures and Related Services.
5523	Level 3 X-Ray and Related Services.
5524	Level 4 X-Ray and Related Services.
5525	Level 5 X-Ray and Related Services.
5526	Level 6 X-Ray and Related Services.
5561	Level 1 Echocardiogram With Contrast.
5562	Level 2 Echocardiogram With Contrast.
5571	Computed Tomography With Contrast and Computed Tomography Angiography.
5582	Magnetic Resonance Imaging and Magnetic Resonance Angiography With Contrast.
5881	Ancillary Outpatient Service When Patient Expires.
8006	CT and CTA With Contrast Composite.
8008	MRI and MRA With Contrast Composite.

d. Payment Offset Policy for Drugs, Biologicals, and Radiopharmaceuticals That Function as Supplies When Used in a Diagnostic Test or Procedure (Other Than Diagnostic Radiopharmaceuticals and Contrast Agents and Drugs and Biologicals That Function as Supplies When Used in a Surgical Procedure)

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), we finalized our policy to package drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure. As a part of this policy, we specifically finalized that skin substitutes and stress agents used in myocardial perfusion imaging (MPI) be policy packaged in CY 2014, in addition to diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs (78 FR 75019). Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we finalized a policy for CY 2014 to deduct from the pass-through payment for skin substitutes and stress agents an amount reflecting the portion of the APC payment associated with predecessor skin substitutes and stress agents in order to ensure no duplicate skin substitute or stress agent payment is made (78 FR 75019).

In CY 2014, we established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor skin substitutes or stress agents when considering a new skin substitute or stress agent for pass-through payment (78 FR 75019). Specifically, in the case of pass-through skin substitutes, we use the policy-packaged drug offset fraction for skin substitute procedural APCs, calculated as 1 minus the following: The cost from single procedure claims in the APC after removing the cost for policy-packaged drugs divided by the cost from single procedure claims in the APC. Because policy-packaged radiopharmaceuticals also would be included in the drug offset fraction for the APC to which MPI procedures are assigned, in the case of pass-through stress agents, we use the policy-packaged drug offset fraction for the procedural APC, calculated as 1 minus the following: The cost from single procedure claims in the APC after removing the cost for policy-packaged drugs excluding policy-packaged diagnostic radiopharmaceuticals divided by the cost from single procedure claims in the APC. To determine the actual APC offset amount for pass-through skin substitutes and pass-through stress agents that takes into consideration the otherwise applicable OPPS payment amount, we multiply the policy-packaged drug offset fraction by the APC payment amount for the procedure with which the pass-through skin substitute or pass-through stress agent is used and, accordingly, reduce the separate OPPS payment for the pass-through skin substitute or pass-through stress agent by this amount (78 FR 75019). In the CY 2016 OPPS/ASC

proposed rule (80 FR 39274), for CY 2016, as we did in CY 2015, we proposed to continue to apply the skin substitute and stress agent offset policy to payment for pass-through skin substitutes and stress agents.

In the proposed rule, we indicated that, for 2016, there will be two skin substitutes (HCPCS codes Q4121 and C9349) with pass-through payment status under the OPPS. We will apply the skin substitute payment offset policy to pass-through payment for these products. Table 43 of the CY 2016 OPPS/ASC proposed rule (80 FR 39274) displayed the proposed APCs to which skin substitute procedures would be assigned in CY 2016 and for which we expect that an APC offset could be applicable in the case of skin substitutes with pass-through status.

Although there are currently no stress agents with pass-through status under the OPPS, we believe that a payment offset is necessary in the event that a new stress agent is approved for pass-through status during CY 2016 in order to provide an appropriate transitional pass-through payment for new stress agents. Table 44 of the CY 2016 OPPS/ASC proposed rule (80 FR 39274) displayed the proposed APCs to which MPI procedures would be assigned in CY 2016 and for which we expect that an APC offset could be applicable in the case of a stress agent with pass-through status.

We did not receive any public comments on these proposals. Therefore, we are finalizing our proposal, without modification, to recognize that when a skin substitute with pass-through payment status is billed with any procedural APC listed in Table 47 below, a specific offset based on the procedural APC will be applied to the payment for the skin substitute to ensure that duplicate payment is not made for the skin substitute. In addition, when a stress agent with pass-through payment status is billed with any procedural APC listed in Table 48 below, a specific offset based on the procedural APC will be applied to the payment for the stress agent to ensure that duplicate payment is not made for the stress agent.

TABLE 47—APCS TO WHICH A SKIN SUBSTITUTE PAYMENT OFFSET ARE APPLICABLE FOR CY 2016

CY 2016 APC	CY 2016 APC title
5054	Level 4 Skin Procedures.
5055	Level 5 Skin Procedures.

TABLE 48—APCS TO WHICH A STRESS AGENT PAYMENT OFFSET ARE APPLICABLE FOR CY 2016

CY 2016 APC	CY 2016 APC title
5722	Level 2 Diagnostic Tests and Related Services.
5593	Level 3 Nuclear Medicine and Related Services.

As we proposed, we will continue to post annually on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Background

Under the policies that we established for the CY 2013 OPPS, we currently pay for drugs, biologicals, and radiopharmaceuticals that do not have pass-through payment status in one of two ways: (1) As a packaged payment included in the payment for the associated service, or (2) as a separate payment (individual APCs). We explained in the April 7, 2000 OPPS final rule with comment period (65 FR 18450) that we generally package the cost of drugs and radiopharmaceuticals into the APC payment rate for the procedure or treatment with which the products are usually furnished. Hospitals do not receive separate payment for packaged items and supplies, and hospitals may not bill beneficiaries separately for any packaged items and supplies whose costs are recognized and paid within the national OPPS payment rate for the associated procedure or service.

Packaging costs into a single aggregate payment for a service, procedure, or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility.

2. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Background

As indicated in section V.B.1. of this final rule with comment period, in accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $95 for CY 2015 (79 FR 66882).

Following the CY 2007 methodology, for the CY 2016 OPPS/ASC proposed rule (80 FR 39275), we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2016 and rounded the resulting dollar amount ($100.22) to the nearest $5 increment, which yielded a figure of $100. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003) from CMS' Office of the Actuary (OACT). We refer below to this series generally as the PPI for Prescription Drugs.

Based on the calculations described above, we proposed a packaging threshold for CY 2016 of $100. For a more detailed discussion of the OPPS drug packaging threshold and the use of the PPI for Prescription Drugs, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086).

Following the CY 2007 methodology, for this CY 2016 OPPS/ASC final rule with comment period, we used the most recently available four quarter moving averaging PPI levels to trend the $50

threshold forward from the third quarter of CY 2005 to the third quarter of CY 2015 and rounded the resulting dollar amount ($97.22) to the nearest $5 increment, which yielded a figure of $100. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics) series code WPUSI07003) from CMS' Office of the Actuary (OACT). Therefore, for this CY 2016 OPPS/ASC final rule with comment period, using the CY 2007 OPPS methodology, we are establishing a packaging threshold for CY 2016 of $100.

b. Cost Threshold for Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals (''Threshold-Packaged Drugs'')

In the CY 2016 OPPS/ASC proposed rule (80 FR 39275), to determine the proposed CY 2016 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2014 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2014 claims processed before January 1, 2015 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.2.c. of the proposed rule, or for the following policy-packaged items that we proposed to continue to package in CY 2016: Anesthesia drugs; contrast agents; stress agents; diagnostic radiopharmaceuticals; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2016, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we proposed for separately payable drugs and biologicals for CY 2016, as discussed in more detail in section V.B.3.b. of the proposed rule) to calculate the CY 2016 proposed rule per day costs. We used the manufacturer submitted ASP data from the fourth quarter of CY 2014 (data that were used for payment purposes in the physician's office setting, effective April 1, 2015) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2016, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2014 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site) because these were the most recent data available for use at the time of development of the proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2015. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2014 hospital claims data to determine their per day cost.

We proposed to package items with a per day cost less than or equal to $100, and identify items with a per day cost greater than $100 as separately payable. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2014 HCPCS codes that were reported to the CY 2015 HCPCS codes that we displayed in Addendum B to the proposed rule (which is available via the Internet on the CMS Web site) for proposed payment in CY 2016.

Comment: The majority of the commenters opposed the continuation of the OPPS packaging threshold of $100 for CY 2016. The commenters believed that, over several years, CMS has rapidly increased the packaging threshold, which contradicts congressional intent. As such, the commenters recommended that CMS eliminate the packaging threshold and provide separate payment for all drugs with HCPCS codes or freeze the packaging threshold at the current level ($95).

Response: The commenters did not specify how they believed our policy is inconsistent with congressional intent. However, as we stated in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68086), we believe that packaging certain items is a fundamental component of a prospective payment system, that updating the packaging threshold of $50 for the CY 2005 OPPS is consistent with industry and government practices, and that the PPI for Prescription Drugs is an appropriate mechanism to gauge Part B drug inflation. Therefore, because packaging is a fundamental component of a prospective payment system that continues to provide important flexibility and efficiency in the delivery of high quality hospital outpatient services, we are not adopting commenters' recommendations to pay separately for all drugs, biologicals, and radiopharmaceuticals for CY 2016, or to eliminate the packaging threshold, or to freeze the packaging threshold at $95.

After consideration of the public comments we received, and consistent with our methodology for establishing the packaging threshold using the most recent PPI forecast data, we are adopting a CY 2016 packaging threshold of $100.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in this CY 2016 OPPS/ASC final rule with comment period, we used ASP data from the first quarter of CY 2015, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective July 1, 2015, along with updated hospital claims data from CY 2014. We note that we also used these data for budget neutrality estimates and impact analyses for this CY 2016 OPPS/ASC final rule with comment period.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B to this final rule with comment period are based on ASP data from the third quarter of CY 2015. These data are the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective July 1, 2015. These payment rates will then be updated in the January 2016 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2016. For items that do not currently

have an ASP-based payment rate, we recalculated their mean unit cost from all of the CY 2014 claims data and updated cost report information available for this CY 2016 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the CY 2016 OPPS/ASC proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for this CY 2016 OPPS/ASC final rule with comment period. Under such circumstances, we proposed to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the proposed CY 2016 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2015. Specifically, for CY 2016, consistent with our historical practice, we proposed to apply the following policies to these HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2015 and that were proposed for separate payment in CY 2016, and that then have per day costs equal to or less than the CY 2016 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2016 final rule, would continue to receive separate payment in CY 2016.
- HCPCS codes for drugs and biologicals that were packaged in CY 2015 and that were proposed for separate payment in CY 2016, and that then have per day costs equal to or less than the CY 2016 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2016 final rule, would remain packaged in CY 2016.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2016 but then have per day costs greater than the CY 2016 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2016 final rule, would receive separate payment in CY 2016.

We did not receive any public comments on our proposed policy to apply the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose cost fluctuates relative to the CY 2016 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2016. Therefore, we are finalizing our proposal, without modification, for CY 2016.

c. High Cost/Low Cost Threshold for Packaged Skin Substitutes

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to finalize the packaging of skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). For the CY 2014 update, assignment to the high cost or low cost skin substitute group depended upon a comparison of the July 2013 ASP+6 percent payment amount for each skin substitute to the weighted average payment per unit for all skin substitutes. The weighted average was calculated using the skin substitute utilization from the CY 2012 claims data and the July 2013 ASP+6 percent payment amounts. The high cost/low cost skin substitute threshold for CY 2014 was $32 per cm². Skin substitutes that had a July 2013 ASP+6 percent amount above $32 per cm² were classified in the high cost group, and skin substitutes that had a July 2013 ASP+6 percent amount at or below $32 per cm² were classified in the low cost group. Any new skin substitutes without pricing information were assigned to the low cost category until pricing information was available to compare to the $32 per cm² threshold for CY 2014. Skin substitutes with pass-through payment status were assigned to the high cost category, with an offset applied as described in section V.A.4.d. of the CY 2015 OPPS/ASC proposed rule (79 FR 40996).

As discussed in the CY 2015 OPPS/ASC proposed rule (79 FR 40998 through 40999) and final rule with comment period (79 FR 66882 through 66885), after the effective date of the CY 2014 packaging policy, some skin substitute manufacturers brought the following issues to our attention regarding the CY 2014 methodology for determining the high cost/low cost threshold:

- Using ASP to determine a product's placement in the high or low cost category may unfairly disadvantage the limited number of skin substitute products that are sold in large sizes (that is, above 150 cm²). Large size skin substitute products are primarily used for burns that are treated on an inpatient basis. These manufacturers contended that nonlinear pricing for skin substitute products sold in both large and small sizes results in lower per cm² prices for large sizes. Therefore, the use of ASP data to categorize products into high and low cost categories can result in placement of products that have significant inpatient use of the large, lower-priced (per cm²) sizes into the low cost category, even though these large size products are not often used in the hospital outpatient department.
- Using a weighted average ASP to establish the high/low cost categories, combined with the drug pass-through policy, will lead to unstable high/low cost skin substitute categories in the future. According to one manufacturer, under our CY 2014 policy, manufacturers with products on pass-through payment status have an incentive to set a very high price because hospitals are price-insensitive to products paid with pass-through payments. As these new high priced pass-through skin substitutes capture more market share, the weighted average ASP high cost/low cost threshold could escalate rapidly, resulting in a shift in the assignment of many skin substitutes from the high cost category to the low cost category.

We agreed with stakeholder concerns regarding the potential instability of the high/low cost categories associated with the drug pass-through policy, as well as stakeholder concerns about the inclusion of large-sized products that are primarily used for inpatients in the ASP calculation, when ASP is used to establish the high cost/low cost categories. As an alternative to using ASP data, in the CY 2015 OPPS/ASC final rule with comment period, we established the high cost/low cost threshold using an alternative methodology (that is, the weighted average mean unit cost (MUC) for all skin substitute products from claims data) that we believed may provide more stable high/low cost categories and resolve the issue associated with large sized products because the MUC will be derived from hospital outpatient claims only. We indicated that the threshold was based on costs from hospital outpatient claims data instead of manufacturer reported sales prices that would not include larger sizes primarily used for inpatient burn cases.

As discussed in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66884), after consideration of the public comments we received on the CY 2015 OPPS/ASC proposed rule, we finalized a policy for CY 2015 to maintain the high cost/low cost APC structure for skin substitute procedures in CY 2015, and we revised the existing methodology used to establish the high/low cost threshold with the alternative MUC methodology. We also finalized for CY 2015 the policies that skin substitutes with pass-through payment status would be assigned to the high cost category, and that skin substitutes with pricing information but without claims data to calculate an MUC would be assigned to either the high cost or low cost category based on the product's ASP+6 percent payment rate. If ASP is not available, we stated we would use WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. We also finalized a policy for CY 2015 that any new skin substitutes without pricing information will be assigned to the low cost category until pricing information is available to compare to the CY 2015 threshold. We stated that new skin substitute manufacturers must submit pricing information to CMS no later than the 15th of the third month prior to the effective date of the next OPPS quarterly update. For example, for a new skin substitute with new pricing information to be included in the July 1, 2015 OPPS update and designated as included in the high cost group, verifiable pricing information must have been provided to CMS no later than April 15, 2015.

We stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66884) that we would evaluate the per day cost (PDC) methodology and compare it to the MUC methodology in CY 2016 once CY 2014 claims data were available. As discussed in the CY 2016 OPPS/ASC proposed rule (80 FR 39277), for CY 2016, we analyzed CY 2014 claims data to calculate a threshold using both the MUC and PDC methods. To calculate a per patient, per day cost for each skin substitute product, we multiplied the total units by the mean unit cost and divided the product by the total number of days. We posted a file on the CMS Web site that provides details on the CY 2016 high/low cost status for each skin substitute product based on a MUC threshold (rounded to the nearest $1) of $25 per cm² and a PDC threshold (rounded to the nearest $1) of $1,050. The file is available on the CMS Web site at: *https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1633-P-OPPS-Skin-Substitute.zip*.

For CY 2016, based on these calculations, we proposed to determine the high/low cost status for each skin substitute product based on either a product's geometric MUC exceeding the geometric MUC threshold or the product's PDC exceeding the PDC threshold. As discussed in the CY 2016 OPPS/ASC proposed rule (80 FR 39277), skin substitutes that exceed either of these thresholds would be assigned to the high cost group and all other products would be assigned to the low cost group. As demonstrated in the aforementioned file that we posted on the CMS Web site, we noted that the majority of high cost products remain high cost under both methodologies. The products shifting to the high-cost category from the low-cost category varied in size. Observing fairly consistent results with both methodologies, we stated in the proposed rule that we believe that, together, both thresholds constitute a more robust methodology for identifying high cost skin substitute products.

We indicated in the CY 2016 OPPS/ASC proposed rule (80 FR 39277) that we would continue to assign skin substitutes with pass-through payment status to the high cost category, and skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC will be assigned to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we would use WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2016 MUC threshold.

For CY 2016, we also proposed to remove all implantable biologicals from the skin substitute cost group list because these products are typically used in internal surgical procedures to reinforce or repair soft tissue, and are not typically used to promote healing of wounds on the skin. The implantable biologicals that we proposed to remove for the skin cost group were identified in Table 45 of the CY 2016 OPPS/ASC proposed rule (80 FR 39277). Implantable biologicals are treated as packaged surgical supplies under the OPPS, which are captured under 42 CFR 419.2(b)(4).

Comment: Several commenters supported CMS' proposal to revise the methodology used to establish the high/low cost threshold from using only a geometric mean unit cost methodology (GMUC) to using either a GMUC methodology or a per day cost (PDC) methodology for all skin substitutes using CY 2014 claims data. The commenters agreed that either methodology would promote stability of assignment to the high and low cost categories and not disadvantage skin substitute products that are sold in large sizes. Commenters also supported using available pricing data for skin substitutes without claims data.

Response: We appreciate the commenters' support. We believe that adopting a policy of using either a GMUC methodology or a PDC methodology will stabilize cost group assignment.

Comment: A few commenters supported CMS' proposal to remove implantable biologicals from the skin substitute cost group list. However, one commenter asked that CMS not remove HCPCS code Q4107 (GraftJacket) because, while this code describes an implantable biological, the biological does have dual usage as a skin substitute.

Response: Based on information provided by the commenter on the duality of use for GraftJacket, we agree that HCPCS code Q4107 should remain on the skin substitute list.

After consideration of the public comments we received, we are finalizing our proposal to remove the implantable biological products (excluding the proposed removal of HCPCS code Q4107 included in the proposed rule) identified in Table 49 below from the skin substitute cost group list for CY 2016.

TABLE 49—IMPLANTABLE BIOLOGICALS FOR REMOVAL FROM SKIN SUBSTITUTE COST GROUP LIST

CY 2016 HCPCS code	CY 2016 short descriptor	CY 2016 status indicator
C9358	SurgiMend, fetal	N

TABLE 49—IMPLANTABLE BIOLOGICALS FOR REMOVAL FROM SKIN SUBSTITUTE COST GROUP LIST—Continued

CY 2016 HCPCS code	CY 2016 short descriptor	CY 2016 status indicator
C9360	SurgiMend, neonatal	N
Q4125	Arthroflex	N
Q4130	Strattice TM	N
Q4142	Xcm biologic tiss matrix 1cm	N

Table 46 of the CY 2016 OPPS/ASC proposed rule (80 FR 39278) showed the proposed CY 2016 high cost/low cost status for each product based on our combined threshold methodology. As noted earlier, for the proposed rule we posted a file on the CMS Web site that provides more information on the high cost/low cost disposition of each product for each threshold methodology. We stated in the proposed rule that, for this CY 2016 OPPS/ASC final rule with comment period, we would update the MUC and PDC threshold amounts using the most recently available CY 2014 claims data and CY 2015 pricing information. The final CY 2016 high cost/low cost status for each skin substitute product is based on a weighted average geometric mean unit cost threshold of $26, and a weighted average per day cost threshold of $773.

We proposed that a skin substitute that is assigned to the high cost group in CY 2015 and exceeds either the MUC or PDC in the proposed rule for CY 2016 would be assigned to the high cost group for CY 2016, even if it no longer exceeds the MUC or PDC CY 2016 thresholds based on updated claims data and pricing information used in this CY 2016 final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposal to maintain the high/low cost APC structure for skin substitute procedures in CY 2016, and our proposal to revise the current methodology used to establish the high/low cost threshold with methodology based on either the geometric mean unit cost or a per day cost. We also are finalizing our proposal that, for CY 2016, skin substitutes with pass-through payment status will be assigned to the high cost category. Skin substitutes with pricing information but without claims data to calculate an MUC will be assigned to either the high cost or low cost category based on the product's ASP+6 percent payment rate. If ASP is not available, we will use WAC+6 percent or 95 percent of AWP to assign a product to either the high cost or low cost category. We also are finalizing our proposal that any new skin substitutes without pricing information will be assigned to the low cost category until pricing information is available to compare to the CY 2016 threshold. New skin substitute manufacturers must submit pricing information to CMS no later than the 15th of the third month prior to the effective date of the next OPPS quarterly update. For example, for a new skin substitute with new pricing information to be included in the July 1 OPPS update and designated as included in the high cost group, verifiable pricing information must be provided to CMS no later than April 15. Table 50 below shows the skin substitute assignments to high cost and low cost groups for CY 2016.

TABLE 50—SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2016

CY 2016 HCPCS code	CY 2016 Short descriptor	HCPCS Code dosage	CY 2016 status indicator	CY 2015 high/low status based on weighted MUC	CY 2016 high/low status based on weighted MUC or weighted PDC
C9349*	PuraPly, PuraPly antimic	1 cm^2	G	High	High.
C9363	Integra Meshed Bil Wound Mat	1 cm^2	N	High	High.
Q4100	Skin Substitute, NOS	1 cm^2	N	Low	Low.
Q4101	Apligraf	1 cm^2	N	High	High.
Q4102	Oasis Wound Matrix	1 cm^2	N	Low	Low.
Q4103	Oasis Burn Matrix	1 cm^2	N	Low	High.
Q4104	Integra BMWD	1 cm^2	N	High	High.
Q4105	Integra DRT	1 cm^2	N	High	High.
Q4106	Dermagraft	1 cm^2	N	High	High.
Q4107	GraftJacket	1 cm^2	N	High	High.
Q4108	Integra Matrix	1 cm^2	N	High	High.
Q4110	Primatrix	1 cm^2	N	High	High.
Q4111	Gammagraft	1 cm^2	N	Low	Low.
Q4115	Alloskin	1 cm^2	N	Low	Low.
Q4116	Alloderm	1 cm^2	N	High	High.
Q4117	Hyalomatrix	1 cm^2	N	Low	Low.
Q4119	Matristem Wound Matrix	1 cm^2	N	Low	Low.
Q4120	Matristem Burn Matrix	1 cm^2	N	Low	High.
Q4121*	Theraskin	1 cm^2	G	High	High.
Q4122	Dermacell	1 cm^2	N	High	High.
Q4123	Alloskin	1 cm^2	N	High	High.
Q4124	Oasis Tri-layer Wound Matrix	1 cm^2	N	Low	Low.
Q4126	Memoderm/derma/tranz/integup	1 cm^2	N	High	High.
Q4127	Talymed	1 cm^2	N	High	High.

TABLE 50—SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2016—Continued

CY 2016 HCPCS code	CY 2016 Short descriptor	HCPCS Code dosage	CY 2016 status indicator	CY 2015 high/low status based on weighted MUC	CY 2016 high/low status based on weighted MUC or weighted PDC
Q4128	Flexhd/Allopatchhd/Matrixhd	1 cm^2	N	High	High.
Q4129	Unite Biomatrix	1 cm^2	N	High	Low.
Q4131	Epifix	1 cm^2	N	High	High.
Q4132	Grafix Core	1 cm^2	N	High	High.
Q4133	Grafix Prime	1 cm^2	N	High	High.
Q4134	hMatrix	1 cm^2	N	High	Low.
Q4135	Mediskin	1 cm^2	N	Low	Low.
Q4136	Ezderm	1 cm^2	N	Low	Low.
Q4137	Amnioexcel or Biodexcel, 1cm	1 cm^2	N	High	High.
Q4138	Biodfence DryFlex, 1cm	1 cm^2	N	High	High.
Q4140	Biodfence 1cm	1 cm^2	N	High	High.
Q4141	Alloskin ac, 1cm	1 cm^2	N	High	High.
Q4143	Repriza, 1cm	1 cm^2	N	Low	Low.
Q4146	Tensix, 1CM	1 cm^2	N	Low	Low.
Q4147	Architect ecm, 1cm	1 cm^2	N	High	High.
Q4148	Neox 1k, 1cm	1 cm^2	N	High	High.
Q4150	Allowrap DS or Dry 1 sq cm	1 cm^2	N	High	High.
Q4151	AmnioBand, Guardian 1 sq cm	1 cm^2	N	Low	Low.
Q4152	Dermapure 1 square cm	1 cm^2	N	High	Low.
Q4153	Dermavest 1 square cm	1 cm^2	N	High	High.
Q4154	Biovance 1 square cm	1 cm^2	N	High	Low.
Q4156	Neox 100 1 square cm	1 cm^2	N	High	Low.
Q4157	Revitalon 1 square cm	1 cm^2	N	Low	Low.
Q4158	MariGen 1 square cm	1 cm^2	N	Low	Low.
Q4159	Affinity 1 square cm	1 cm^2	N	High	High.
Q4160	NuShield 1 square cm	1 cm^2	N	High	High.
Q4161**	Bio-Connekt per square cm	1 cm^2	N	N/A	Low.
Q4162**	Amnio bio and woundex flow	1 cm^2	N	N/A	Low.
Q4163**	Amnion bio and woundex sq cm	1 cm^2	N	N/A	Low.
Q4164**	Helicoll, per square cm	1 cm^2	N	N/A	Low.
Q4165**	Keramatrix, per square cm	1 cm^2	N	N/A	Low.

*Pass-through status in CY 2016.
**New HCPCS code for CY 2016.

d. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66776), we began recognizing, for OPPS payment purposes, multiple HCPCS codes reporting different dosages for the same covered Part B drugs or biologicals in order to reduce hospitals' administrative burden by permitting them to report all HCPCS codes for drugs and biologicals. In general, prior to CY 2008, the OPPS recognized for payment only the HCPCS code that described the lowest dosage of a drug or biological. During CYs 2008 and 2009, we applied a policy that assigned the status indicator of the previously recognized HCPCS code to the associated newly recognized code(s), reflecting the packaged or separately payable status of the new code(s).

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believed that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39279), we proposed to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2016.

For CY 2016, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2014 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for the CY 2016 OPPS/ASC proposed rule and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2014 claims data to make the proposed packaging determinations for these drugs: HCPCS code J3471 (Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)) and HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP+6

percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to $100 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than $100 (so that all HCPCS codes for the same drug or biological would be separately payable).

The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2016 was displayed in Table 47 of the CY 2016 OPPS/ASC proposed rule (80 FR 39279 through 39280).

We did not receive any public comments on this proposal. Therefore, we are finalizing our CY 2016 proposal, without modification, to continue to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages. Table 51 below displays the packaging status of each drug and biological HCPCS code to which our methodology applies for CY 2016.

TABLE 51—HCPCS CODES TO WHICH THE CY 2016 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2016 HCPCS code	CY 2016 Long descriptor	CY 2016 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1070	Injection, testosterone cypionate, up to 100 mg	N
J1080	Injection, testosterone cypionate, 1 cc, 200 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	N
J1560	Injection, gamma globulin, intramuscular over 10 cc	N
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3120	Injection, testosterone enanthate, up to 100 mg	N
J3130	Injection, testosterone enanthate, up to 200 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7050	Infusion, normal saline solution , 250 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml = 1 unit)	N
J7030	Infusion, normal saline solution , 1000 cc	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	K
J8521	Capecitabine, oral, 500 mg	K
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

3. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary. Most physician Part B drugs are paid at ASP+6 percent pursuant to section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS

payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.

It has been our longstanding policy to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In the CY 2016 OPPS/ASC proposed rule (80 FR 39280), we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

Since CY 2006, we have attempted to establish a drug payment methodology that reflects hospitals' acquisition costs for drugs and biologicals while taking into account relevant pharmacy overhead and related handling expenses. We have attempted to collect more data on hospital overhead charges for drugs and biologicals by making several proposals that would require hospitals to change the way they report the cost and charges for drugs. None of these proposals were adopted due to significant stakeholder concern, including that hospitals stated that it would be administratively burdensome to report hospital overhead charges. We established a payment policy for separately payable drugs and biologicals, authorized by section 1833(t)(14)(A)(iii)(I) of the Act, based on an ASP+X amount that is calculated by comparing the estimated aggregate cost of separately payable drugs and biologicals in our claims data to the estimated aggregate ASP dollars for separately payable drugs and biologicals, using the ASP as a proxy for average acquisition cost (70 FR 68642 through 68643). We referred to this methodology as our standard drug payment methodology. Taking into consideration comments made by the pharmacy stakeholders and acknowledging the limitations of the reported data due to charge compression and hospitals' reporting practices, we added an ''overhead adjustment'' in CY 2010 (an internal adjustment of the data) by redistributing cost from coded and uncoded packaged drugs and biologicals to separately payable drugs in order to provide more appropriate payments for drugs and biologicals in the HOPD. We continued this methodology, and we further refined it in CY 2012 by finalizing a policy to update the redistribution amount for inflation and to keep the redistribution ratio constant between the proposed rule and the final rule. For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385).

Because of continuing uncertainty about the full cost of pharmacy overhead and acquisition cost, based in large part on the limitations of the submitted hospital charge and claims data for drugs, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386), we indicated our concern that the continued use of the standard drug payment methodology (including the overhead adjustment) still may not appropriately account for average acquisition and pharmacy overhead cost and, therefore, may result in payment rates that are not as predictable, accurate, or appropriate as they could be. Section 1833(t)(14)(A)(iii)(II) of the Act requires an alternative methodology for determining payment rates for SCODS wherein, if hospital acquisition cost data are not available, payment shall be equal (subject to any adjustment for overhead costs) to payment rates established under the methodology described in section 1842(o), 1847A, or 1847B of the Act. We refer to this alternative methodology as the ''statutory default.'' In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386), we noted that section 1833(t)(14)(A)(iii)(II) of the Act authorizes the Secretary to calculate and adjust, as necessary, the average price for a drug in the year established under section 1842(o), 1847A, or 1847B of the Act, as the case may be, in determining payment for SCODs. Pursuant to sections 1842(o) and 1847A of the Act, Part B drugs are paid at ASP+6 percent when furnished in physicians' offices. We indicated that we believe that establishing the payment rates based on the statutory default of ASP+6 percent is appropriate as it yields increased predictability in payment for separately payable drugs and biologicals under the OPPS and, therefore, we finalized our proposal for CY 2013 to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We also finalized our proposal that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals, that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals for CY 2013 (77 FR 68389). We continued our final policy of paying the statutory default for both CY 2014 and CY 2015.

b. CY 2016 Payment Policy

In the CY 2016 OPPS/ASC proposed rule (80 FR 39281), for CY 2016 and subsequent years, we proposed to continue our CY 2015 policy and pay for separately payable drugs and biologicals at ASP+6 percent pursuant to section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We proposed that the ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. We also proposed that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals.

Comment: Commenters supported CMS' proposal to pay for separately payable drugs and biologicals based on the statutory default rate of ASP+6 percent. A few commenters supported CMS' proposal, but recommended that CMS examine ways to compensate hospitals for the unique, higher overhead and handling costs associated with therapeutic radiopharmaceuticals.

Response: We appreciate the commenters' support. We continue to

believe that ASP+6 percent based on the statutory default is appropriate for hospitals for CY 2016 and that this percentage amount includes payment for acquisition and overhead cost. We see no evidence that an additional overhead adjustment is required for separately payable drugs, biologicals, and therapeutic radiopharmaceuticals for CY 2016.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). The ASP+6 percent payment amount for separately payable drugs and biologicals requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals for CY 2016. In addition, we are finalizing our proposal that payment for separately payable drugs and biologicals be included in the budget neutrality adjustments, under the requirements of section 1833(t)(9)(B) of the Act, and that the budget neutral weight scaler is not applied in determining payment of these separately paid drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this final rule with comment period (available via the Internet on the CMS Web site), which illustrate the final CY 2016 payment of ASP+6 percent for separately payable non-pass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective October 1, 2015, or WAC, AWP, or mean unit cost from CY 2014 claims data and updated cost report information available for this final rule with comment period. In general, these published payment rates are not reflective of actual January 2016 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2016 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the fourth quarter of 2015 (October 1, 2015 through December 31, 2015) are used to set the payment rates that are released for the quarter beginning in January 2016 near the end of December 2015. In addition, payment rates for drugs and biologicals in Addenda A and B to this final rule with comment period for which there was no ASP information available for October 2015 are based on mean unit cost in the available CY 2014 claims data. If ASP information becomes available for payment for the quarter beginning in January 2016, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for this final rule with comment period (reflecting October 2015 ASP data) that do not have ASP information available for the quarter beginning in January 2016. These drugs and biologicals will then be paid based on mean unit cost data derived from CY 2014 hospital claims. Therefore, the payment rates listed in Addenda A and B to this final rule with comment period are not for January 2016 payment purposes and are only illustrative of the CY 2016 OPPS payment methodology using the most recently available information at the time of issuance of this final rule with comment period.

4. Payment Policy for Therapeutic Radiopharmaceuticals

Beginning in CY 2010 and continuing for CY 2015, we established a policy to pay for separately paid therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2016. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39281), we proposed for CY 2016 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also proposed to rely on CY 2014 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is available. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

The proposed CY 2016 payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals were included in Addenda A and B to the proposed rule (which are available via the Internet on the CMS Web site).

Comment: Several commenters supported CMS' proposal to pay for separately payable therapeutic radiopharmaceuticals under the statutory default payment rate of ASP+6 percent if ASP data are submitted to CMS.

Response: We appreciate the commenters' support. We continue to believe that providing payment for therapeutic radiopharmaceuticals based on ASP or mean unit cost if ASP information is not available would provide appropriate payment for these products. When ASP data are not available, we believe that paying for therapeutic radiopharmaceuticals using mean unit cost will appropriately pay for the average hospital acquisition and associated handling costs of nonpass-through separately payable therapeutic radiopharmaceuticals. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60523), although using mean unit cost for payment for therapeutic radiopharmaceuticals when ASP data are not available is not the usual OPPS process (the usual process relies on alternative data sources such as WAC or AWP when ASP information is temporarily unavailable, prior to defaulting to the mean unit cost from hospital claims data), we continue to believe that WAC or AWP is not an appropriate proxy to provide OPPS payment for average therapeutic radiopharmaceutical acquisition cost and associated handling costs when manufacturers are not required to submit ASP data. Payment based on WAC or AWP under the established OPPS methodology for payment of separately payable drugs and biologicals is usually temporary for a calendar quarter until a manufacturer is able to submit the required ASP data in accordance with the quarterly ASP submission timeframes for reporting under section 1847A of the Act. Because ASP reporting for OPPS payment of

separately payable therapeutic radiopharmaceuticals is not required, a manufacturer's choice to not submit ASP could result in payment for a separately payable therapeutic radiopharmaceutical based on WAC or AWP for a full year, a result that we believe would be inappropriate.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent. We also are finalizing our proposal to continue to rely on CY 2014 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The CY 2016 final rule payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this final rule with comment period (which are available via the Internet on the CMS Web site).

5. Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is currently produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States would like to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, and conversion to such production has begun and is expected to be completed by CY 2017. We expect this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

Therefore, for CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources. The time period for this additional payment was not to exceed 5 years from January 1, 2013 (77 FR 68321).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68316) that our expectation was that the transition to non-HEU sourced Mo-99 would be completed within 4 to 5 years and that there might be a need to make differential payments for a period of 4 to 5 years. We further stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted. As discussed in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66892), we reassessed this payment for CY 2015 and did not identify any new information that would cause us to modify payment. We stated that we were continuing the policy of providing an additional $10 payment for radioisotopes produced by non-HEU sources for CY 2015. We also stated that, although we will reassess this policy annually, consistent with the original policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321), we do not anticipate that this additional payment would extend beyond CY 2017.

We reassessed this payment for CY 2016 and did not identify any new information that would cause us to modify payment. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39282), for CY 2016, we proposed to continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources.

Comment: A few commenters requested that CMS extend payment for HCPCS code Q9969 to CY 2017 and beyond.

Response: We stated in our CY 2013 OPPS/ASC final rule with comment period (77 FR 68316) that our expectation was that the transition to non-HEU sourced Mo-99 would be completed within 4 to 5 years and that there might be a need to make differential payments for a period of 4 to 5 years. We further stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted. We reassessed this payment for CY 2016 and have not identified any new information that would cause us to modify payment at this time. We are continuing the policy of providing an additional $10 payment for radioisotopes produced by non-HEU sources for CY 2016. Although we will reassess this policy annually, consistent with the original policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321), we do not anticipate that this additional payment would extend beyond CY 2017.

6. Payment for Blood Clotting Factors

For CY 2015, we provided payment for blood clotting factors under the same methodology as other non-pass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (79 FR 66893). That is, for CY 2015, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2015 updated furnishing fee was $0.197 per unit.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39282), for CY 2016, we proposed to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician office and inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update was based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we were not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/*

McrPartBDrugAvgSalesPrice/index.html.

Comment: Commenters supported CMS' proposal to continue to apply the furnishing fee for blood clotting factors provided in the OPD. The commenters also supported CMS' proposal to pay for separately payable drugs at ASP+6 percent based on the statutory default for CY 2016.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS Web site.

7. Payment for Non-Pass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) did not address the OPPS payment in CY 2005 and subsequent years for drugs, biologicals, and radiopharmaceuticals that have assigned HCPCS codes, but that do not have a reference AWP or approval for payment as pass-through drugs or biologicals. Because there was no statutory provision that dictated payment for such drugs, biologicals, and radiopharmaceuticals in CY 2005, and because we had no hospital claims data to use in establishing a payment rate for them, we investigated several payment options for CY 2005 and discussed them in detail in the CY 2005 OPPS final rule with comment period (69 FR 65797 through 65799).

For CYs 2005 to 2007, we implemented a policy to provide separate payment for new drugs, biologicals, and radiopharmaceuticals with HCPCS codes (specifically those new drug, biological, and radiopharmaceutical HCPCS codes in each of those calendar years that did not crosswalk to predecessor HCPCS codes) but which did not have pass-through status, at a rate that was equivalent to the payment they received in the physician's office setting, established in accordance with the ASP methodology for drugs and biologicals, and based on charges adjusted to cost for radiopharmaceuticals. Beginning in CY 2008 and continuing through CY 2015, we implemented a policy to provide payment for new drugs and biologicals with HCPCS codes (except those that are policy-packaged), but which did not have pass-through status and were without OPPS hospital claims data, at an amount consistent with the final OPPS payment methodology for other separately payable non-pass-through drugs and biologicals for the given year.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39282), for CY 2016, we proposed to continue this policy and provide payment for new drugs, biologicals, and therapeutic radiopharmaceuticals that do not have pass-through status at ASP+6 percent, consistent with the proposed CY 2016 payment methodology for other separately payable non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals, which was proposed to be ASP+6 percent as discussed earlier in this section. We stated that we believe this proposed policy would ensure that new nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals would be treated like other drugs, biologicals, and therapeutic radiopharmaceuticals under the OPPS.

For CY 2016, we also proposed to continue to package payment for all new nonpass-through policy-packaged products (diagnostic radiopharmaceuticals; contrast agents; stress agents; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure) with HCPCS codes but without claims data (those new proposed CY 2016 HCPCS codes that do not replace predecessor HCPCS codes). This is consistent with the CY 2014 final packaging policy for all existing nonpass-through diagnostic radiopharmaceuticals; contrast agents; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in more detail in section II.A.3. of this final rule with comment period.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2016 and subsequent years, we proposed to continue our policy of using the WAC for the product to establish the initial payment rate for new nonpass-through drugs and biologicals with HCPCS codes, but which are without OPPS claims data. However, we noted that if the WAC is also unavailable, we would make payment at 95 percent of the product's most recent AWP. We also proposed to assign status indicator ''K'' (Separately paid nonpass-through drugs and biologicals, including therapeutic radiopharmaceuticals) to HCPCS codes for new drugs and biologicals without OPPS claims data and for which we have not granted pass-through status. With respect to new nonpass-through drugs and biologicals for which we do not have ASP data, we proposed that once their ASP data become available in later quarterly submissions, their payment rates under the OPPS would be adjusted so that the rates would be based on the ASP methodology and set to the proposed ASP-based amount (proposed for CY 2016 at ASP+6 percent) for items that have not been granted pass-through status. This proposed policy, which utilizes the ASP methodology for new nonpass-through drugs and biologicals with an ASP, is consistent with prior years' policies for these items and would ensure that new nonpass-through drugs and biologicals would be treated like other drugs and biologicals under the OPPS, unless they are granted pass-through status.

Similarly, we proposed to continue to base the initial payment for new therapeutic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on the WACs for these products if ASP data for these therapeutic radiopharmaceuticals are not available. If the WACs also are unavailable, we proposed to make payment for new therapeutic radiopharmaceuticals at 95 percent of the products' most recent AWP because we would not have mean costs from hospital claims data upon which to base payment. As we proposed with new drugs and biologicals, we proposed to continue our policy of assigning status indicator ''K'' to HCPCS codes for new therapeutic radiopharmaceuticals without OPPS claims data for which we have not granted pass-through status.

Consistent with other ASP-based payment, for CY 2016, we proposed to announce any changes to the payment amounts for new drugs and biologicals in this CY 2016 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2016 if later quarter ASP submissions (or more recent WACs or AWPs) indicate that changes to the payment rates for these drugs and biologicals are necessary. The payment rates for new therapeutic radiopharmaceuticals also would be changed accordingly based on later quarter ASP submissions. We note that

the new CY 2016 HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals were not available at the time of development of the proposed rule. However, these drugs, biologicals, and therapeutic radiopharmaceuticals are included in Addendum B to this CY 2016 OPPS/ASC final rule with comment period (which is available via the Internet on the CMS Web site), where they are assigned comment indicator ''NI.'' This comment indicator reflects that their interim final OPPS treatment is open to public comment in this CY 2016 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2014 and/or CY 2015 for which we did not have CY 2014 hospital claims data available for the proposed rule and for which there are no other HCPCS codes that describe different doses of the same drug, but which have pricing information available for the ASP methodology. In order to determine the packaging status of these products for CY 2016, we proposed to continue our policy to calculate an estimate of the per day cost of each of these items by multiplying the payment rate of each product based on ASP+6 percent, similar to other nonpass-through drugs and biologicals paid separately under the OPPS, by an estimated average number of units of each product that would typically be furnished to a patient during 1 day in the hospital outpatient setting. This rationale was first adopted in the CY 2006 OPPS/ASC final rule with comment period (70 FR 68666 through 68667).

We proposed to package items for which we estimated the per day administration cost to be less than or equal to $100 and to pay separately for items for which we estimated the per day administration cost to be greater than $100 (with the exception of diagnostic radiopharmaceuticals; contrast agents; stress agents; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure, which we proposed to continue to package regardless of cost) in CY 2016. We also proposed that the CY 2016 payment for separately payable items without CY 2014 claims data would be ASP+6 percent, similar to payment for other separately payable nonpass-through drugs and biologicals under the OPPS. In accordance with the ASP methodology paid in the physician's office setting, in the absence of ASP data, we proposed to use the WAC for the product to establish the initial payment rate and, if the WAC is also unavailable, we would make payment at 95 percent of the most recent AWP available. The proposed estimated units per day and status indicators for these items were displayed in Table 48 of the proposed rule (80 FR 39284).

Finally, there were 33 drugs and biologicals, shown in Table 49 of the proposed rule (80 FR 39284), that were payable in CY 2014 but for which we lacked CY 2014 claims data and any other pricing information for the ASP methodology for the CY 2016 OPPS/ASC proposed rule. For CY 2010, we finalized a policy to assign status indicator ''E'' (Not paid by Medicare when submitted on outpatient claims [any outpatient bill type]) whenever we lacked claims data and pricing information and were unable to determine the per day cost of a drug or biological. In addition, we noted that we would provide separate payment for these drugs and biologicals if pricing information reflecting recent sales became available mid-year for the ASP methodology.

For CY 2016, as we finalized in CY 2015 (79 FR 66894), we proposed to continue to assign status indicator ''E'' to drugs and biologicals that lack CY 2014 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2014 hospital claims data or data based on the ASP methodology that were assigned status indicator ''E'' on this basis at the time of the proposed rule for CY 2016 were displayed in Table 49 of the proposed rule (80 FR 39284). We also proposed to continue our policy to assign the products status indicator ''K'' and pay for them separately for the remainder of CY 2016 if pricing information becomes available.

We did not receive any specific public comments regarding our proposed payment for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes, but without OPPS hospital claims data. Many commenters supported our proposal to pay for separately payable drugs at ASP+6 percent under the statutory default. However, these comments were not specific to new drugs and biologicals with HCPCS codes but without OPPS claims data.

After consideration of the public comments we received, we are finalizing our CY 2016 proposal without modification, including our proposal to assign drug or biological products status indicator ''K'' and pay for them separately for the remainder of CY 2015 if pricing information becomes available. Table 52 below shows the drugs and biologicals without CY 2014 claims data. Table 53 shows the drugs and biologicals without CY 2014 claims data and without pricing information for the ASP methodology.

TABLE 52—DRUGS AND BIOLOGICALS WITHOUT CY 2014 CLAIMS DATA

CY 2016 HCPCS code	CY 2016 long descriptor	Estimated average number of units per day	CY 2016 status indicator	CY 2016 APC
90581	Anthrax vaccine, for subcutaneous or intramuscular use	1	N	N/A
C9293	Injection, glucarpidase, 10 units	400	K	9293
J0215	Injection, alefacept, 0.5 mg	29	K	1633
J0630	Injection, calcitonin salmon, up to 400 units	2	K	1433
J1324	Injection, enfuvirtide, 1 mg	169	K	1361
J1556	Inj, Imm Glob Bivigam, 500mg	78	K	9130
J2670	Tolazoline hcl injection	1	K	1457
J3060	Inj, Taliglucerace Alfa 10 u	479	K	9294
J3355	Injection, urofollitropin, 75 IU	2	K	1741
J3489	Injection, Zoledronic Acid, 1mg	4	K	1356
J7191	Factor VIII (porcine)	8,500	K	1464
J7196	Injection, antithrombin recombinant, 50 IU	268	K	1332
J7316	Inj, Ocriplasmin, 0.125 mg	3	K	9298
J7513	Daclizumab, parenteral	5	K	1612
J8650	Nabilone, oral, 1 mg	4	K	1424

TABLE 52—DRUGS AND BIOLOGICALS WITHOUT CY 2014 CLAIMS DATA—Continued

CY 2016 HCPCS code	CY 2016 long descriptor	Estimated average number of units per day	CY 2016 status indicator	CY 2016 APC
J9047	Injection, carfilzomib, 1 mg	57	K	9295
J9262	Inj, omacetaxine mep, 0.01mg	481	K	9297
J9306	Injection, pertuzumab, 1 mg	450	K	1471
J9354	Inj, Ado-trastuzumab Emt 1mg	262	K	9131
J9400	Inj, ziv-aflibercept, 1mg	326	K	9296
Q2050	Injection, Doxorubicin Hydrochloride, Liposomal, Not Otherwise Specified, 10 mg.	7	K	7046
Q3027	Injection, Interferon Beta-1a, 1 mcg For Intramuscular Use	3	K	1472

TABLE 53—DRUGS AND BIOLOGICALS WITHOUT CY 2014 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2016 HCPCS code	CY 2016 long descriptor	CY 2016 status indicator
90296	Diphtheria antitoxin, equine, any route	E
90477	Adenovirus vaccine, type 7, live, for oral use	E
90681	Rotavirus vaccine, human, attenuated, 2 dose schedule, live, for oral use	E
J0190	Injection, biperiden lactate, per 5 mg	E
J0205	Injection, alglucerase, per 10 units	E
J0350	Injection, anistreplase, per 30 units	E
J0365	Injection, aprotonin, 10,000 kiu	E
J0395	Injection, arbutamine hcl, 1 mg	E
J0710	Injection, cephapirin sodium, up to 1 gm	E
J0888	Epoetin Beta, non-esrd	E
J1180	Injection, dyphylline, up to 500 mg	E
J1433	Inj Ferric Pyrophosphate Cit	E
J1435	Injection, estrone, per 1 mg	E
J1452	Injection, fomivirsen sodium, intraocular, 1.65 mg	E
J1562	Injection, immune globulin (vivaglobin), 100 mg	E
J1655	Injection, tinzaparin sodium, 1000 iu	E
J1835	Injection, itraconazole, 50 mg	E
J2513	Injection, pentastarch, 10% solution, 100 ml	E
J2725	Injection, protirelin, per 250 mcg	E
J2940	Injection, somatrem, 1 mg	E
J3320	Injection, spectinomycin dihydrochloride, up to 2 gm	E
J3400	Injection, triflupromazine hcl, up to 20 mg	E
J7505	Muromonab-cd3, parenteral, 5 mg	E
J8562	Fludarabine phosphate, oral, 10 mg	E
J9160	Injection, denileukin diftitox, 300 micrograms	E
J9215	Injection, interferon, alfa-n3, (human leukocyte derived), 250,000 iu	E
J9300	Injection, gemtuzumab ozogamicin, 5 mg	E
Q0515	Injection, sermorelin acetate, 1 microgram	E
Q9980	Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg	E

C. Self-Administered Drugs (SADs) Technical Correction

Sections 1861(s)(2)(A) and (s)(2)(B) of the Act define covered ''medical and other health services'' to include both ''services and supplies'' and ''hospital services'', which both, in turn, include drugs and biologicals not usually self-administered by the patient. Our regulations at 42 CFR 410.29 set forth limitations on payment of drugs and biologicals under Medicare Part B, and capture the description of self-administered drugs noted in sections 1861(s)(2)(A) and (s)(2)(B) of the Act. In our review of § 410.29, which defines exclusions to Medicare Part B payment for drugs and biologicals, we noted that paragraph (a), as currently written, excludes payment for any drug or biological that can be self-administered. In the CY 2016 OPPS/ASC proposed rule (80 FR 39285), we proposed to make a technical correction that would amend the description of these drugs and biologicals at § 410.29(a) to more appropriately reflect the statutory language. Specifically, we proposed to delete the phrase ''any drug or biological that can be self-administered'' and replace it with the phrase ''any drug or biological which is usually self-administered by the patient''.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposed technical correction to § 410.29 to amend the description of self-administered drugs and biologicals to more appropriately reflect the statutory language.

D. OPPS Payment for Biosimilar Biological Products

1. Background

The Affordable Care Act authorized an abbreviated pathway for the licensing of biosimilar biological products. Under this abbreviated pathway, a proposed biological product that is demonstrated to be biosimilar to a reference product can rely on certain existing scientific knowledge about the safety, purity, and potency of the reference product to support licensure. Section 3139 of the

Affordable Care Act amended section 1847A of the Act to add the definition of biosimilar biological product and set forth a payment methodology for biosimilar biological products. In 2010, CMS published regulations for the payment for biosimilar biological products that are administered in a physician's office (75 FR 73393 through 73394). However, at that time, it was not clear how or when the new Food and Drug Administration (FDA) approval pathway would be implemented or when biosimilar products would be approved.

The FDA approved the first biosimilar under the new pathway on March 6, 2015. In the CY 2016 OPPS/ASC proposed rule (80 FR 39285), we stated that by the end of 2015, we anticipated that the FDA may approve several more biosimilar biological products, including products that have a common previously licensed reference product. Although we described our Medicare Part B payment policy for biosimilar biological products when administered in the physician office setting in the CY 2011 MPFS final rule with comment period, we did not describe how payment would be made for these products when administered in the hospital outpatient department.

2. Payment Policy for Biosimilar Biological Products

Section 1833(t)(14)(A)(iii) of the Act defines payment policy for separately covered outpatient drugs (SCODs), and currently, CMS pays for SCODs under the payment methodology set forth at section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). Through rulemaking, CMS adopted this payment methodology to apply to separately payable drugs and biologicals that are not SCODs. Under this authority, the payment rate for SCODs and applicable separately payable drugs and biologicals is determined in accordance with sections 1842(o) and 1847A of the Act, which generally equates to average sales price (ASP) plus 6 percent.

As noted above, the Affordable Care Act amended section 1847A of the Act to add the definition of biosimilar biological product and set forth a payment methodology for biosimilar biological products. Since the statutory authority under section 1833(t)(14)(A)(iii)(II) of the Act authorizes payment in accordance with section 1847A of the Act, and provides additional discretionary authority for such payments to be calculated and adjusted by the Secretary as necessary, we believe that it is reasonable to adopt a policy to pay for biosimilar biological products as provided under section 1847A(b)(8) of the Act. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39285), we proposed to extend the application of the methodology for determining the amount of payment applicable to SCODs authorized by section 1833(t)(14)(A)(iii)(II) of the Act, which, through rulemaking, is applicable to separately paid drugs and biologicals, to biosimilar biological products provided under the OPPS. This equates to a payment determined under section 1847A of the Act. That is, we proposed to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act. In addition, we proposed that nonpass-through biosimilar biological products would be subject to our threshold-packaged policy as described in section V.B.2. of the proposed rule and this final rule with comment period.

Consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, we proposed that HCPCS coding and modifiers for biosimilar biological products will be based on policy established under the CY 2016 MPFS rule. We stated in the proposed rule that public comments on HCPCS codes and modifiers for biosimilar biological products should be submitted in response to the CY 2016 MPFS proposed rule.

We received several public comments on the proposed HCPCS coding and modifiers for biosimilar biological products. As proposed, under the OPPS, we will use the HCPCS codes and modifiers for biosimilar biological products based on policy established under the CY 2016 MPFS final rule with comment period. Therefore, we are considering the public comments received on biosimilar biological product HCPCS coding and modifiers in response to the CY 2016 OPPS/ASC proposed rule to be outside the scope to the proposed rule and we are not addressing them in this CY 2016 OPPS/ASC final rule with comment period. We refer readers to the CY 2016 MPFS final rule with comment period.

We are finalizing our proposal, without modification, to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act. In addition, we are finalizing our proposal, without modification, to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy.

3. OPPS Transitional Pass-Through Payment Policy for Biosimilar Biological Products

Section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable hospital outpatient department fee schedule amount. Because section 1842(o)(1)(C) of the Act cross references section 1847A of the Act, we believe that it is reasonable to infer that biosimilar biological products are eligible for transitional pass-through payment, and that such payment amount may be set as the difference between the amount paid under section 1842(o) of the Act (that is, the payment allowance of the product determined under section 1847A(b)(8) of the Act) and the otherwise applicable hospital outpatient department fee schedule amount. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39285), we proposed to extend pass-through payment eligibility to biosimilar biological products and to establish pass-through payment based on the difference between the amount paid under section 1842(o) of the Act (that is, the payment allowance of the product determined under section 1847A(b)(8) of the Act) and the otherwise applicable hospital outpatient department fee schedule amount.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39285), we solicited public comments on our proposed payment policies for biosimilar biological products, including whether biosimilar biological products should be eligible for transitional pass-through payment, and the appropriate methodologies for determining payment for biosimilar biological products eligible for transitional pass-through payment.

Comment: Commenters supported our proposed policy to extend pass-through payment eligibility to biosimilar biological products.

Response: We appreciate the commenters' support. We clarify that pass-through payment will be made to the first eligible biosimilar biological product to a reference product. Subsequent biosimilar biological products to a reference product will not meet the newness criterion at 42 CFR 419.64, and therefore will be ineligible for pass-through payment.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to extend pass-through payment eligibility to biosimilar biological products and to establish

pass-through payment based on the difference between the amount paid under section 1842(o) of the Act (that is, the payment allowance of the product determined under section 1847A(b)(8) of the Act) and the otherwise applicable hospital outpatient department fee schedule amount.

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate prorata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2016 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2016. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2015 or beginning in CY 2016. The sum of the CY 2016 pass-through estimates for these two groups of device categories equals the total CY 2016 pass-through spending estimate for device categories with pass-through status. We base the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010 that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the CY 2016 OPPS/ASC proposed rule (80 FR 39286), for CY 2016, we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 to 66888). Therefore, as we did beginning in CY 2015, for CY 2016, we also proposed to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

We did not receive any public comments on our proposed methodology or the proposed estimate for pass-through spending for devices. Therefore, we are finalizing our proposal to base the pass-through estimate for devices on our established methodology, as described above.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. We note that the Part B drug CAP program has been postponed since CY 2009, and such a program has not been reinstated for CY 2016. Because, as we proposed to pay for most non-pass-through separately payable drugs and biologicals under the CY 2016 OPPS at ASP+6 percent, as we discussed in section V.B.3. of the proposed rule and this final rule with comment period, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and biologicals, and because, as we proposed to pay for CY 2016 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of the proposed rule, our estimate of drug and biological pass-through payment for CY 2016 for this group of items is $0, as discussed below.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through status, will always be packaged into payment for the associated procedures and these products will not be separately paid. In addition, we policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section II.A.3. of this final rule with comment period. In the CY 2016 OPPS/ASC proposed rule (80 FR 39286), we proposed that all of these policy-packaged drugs and biologicals with pass-through status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2016. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through status approved prior to CY 2016 is not $0, as discussed below. In section V.A.4. of this final rule with comment period, we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we proposed to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving

pass-through payment, we proposed to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2016. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible in the remaining quarters of CY 2015 or beginning in CY 2016. The sum of the CY 2016 pass-through estimates for these two groups of drugs and biologicals equals the total CY 2016 pass-through spending estimate for drugs and biologicals with pass-through status.

B. Estimate of Pass-Through Spending

In the CY 2016 OPPS/ASC proposed rule (80 FR 39286), we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2016, consistent with section 1833(t)(6)(E)(ii)(II) of the Act, and our OPPS policy from CY 2004 through CY 2015 (79 FR 66897 through 66898).

For the first group, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2016, there are three active categories for CY 2016. For CY 2015, we established one new device category subsequent to the publication of the CY 2015 OPPS/ASC proposed rule, HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components), that was effective January 1, 2015. We estimated in the proposed rule that HCPCS code C2624 will cost $50.5 million in pass-through expenditures in CY 2016. Effective Apri1 1, 2015, we established that HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) will be eligible for pass-through payment. We estimated that HCPCS code C2623 will cost $73 million in pass-through expenditures in CY 2016. Effective July 1, 2015, we established that HCPCS code C2613 (Lung biopsy plug with delivery system) will be eligible for pass-through payment. We estimated that HCPCS code C2613 will cost $3.3 million in pass-through expenditures in CY 2016. Based on the three device categories of HCPCS codes C2624, C2623, and C2613, in the CY 2016 OPPS/ASC proposed rule (80 FR 39287), we proposed an estimate for the first group of devices of $126.8 million.

We did not receive any public comments on our proposed estimate for the first group of devices that included HCPCS codes C2624, C2623 and C2613. Therefore, we are finalizing the proposed estimate for this first group of devices of $126.8 million for CY 2016.

In estimating our proposed CY 2016 pass-through spending for device categories in the second group, we included: Additional device categories that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2016; and contingent projections for new device categories established in the second through fourth quarters of CY 2016. In the CY 2016 OPPS/ASC proposed rule (80 FR 39287), we proposed to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For the proposed rule, the estimate of CY 2016 pass-through spending for this second group of device categories was $10 million.

We did not receive any public comments on our proposed estimate for the second group of devices. Therefore, we are finalizing the proposed estimate for this second group of devices of $10 million for CY 2016.

To estimate proposed CY 2016 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for CY 2016, we proposed to use the most recent Medicare physician claims data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals to project the CY 2016 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2016, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately paid at ASP+6 percent, which is zero for this group of drugs. Because payment for policy-packaged drugs and biologicals is packaged if the product was not paid separately due to its pass-through status, we proposed to include in the CY 2016 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment. For the proposed rule, using the proposed methodology described above, we calculated a CY 2016 proposed spending estimate for this first group of drugs and biologicals of approximately $5.2 million.

We did not receive any public comments on our proposed methodology for calculating the spending estimate for the first group of drugs and biologicals.

For this final rule with comment period, using the methodology described above, we calculated a final CY 2016 spending estimate for the first group of drugs and biologicals of approximately $12.8 million.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39287), we also estimated proposed CY 2016 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the proposed rule were newly eligible for pass-through payment in CY 2016, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2016, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2016). We proposed to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2016 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2016 pass-through payments for this second group of

drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $4.6 million.

We did not receive any public comments on our proposed methodology for calculation of the spending estimate of the second group of drugs and nonimplantable biologicals, and therefore are finalizing its use in this final rule with comment period for CY 2016.

For this final rule with comment period, using our finalized methodology for estimating CY 2016 pass-through payments for this second group of drugs, we calculated a spending estimate for this second group of drugs and biologicals of approximately $11.2 million. Our CY 2016 estimate for total pass-through spending for drugs and biologicals (spending for the first group of drugs and biologicals ($12.8 million) plus spending for the second group of drugs and biologicals ($11.2 million)) equals approximately $24 million.

In summary, in accordance with the methodology described above in this section, for this final rule with comment period, we estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2016 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2016 will be approximately $160.8 million (approximately $136.8 million for device categories and approximately $24 million for drugs and biologicals), which represents 0.26 percent of total projected OPPS payments for CY 2016. Therefore, we estimate that pass-through spending in CY 2016 will not amount to 2.0 percent of total projected OPPS CY 2016 program spending.

VII. OPPS Payment for Hospital Outpatient Visits

A. Payment for Hospital Outpatient Clinic and Emergency Department Visits

Since April 7, 2000, we have instructed hospitals to report facility resources for clinic and emergency department (ED) hospital outpatient visits using the CPT E/M codes and to develop internal hospital guidelines for reporting the appropriate visit level (65 FR 18451). Because a national set of hospital-specific codes and guidelines does not currently exist, we have advised hospitals that each hospital's internal guidelines that determine the levels of clinic and ED visits to be reported should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the codes.

While many hospitals have advocated for hospital-specific national guidelines for visit billing since the OPPS started in 2000, and we have signaled in past rulemaking our intent to develop guidelines, this complex undertaking has proven challenging. Our work with interested stakeholders, such as hospital associations, along with a contractor, has confirmed that no single approach could consistently and accurately capture hospitals' relative costs. Public comments received on this issue, as well as our own knowledge of how clinics operate, have led us to conclude that it is not feasible to adopt a set of national guidelines for reporting hospital clinic visits that can accommodate the enormous variety of patient populations and service-mix provided by hospitals of all types and sizes throughout the country. Moreover, no single approach has been broadly endorsed by the stakeholder community.

With respect to outpatient clinic visits, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75045), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) for hospital use only, representing any and all clinic visits under the OPPS, and assigned HCPCS code G0463 to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits (five levels for new patient clinic visits and five levels for established patient clinic visits) previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

With respect to ED visits, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we also stated our policy that we would continue to use our existing methodology to recognize the existing CPT codes for Type A ED visits as well as the five HCPCS codes that apply to Type B ED visits, and to establish the OPPS payment under our established standard process. We refer readers to the CY 2014 OPPS/ASC final rule with comment period for a detailed discussion of the public comments and our rationale for the CY 2014 policies (78 FR 75036 through 75043).

In the CY 2016 OPPS/ASC proposed rule (80 FR 39287 through 39288), for CY 2016, we proposed to continue the current policy, adopted in CY 2014, for clinic and ED visits. HCPCS code G0463 (for hospital use only) will represent any and all clinic visits under the OPPS. As part of our broader initiative to restructure APCs across the OPPS to collectively group services that are clinically similar and have similar resource costs within the same APC, we proposed to reassign HCPCS code G0463 from existing APC 0634 to renumbered APC 5012 (Level 2 Examinations and Related Services), formerly APC 0632. Renumbered APC 5012 includes other services that are clinically similar with similar resource costs to HCPCS code G0463, such as HCPCS code G0402 (Initial preventive physical examination). We proposed to use CY 2014 claims data to develop the CY 2016 OPPS payment rate for HCPCS code G0463 based on the total geometric mean cost of HCPCS code G0463, as CY 2014 is the first year for which claims data are available for this code. Finally, as we established in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75042), there is no longer a policy to recognize a distinction between new and established patient clinic visits.

Comment: A few commenters requested that CMS discontinue the single HCPCS G-code for reporting clinic visits and return to a reporting structure that recognizes differences in clinical acuity and resource utilization. The commenters expressed concern that CMS' clinic visit coding policy creates a payment bias that unfairly penalizes certain providers, such as cancer hospitals, which provide care for more severely ill Medicare beneficiaries. One commenter believed that utilization of the single HCPCS G-code for reporting clinic visits does not provide a distinction between new and established patients and is administratively burdensome, as HCPCS G-codes are only recognized by Medicare.

Response: We believe that the spectrum of hospital resources provided during an outpatient hospital clinic visit is appropriately captured and reflected in the single level payment for clinic visits. We believe the proposed payment rate for APC 5012 represents an appropriate payment for clinic visits as it is based on the geometric mean costs of all visits. Although the cost for any given clinic visit may be higher or lower than the geometric mean cost of APC 5012, the payment remains appropriate to the hospital delivering a variety of

clinic visits. The high volume of claims used for ratesetting for HCPCS code G0463 allows us to have accurate data upon which to develop appropriate payment rates. With regard to specific concerns for hospitals that treat patients with a more complex case-mix, we note that the relatively low estimated cost of clinic visits overall would result in lesser underpayment or overpayment for hospitals that may serve a population with a more complex case-mix. In addition, past stakeholder and commenter support for eliminating distinctions for new and established patients (78 FR 75040 through 75041) suggests that hospitals prefer the administrative ease of not tracking new or established patients. Consistent with our longstanding practice, we will continue to monitor clinic visit costs under the OPPS.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to use HCPCS code G0463 (for hospital use only) to represent any and all clinic visits under the OPPS for CY 2016. In addition, we are finalizing our proposal to reassign HCPCS code G0463 from existing APC 0634 to renumbered APC 5012 and to use CY 2014 claims data to develop the CY 2016 OPPS payment rate for HCPCS code G0463 based on the total geometric mean cost of HCPCS code G0463, as CY 2014 is the first year for which claims data are available for this code. We note again that, as we established in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75042), we no longer have a policy to recognize a distinction between new and established patient clinic visits.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75040), we stated that additional study was needed to fully assess the most suitable payment structure for ED visits, including the particular number of visit levels that would not underrepresent resources required to treat the most complex patients, such as trauma patients, and that we believed it was best to delay any change in ED visit coding while we reevaluate the most appropriate payment structure for Type A and Type B ED visits. At this time, we continue to believe that additional study is needed to assess the most suitable payment structure for ED visits. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39288), we did not propose any change in ED visit coding. Rather, for CY 2016, we proposed to continue to use our existing methodology to recognize the existing five CPT codes for Type A ED visits as well as the five HCPCS codes that apply to Type B ED visits, and to establish the proposed CY 2016 OPPS payment rates using our established standard process. We stated that we may propose changes to the coding and APC assignments for ED visits in future rulemaking.

Comment: Commenters supported CMS' proposal to continue its current methodology to recognize the existing five CPT codes for Type A ED visits, as well as the five HCPCS codes for Type B ED visits for CY 2016, and to establish the associated CY 2016 OPPS payment rates using its standard process. One commenter urged CMS to develop standard ED visit guidelines for a 5-level E/M system for the ED.

Response: We appreciate the commenters' support. As we have in the past (76 FR 74345 through 74346), we acknowledge that it would be desirable to many hospitals to have national ED visit guidelines for a 5-level E/M system for the ED. However, we also understand that it would be disruptive and administratively burdensome to other hospitals that have successfully adopted internal guidelines to have to implement new national guidelines, particularly while we address the problems that would inevitably arise with the implementation of a new set of guidelines being applied by thousands of hospitals.

Comment: One commenter recommended, as an alternative to our proposed policy, that CMS develop, on a short-term basis, a set of three trauma-specific HCPCS codes for all trauma patients for whom a trauma team is activated. The commenter also recommended that CMS consider a long-term restructuring of payment for trauma care, developed by specifically taking the following steps:

- CMS should rigorously evaluate historical trauma cases data to better understand the precise nature of trauma care and how it is reimbursed.
- Armed with this understanding, CMS should develop a complete value-based reimbursement model for trauma care, distinct from the fee-for-service reimbursement for ED visits, based on the conceptual framework of the Trauma Center Association of America (TCAA).
- CMS should test its value-based reimbursement model through a pilot program or simulation to ensure that it accurately compensates trauma centers for providing an appropriate level of care.
- CMS should incorporate its restructured model into the hospital OPPS as expeditiously as possible.

Response: We appreciate the alternatives presented by the commenter. We will take this recommendation into consideration as we continue to study and fully consider the most appropriate payment structure for Type A and Type B ED visits.

After consideration of the public comments we received, we are finalizing our proposals, without modification, to continue to use our existing methodology to recognize the existing CPT codes for Type A ED visits as well as the five HCPCS codes that apply to Type B ED visits, and to establish the CY 2016 OPPS payment rates using our established standard process. We intend to further explore the issues described above related to ED visits, including concerns about excessively costly patients, such as trauma patients. We note that we may propose changes to the coding and APC assignments for ED visits in the future rulemaking.

B. Payment for Critical Care Services

For the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). In the CY 2014 OPPS/ASC final rule with comment period, we continued to use the methodology established in the CY 2011 OPPS/ASC final rule with comment period for calculating a payment rate for critical care services that includes packaged payment of ancillary services, for example electrocardiograms, chest X-rays, and pulse oximetry. Critical care services are described by CPT codes 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) and 99292 (Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)).

Since CY 2013, we have stated that we would continue to monitor the hospital claims data for CPT code 99291 in order to determine whether revisions to our current payment policy for critical care services are warranted based on changes in hospitals' billing practices. Because the CY 2011 through CY 2014 claims data (used for CY 2013 through CY 2016 ratesetting, respectively) do not demonstrate any significant change in hospital billing practices for critical care services, we continue to believe that it would be inappropriate to pay separately for the ancillary services that hospitals typically report in addition to CPT codes for critical care services. Based on this pattern of billing practices, we continue to believe that packaging ancillary services into critical care

services is appropriate. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39288), for CY 2016 and subsequent years, we proposed to continue our policy (that has been in place since CY 2011) to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data. We also proposed to continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment.

Comment: One commenter opposed the claims processing edits conditionally packaging payment for the ancillary services that are reported on the same date of service as critical care services. The commenter also encouraged CMS to use recent data in setting the rates for critical care.

Response: As we stated in the proposed rule (80 FR 39288), because the CY 2011 through CY 2014 claims data (used for CY 2013 through CY 2016 ratesetting, respectively) do not demonstrate any significant change in hospital billing practices for critical care services, we continue to believe that it would be inappropriate to pay separately for the ancillary services that hospitals typically report in addition to CPT codes for critical care services. Based on this pattern of billing practices, we continue to believe that packaging ancillary services into critical care services is appropriate. We note that CY 2014 claims data used for CY 2016 ratesetting represents the most recent complete year of available claims data.

After consideration of the public comments we received, we are finalizing our proposals, without modification, to continue our policy to recognize the existing CPT codes for critical care services and establish a payment rate based on historical claims data, and to continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment.

C. Payment for Chronic Care Management Services

In the CY 2015 OPPS/ASC final rule with comment period, we assigned CPT code 99490 to APC 0631 (Level 1 Examinations and Related Services), with a payable status indicator of ''V,'' under general physician supervision. (We note that in the CY 2016 OPPS/ASC proposed rule (80 FR 39288), for CY 2016 and subsequent years, we proposed to renumber APC 0631 as APC 5011.) The current code descriptor for CPT code 99490 is ''Chronic care management services (CCM), at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month), with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;
- Chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; and
- Comprehensive care plan established, implemented, revised, or monitored.''

CPT code 99490 is a physician-directed service, where the physician is directing the clinical staff time spent on care management for a specific patient. As a physician-directed service, payment under the OPPS for services described by CPT code 99490 is made to the hospital when the hospital's clinical staff furnishes the service at the direction of the physician (or other appropriate nonphysician practitioner) who meets all the requirements to bill for services described by CPT code 99490 under the MPFS. The billing physician or nonphysician practitioner directing the CCM services must meet the requirements to bill CPT code 99490 under the MPFS. These requirements are the same, regardless of whether the services described by CPT code 99490 are furnished in the office or in the HOPD.

While the services described by CPT code 99490 has been payable under the OPPS since January 1, 2015, we have received questions about specific requirements for hospitals to bill this code beyond those requirements discussed in the CY 2015 MPFS final rule with comment period (79 FR 67721). In response to these questions, we posted frequently asked questions (FAQs) and answers on the CMS Web site on May 8, 2015. These FAQs can be accessed on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/*. In reviewing the questions from hospitals on billing of CCM services, we identified several issues that we believe need to be clarified. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39289), for CY 2016 and subsequent years, we proposed additional requirements for hospitals to bill and receive OPPS payment for CMM services described by CPT code 99490. These proposed requirements, discussed below, are in addition to those already required under the OPPS for billing for services described by CPT code 99490 in CY 2015.

In accordance with the CPT code descriptor for CPT code 99490, a hospital can only bill CMM services described by CPT code 99490 and receive payment under the OPPS for furnishing clinical staff services under a physician's or other appropriate nonphysician practitioner's direction to a patient that has multiple (two or more) chronic conditions expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. While we have always expected the hospital furnishing the clinical staff portion of CCM services, as described by CPT code 99490, to have an established relationship with the patient and to provide care and treatment to the patient during the course of illness (that is, the chronic conditions that are expected to last at least 12 months), we have not previously specified through notice-and-comment rulemaking that the hospital must have an established relationship with the patient as a requirement for billing and OPPS payment for CMM services described by CPT code 99490. Therefore, for CY 2016 and subsequent years, we proposed that a hospital would be able to bill CPT code 99490 for CCM services only when furnished to a patient who has been either admitted to the hospital as an inpatient or has been a registered outpatient of the hospital within the last 12 months and for whom the hospital furnished therapeutic services. Section 20.2, Chapter 4 of the Medicare Claims Processing Manual (Pub. 100–04) defines a hospital outpatient as a person who has not been admitted by the hospital as an inpatient but is registered on the hospital records as an outpatient and receives services (other than supplies alone) from the hospital. We believe that hospitals furnishing services described by CPT code 99490 are, in all likelihood, already meeting this requirement because they are providing CCM services described by CPT code 99490 to patients for whom they already provide care and treatment. However, we proposed to adopt the relationship requirement as an explicit condition for billing and payment of CCM services under the OPPS.

As outlined in the CY 2015 MPFS final rule with comment period (79 FR 67721 through 67722), practitioners furnishing and billing CCM services as described by CPT code 99490 under the MPFS are required to (1) inform the beneficiary about the availability of the CCM services from the practitioner and

obtain his or her written agreement to have the service(s) provided; (2) document in the beneficiary's medical record that all elements of the CCM service(s) were explained and offered to the beneficiary, noting the beneficiary's decision to accept or decline the service; and (3) inform the beneficiary that only one practitioner can furnish and be paid for these services during the calendar month service period. For CY 2016 and subsequent years, we proposed to adopt analogous requirements for billing services described by CPT code 99490 under the OPPS. Specifically, we proposed, for CY 2016 and subsequent years, that hospitals furnishing and billing services described by CPT code 99490 under the OPPS would be required to have documented in the hospital's medical record the patient's agreement to have the services provided or, alternatively, to have the patient's agreement to have the CCM services provided documented in a beneficiary's medical record that the hospital can access. In addition, for CY 2016 and subsequent years, we proposed to require hospitals furnishing and billing for the CCM services described by CPT code 99490 under the OPPS to have documented in the hospital medical record (or beneficiary medical record that the hospital can access) that all elements of the CCM services were explained and offered to the beneficiary, including a notation of the beneficiary's decision to accept or decline the services. If the hospital is billing for the CCM services, we would expect the physician or practitioner under whose direction the services are furnished to have discussed with the beneficiary that hospital clinical staff will furnish the services and that the beneficiary could be liable for two separate copayments from both the hospital and the physician. Consistent with the MPFS requirement that only one practitioner can furnish and be paid for services described by CPT code 99490 during the calendar month service period, we proposed, for the OPPS for CY 2016 and subsequent years, that only one hospital can furnish and be paid for services described by CPT code 99490 during the calendar month service period. The physician or other appropriate nonphysician practitioner directing the CCM services should inform the beneficiary that only one hospital can furnish and be paid for these services during the calendar month service period. These proposed requirements are consistent with and support the MPFS requirements set forth in the CY 2015 MPFS final rule with comment period (79 FR 67728).

Comment: Commenters generally supported CMS' proposed policy to adopt billing requirements for CMM services described by CPT code 99490 analogous to those required for billing under the MPFS for CY 2016 and subsequent years. A few commenters encouraged CMS to continue to actively work with stakeholders to ensure that the implementation of these codes will not be administratively burdensome. Another commenter requested that CMS clarify in the final rule whether one hospital (paid under OPPS) and one practitioner (paid under the MPFS) may furnish and be paid for services described by CPT code 99490 during a calendar month, or whether only one provider across all care settings may be paid for the service. One commenter requested that CMS amend the hospital claim form so that the ''place of service'' code can be noted to permit better data capture and monitoring of the settings in which CCM services are provided.

Response: We appreciate commenters' support for our proposal. We look forward to hearing from stakeholders about the administrative requirements associated with hospital billing of CMM services described by CPT code 99490.

We reiterate that one hospital (paid under the OPPS) and one practitioner (paid under the MPFS) may furnish and be paid for services described by CPT code 99490 during a calendar month when CCM services are furnished by a physician in an HOPD to an eligible patient. Specifically, in this scenario, the physician or nonphysician practitioner may bill Medicare for services described by CPT code 99490 under the MPFS and report the hospital outpatient setting as the place of service. The hospital also may bill for the services described by CPT code 99490 under the OPPS. The physician or nonphysician practitioner would be paid under the MPFS at the facility rate, and the hospital would be paid under the OPPS.

Comment: With respect to the proposed requirement that a patient must have either been admitted to the hospital as an inpatient or have been a registered outpatient of the hospital and received therapeutic services from the hospital within the last 12 months, one commenter requested that CMS permit a hospital to bill for services described by CPT 99490 if the physician or nonphysician practitioner providing general supervision previously furnished CCM services for the beneficiary, but the physician's or nonphysician practitioner's practice was subsequently acquired by a hospital that does not have an established relationship with the patient.

Response: Because only one hospital may furnish CCM services to a patient during a billing period and the patient's consent to have such services furnished must be documented in the medical record, we believe it is necessary for the hospital to have an established relationship with the patient, as we proposed. We note that a physician or other qualified nonphysician practitioner who previously billed CCM services for a patient under the MPFS at the nonfacility rate could continue to do so (assuming that all requirements for billing under the MPFS are met). However, if the place of service becomes a hospital outpatient department, payment under the MPFS would be made. We also believe, given that patients who receive CCM services have multiple chronic conditions, patients would be likely to have an established relationship with the hospital. Accordingly, we do not believe that we should modify this requirement at this time.

Comment: Commenters requested that CMS: (1) Classify the services described by CPT code 99490 as a preventive service; and (2) allow for billing and separate payment of complex chronic care codes (CPT 99487 and 99489) at similar rates to the AMA Relative Value Scale Update Committee's (RUC's) recommended values.

Response: The services described by CPT code 99490 are not preventive services because they do not have a USPSTF rating of A or B, nor are they explicitly defined as a preventive service in the statute. In addition, the complex CCM services described by CPT codes 99487 and 99489 are currently eligible to be reported when performed in the outpatient hospital setting and are assigned status indicator ''N,'' which indicates that payment is packaged for these services. We may consider separate payment for complex CMM services described by CPT codes 99497 and 99489 in future rulemaking.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to require hospitals, in order to bill and receive OPPS payment for CMM services described by CPT code 99490, to have documented in the hospital's medical record the patient's agreement to have the services provided or, alternatively, to have the patient's agreement to have the CCM services provided documented in a beneficiary's medical record that the hospital can access. In addition, for CY 2016 and subsequent years, we are requiring hospitals furnishing and billing for the CCM services described by CPT code 99490 under the OPPS to have

documented in the hospital medical record (or beneficiary medical record that the hospital can access) that all elements of the CCM services were explained and offered to the beneficiary, including a notation of the beneficiary's decision to accept or decline the services. In addition, only one hospital under the OPPS (in addition to only one practitioner under the MPFS) can furnish and be paid for services described by CPT code 99490 during the calendar month service period.

In addition, a number of scope of service elements for CCM services were finalized as requirements to bill for CCM services described by CPT code 99490 in the CY 2015 MPFS final rule with comment period (79 FR 67715 through 67728). For CY 2016 and subsequent years, in the CY 2016 OPPS/ASC proposed rule (80 FR 39289 through 39290), we proposed to require analogous scope of service elements for the CCM services, listed below, to be met in order for hospitals to bill and receive OPPS payment for furnishing CCM services described by CPT code 99490. Specifically, we proposed to require a hospital that bills and receives OPPS payment for their clinical staff furnishing CCM services described by CPT code 99490 under the direction of a physician or other qualified nonphysician practitioner to provide—

- Structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary record. A full list of problems, medications, and medication allergies in the electronic health record (EHR) must inform the care plan, care coordination, and ongoing clinical care.
- Access to care management services 24 hours a day/7 days a week (providing the beneficiary with a means to make timely contact with health care providers to address his or her urgent chronic care needs, regardless of the time of day or day of the week).
- Continuity of care with a designated practitioner or member of the care team with whom the beneficiary is able to get successive routine appointments.
- Care management for chronic conditions, including systematic assessment of the beneficiary's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of beneficiary self-management of medications.
- Documentation of the creation of a patient-centered care plan based on a physical, mental, cognitive, psychosocial, functional, and environmental assessment or reassessment and an inventory of resources and supports (a comprehensive care plan for all health issues). Electronically capture care plan information, make this information available on a 24 hour/7 day a week basis to all practitioners furnishing CCM services, and electronically share, as appropriate, with other practitioners and providers.
- A written or electronic copy of the care plan provided to the beneficiary, and document its provision in the electronic medical record using certified information technology (IT).
- Management of care transitions between and among health care providers and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities, or other health care facilities. Electronic transmission of a clinical summary created using certified health IT to support care transitions.
- Coordination with home-based and community-based clinical service providers required to support the patient's psychosocial needs and functional deficits. Communication to and from home-based and community-based providers regarding these patient needs must be documented in the patient's medical record.
- Enhanced opportunities for the beneficiary and any caregiver to communicate with the practitioner regarding the beneficiary's care through not only telephone access, but also through the use of secure messaging, internet, or other asynchronous non-face-to-face consultation methods.

Lastly, with respect to the EHR, for CY 2016 and subsequent years, we proposed to adopt the requirements set forth in the CY 2015 MPFS final rule with comment period (79 FR 67723 through 67724) and detailed below for billing services described by CPT code 99490 under the OPPS. Specifically, for CY 2016 and subsequent years, we proposed to require the use of EHR technology that has been certified under the ONC Health Information Technology (IT) Certification Program as requisite for hospitals furnishing and receiving payment under the OPPS for the clinical staff portion of CCM services, to ensure that hospitals have adequate capabilities to allow members of the interdisciplinary care team to have timely access to the most updated information informing the care plan. We proposed, for hospital payment under the OPPS, that the CCM services as described by CPT code 99490 must be furnished using, at a minimum, the Edition(s) of certification criteria that is acceptable for purposes of the EHR Incentive Programs as of December 31 of the calendar year preceding each MPFS payment year to meet the following core technology capabilities: Structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary. We also proposed to require hospitals to use certified IT to fulfill the CCM scope of service requirements whenever the requirements reference a health or medical record. This would ensure that requirements for billing CCM services under the MPFS and the OPPS are consistent throughout each MPFS and OPPS payment year, and are automatically updated according to the certification criteria required for the EHR Incentive Programs. For payment for CCM services under the OPPS in CY 2016, this policy would allow hospitals to use EHR technology certified to, at a minimum, the 2014 Edition of certification criteria to meet the final core capabilities for CCM services and to fulfill the scope of service requirements for CCM services whenever the requirements reference a health or medical record. The CY 2015 MPFS final rule with comment period (79 FR 67728) includes a detailed table summarizing when certified health IT is required to support the scope of service requirements. We remind stakeholders that, for all electronic sharing of beneficiary information under our final CCM services policies, HIPAA standards apply in the usual manner.

Comment: One commenter urged CMS to avoid placing overly burdensome requirements for billing and payment for services described by CPT code 99490. The commenter recommended that CMS eliminate the requirement for use of certified EHRs because current certified EHRs do not include standards and capabilities supporting chronic care management that are core services for CCM. Another commenter asked that CMS end its tacit acceptance of information blocking in Federal programs. The commenter encouraged CMS to create demand side pressure on vendors by limiting billing for the CCM services to only those providers who use systems that do not limit information exchange as defined in the ONC report to Congress. Some commenters encouraged CMS to allow the care plan to be shared with community providers through facsimile methods when electronic options are not available.

Response: We disagree with the commenter's assertion that the requirement for use of a certified EHR

when performing CCM services is overly burdensome and reiterate our belief that the use of certified health IT is an important tool for delivering several core elements of CCM services. We recognize that certified health IT does not currently possess all of the capabilities needed to deliver CCM services, and accordingly, we have restricted requirements around the use of certified EHRs to a narrow set of elements. We also have provided flexibility with respect to the technology needed to support elements such as the transmission of clinical summaries created using certified health IT.

We appreciate the comments regarding the challenges that information blocking is likely to pose to providers furnishing CCM services that are required to deliver care coordination services for beneficiaries. While we did not include any proposal to tie the ability to bill for CCM services to information blocking in the proposed rule, we may consider such action in the future. For further information, we refer readers to ONC's April 2015 Report to Congress on health information blocking, which is available on the Web site at: *http://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf*.

We believe it is important that providers furnishing CCM services are able to share care plan information electronically with other providers to support robust care coordination. We note that we did not identify any specific electronic tool or format for sharing care plan information, and we encourage providers furnishing CCM services to explore a range of innovative solutions in this area. In the future, we may consider issuing subregulatory guidance providing an exception to the requirement to transmit clinical summaries and care plan information electronically by a means other than facsimile, when the receiving practitioner or provider is not billing Medicare for the CCM service and is only able or willing to receive the required information by facsimile.

Comment: One commenter asked CMS to clarify whether the required EHR system used for CCM is one that has been certified as an inpatient EHR or as an ambulatory EHR. The commenter also asked CMS to clarify whether the required EHR system must be able to generate a specific form of the clinical summary (such as that specified for the Transitions of Care—create and transmit transition of care/referral summaries certification criterion—at 45 CFR 170.314(b)(2)) or if there is discretion for a hospital to use a different format for and the content of the clinical summary other than a summary that contains any particular structured content. The commenter asked if there was any particular prescription for the content and specification of the clinical summary, including whether such are limited to those required for certification under § 170.314(b)(2).

Response: In the proposed rule, we did not identify a specific type of certification for the system used by a provider furnishing CCM services. We are clarifying that the technology certified for either the inpatient setting or the outpatient setting may be used to furnish CCM services, provided it meets the relevant requirements. Furthermore, we proposed that providers must support care transitions using electronic transmission of a clinical summary created using certified health IT, but we did not identify the specific certification criteria that provider technology must meet. We are clarifying that, as long as the clinical summary has been created using certified health IT and is electronically transmitted, providers can meet the CCM requirements. For instance, the clinical summaries currently generated by EHR systems in accordance with the 2014 Edition certification criterion for inpatient settings at § 170.314(b)(2) of the regulations would meet the requirements to bill for CCM services.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to require analogous scope of service elements for the CCM services to be met in order for hospitals to bill and receive OPPS payment for furnishing CCM services described by CPT code 99490.

VIII. Payment for Partial Hospitalization Services

A. Background

Partial hospitalization is an intensive outpatient program of psychiatric services provided to patients as an alternative to inpatient psychiatric care for individuals who have an acute mental illness. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a CMHC (as defined in subparagraph (B)), and which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit.

Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the OPD services to be covered under the OPPS. The Medicare regulations that implement this provision specify, under 42 CFR 419.21, that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs as well as Medicare Part B services furnished to hospital outpatients designated by the Secretary, which include partial hospitalization services (65 FR 18444 through 18445).

Section 1833(t)(2)(C) of the Act, in pertinent part, requires the Secretary to establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, subparagraph (B) provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we have developed the PHP APCs. Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we established a per diem payment methodology for the PHP APCs, effective for services furnished on or after July 1, 2000 (65 FR 18452 through 18455). Under this methodology, the

median per diem costs have been used to calculate the relative payment weights for PHP APCs.

From CY 2003 through CY 2006, the median per diem costs for CMHCs fluctuated significantly from year to year, while the median per diem costs for hospital-based PHPs remained relatively constant. We were concerned that CMHCs may have increased and decreased their charges in response to Medicare payment policies. Therefore, we began efforts to strengthen the PHP benefit through extensive data analysis and policy and payment changes finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). We made two refinements to the methodology for computing the PHP median: The first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill. We refer readers to a complete discussion of these refinements in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676).

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tiered payment approach for PHP services under which we paid one amount for days with 3 services under APC 0172 (Level 1 Partial Hospitalization) and a higher amount for days with 4 or more services under APC 0173 (Level 2 Partial Hospitalization). We refer readers to section X.B. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68693) for a full discussion of the two-tiered payment system. In addition, for CY 2009, we finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694).

Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements under 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). These changes have helped to strengthen the PHP benefit. We also revised the partial hospitalization benefit to include several coding updates. We refer readers to section X.C.3. of the CY 2009 OPPS/ASC final rule with comment period (73 FR 68695 through 68697) for a full discussion of these requirements.

For CY 2010, we retained the two-tiered payment approach for PHP services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In CY 2011, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. In addition, in accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth under section 1861(ff)(3)(B) of the Act. We discussed our finalized policies for these two provisions of HCERA 2010 in section X.C. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71990).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we also established four separate PHP APC per diem payment rates, two for CMHCs (for Level 1 and Level 2 services) and two for hospital-based PHPs (for Level 1 and Level 2 services), based on each provider's own unique data. As stated in the CY 2011 OPPS/ASC proposed rule (75 FR 46300) and the final rule with comment period (75 FR 71991), for CY 2011, using CY 2009 claims data, CMHC costs had significantly decreased again. We attributed the decrease to the lower cost structure of CMHCs compared to hospital-based PHP providers, and not the impact of the CY 2009 policies. CMHCs have a lower cost structure than hospital-based PHP providers, in part, because the data showed that CMHCs generally provide fewer PHP services in a day and use less costly staff than hospital-based PHPs. Therefore, it was inappropriate to continue to treat CMHCs and hospital-based providers in the same manner regarding payment, particularly in light of such disparate differences in costs. We also were concerned that paying hospital-based PHPs at a lower rate than their cost structure reflects could lead to hospital-based PHP closures and possible access problems for Medicare beneficiaries because hospital-based PHPs are located throughout the country and, therefore, offer the widest access to PHP services. Creating the four payment rates (two for CMHCs and two for hospital-based PHPs) based on each provider's data supported continued access to the PHP benefit, while also providing appropriate payment based on the unique cost structures of CMHCs and hospital-based PHPs. In addition, separation of data by provider type was supported by several hospital-based PHP commenters who responded to the CY 2011 OPPS/ASC proposed rule (75 FR 71992).

For CY 2011, we instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates based solely on CMHC data. For CY 2011, under the transition methodology, CMHC PHP APCs Level 1 and Level 2 per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based PHP median costs and the CY 2011 final CMHC median costs and then adding that number to the CY 2011 final CMHC median costs. A 2-year transition under this methodology moved us in the direction of our goal, which is to pay appropriately for PHP services based on each provider type's data, while at the same time allowing providers time to adjust their business operations and protect access to care for beneficiaries. We also stated that we would review and analyze the data during the CY 2012 rulemaking cycle and, based on these analyses, we might further refine the payment mechanism. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion.

After publication of the CY 2011 OPPS/ASC final rule with comment period, a CMHC and one of its patients filed an application for a preliminary injunction, challenging the OPPS payment rates for PHP services provided by CMHCs in CY 2011 as adopted in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71995). We refer readers to the court case, *Paladin Cmty. Mental Health Ctr.* v. *Sebelius*, 2011 WL 3102049 (W.D.Tex. 2011), *aff'd*, 684 F.3d 527 (5th Cir. 2012) (*Paladin*). The plaintiffs in the *Paladin* case challenged the agency's use of cost data derived from both hospitals and CMHCs in determining the relative payment weights for the OPPS payment rates for PHP services furnished by CMHCs, alleging that section 1833(t)(2)(C) of the

Act requires that such relative payment weights be based on cost data derived solely from hospitals. As discussed above, section 1833(t)(2)(C) of the Act requires CMS to establish relative payment weights for covered OPD services (and any groups of such services) based on hospital costs. Numerous courts have held that ''based on'' does not mean ''based exclusively on.'' On July 25, 2011, the District Court dismissed the plaintiffs' complaint and application for a preliminary injunction for lack of subject-matter jurisdiction, which the plaintiffs appealed to the United States Court of Appeals for the Fifth Circuit. On June 15, 2012, the Court of Appeals affirmed the District Court's dismissal for lack of subject-matter jurisdiction and found that the Secretary's payment rate determinations for PHP services are not a facial violation of a clear statutory mandate (*Paladin*, 684 F.3d at 533).

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), we determined the relative payment weights for PHP services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for hospital-based PHP services based exclusively on hospital data. The statute is reasonably interpreted to allow the relative payment weights for the OPPS payment rates for PHP services provided by CMHCs to be based solely on CMHC data and relative payment weights for hospital-based PHP services to be based exclusively on hospital data. Section 1833(t)(2)(C) of the Act requires the Secretary to establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on hospital costs. In pertinent part, subparagraph (B) provides that the Secretary may establish groups of covered OPD services so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with subparagraph (B), we developed the PHP APCs, as set forth in § 419.31 of the regulations (65 FR 18446 and 18447; 63 FR 47559 through 47562 and 47567 through 47569). As discussed above, PHP services are grouped into APCs.

Based on section 1833(t)(2)(C) of the Act, we believe that the word ''establish'' can be interpreted as applying to APCs at the inception of the OPPS in 2000 or whenever a new APC is added to the OPPS. In creating the original APC for PHP services (APC 0033), we did ''establish'' the initial relative payment weight for PHP services, provided in both hospital-based and CMHC-based settings, only on the basis of hospital data. Subsequently, from CY 2003 through CY 2008, the relative payment weights for PHP services were based on a combination of hospital and CMHC data. For CY 2009, we established new APCs for PHP services based exclusively on hospital data. Specifically, we adopted a two-tiered APC methodology (in lieu of the original APC 0033) under which CMS paid one rate for days with 3 services (APC 0172) and a different payment rate for days with 4 or more services (APC 0173). These two new APCs were established using only hospital data. For CY 2011, we added two new APCs (APCs 0175 and 0176) for PHP services provided by hospitals and based the relative payment weights for these APCs solely on hospital data. APCs 0172 and 0173 were designated for PHP services provided by CMHCs and were based on a mixture of hospital and CMHC data. As the Secretary argued in the *Paladin* case, the courts have consistently held that the phrase ''based on'' does not mean ''based exclusively on.'' Thus, the relative payment weights for the two APCs for PHP services provided by CMHCs in CY 2011 were ''based on'' hospital data, no less than the relative payment weights for the two APCs for hospital-based PHP services.

Although we used hospital data to establish the relative payment weights for APCs 0033, 0172, 0173, 0175, and 0176 for PHP services, we believe that we have the authority to discontinue the use of hospital data in determining the OPPS relative payment weights for PHP services provided by CMHCs. Other parts of section 1833(t)(2)(C) of the Act make plain that the data source for the relative payment weights is subject to change from one period to another. Section 1833(t)(2)(C) of the Act provides that, in establishing the relative payment weights, the Secretary shall use data on claims from 1996 and use data from the most recent available cost reports. We used 1996 data (in addition to 1997 data) in determining only the original relative payment weights for 2000. In the ensuing calendar year updates, we continually used more recent cost report data.

Moreover, section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. For purposes of the CY 2012 update, we exercised our authority under section 1833(t)(9)(A) of the Act to change the data source for the relative payment weights for PHP services provided by CMHCs based on new cost data, and other relevant information and factors.

In the CY 2014 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs, on geometric mean costs rather than on the median costs. For CY 2014, we established the four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims and cost data for each provider type. We refer readers to the CY 2014 OPPS/ASC final rule with comment period for a more detailed discussion (78 FR 75047 through 75050).

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on PHP APC geometric mean per diem costs using the most recent claims and cost data for each provider type.

B. PHP APC Update for CY 2016

1. PHP APC Geometric Mean per Diem Costs

In the CY 2016 OPPS/ASC proposed rule (80 FR 39290 through 39299), for CY 2016, we proposed to continue to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. We proposed to compute CMHC PHP APC geometric mean per diem costs for Level 1 (3 services per day) and Level 2 (4 or more services per day) PHP services using only CY 2014 CMHC claims data and the most recent cost data, and hospital-based PHP APC geometric mean per diem costs for Level 1 and Level 2 PHP services using only CY 2014 hospital-based PHP claims data and the most recent cost data. These proposed geometric mean per diem costs were shown in Tables 50 and 51 of the CY 2016 OPPS/ASC proposed rule (80 FR 39295). To prevent confusion, we referred to the per diem information listed in Tables 50 and 51 of the CY 2016 OPPS/ASC proposed rule as the proposed PHP APC per diem costs or the proposed PHP APC geometric mean per diem costs, and the per diem information listed in Addendum A to the CY 2016 OPPS/ASC proposed rule as the proposed PHP APC per diem payment rates or the proposed PHP APC geometric mean per diem

payment rates. The PHP APC per diem costs are the provider-specific costs derived from the most recent claims and cost data. The PHP APC per diem payment rates are the national unadjusted payment rates calculated after applying the OPPS budget neutrality adjustments described in sections II.A.4. and II.B. of the CY 2016 OPPS/ASC proposed rule and this final rule with comment period.

As part of the effort to increase the accuracy of the PHP per diem costs, we completed an extensive analysis of the claims and cost data, which included provider service usage, coding practices, and the ratesetting methodology. As part of our analysis, we also identified aberrant data from several providers that impacted the calculation of the proposed PHP geometric mean per diem costs. Aberrant data are claims and/or cost data that are so abnormal that they skew the resulting geometric mean per diem costs. For example, we found claims with excessive CMHC charges resulting in CMHC geometric mean costs per day that were approximately the same as or more than the daily payment for inpatient psychiatric facility services. For an outpatient program like PHP, because it does not incur room and board costs such as an inpatient stay would, these costs per day were excessive. In addition, we found some CMHCs had very low costs per day (less than $25 per day). We stated in the CY 2016 OPPS/ASC proposed rule (80 FR 39293) that without using a trimming process, the data from these providers would inappropriately skew the geometric mean per diem cost for Level 2 CMHC PHP services. Without the trim, the CMHC PHP APC geometric mean per diem cost was $172.62 for Level 2 services, which significantly diverges from the median cost per day of $148.14. When data are not skewed and are normally distributed, measures of central tendency such as the median and geometric mean will be very similar to each other. The differences between these two measures for CMHCs suggested skewing. Further analysis of the data confirmed that there were a few providers with extreme cost per day values, which led us to propose using a ±2 standard deviation trim.

During our claims and cost data analysis, we also found aberrant data from some hospital-based PHP providers. Nearly all hospital-based PHPs recorded their costs using cost center 9000 (''Clinic'') as the source for the CCR for individual or group therapy services, psychiatric testing, and education/training services. These services comprise the majority of the PHP services provided. The existing OPPS ±3 standard deviation trim removed very extreme CCRs for cost center 9000, which were less than 0.0206 or greater than 28.3446, by defaulting two providers that failed this trim to their overall hospital ancillary CCR. However, the calculation of the ±3 standard deviations used to define the trim for cost center 9000 was influenced by these two providers, which had very extreme CCRs of 178.0224 and 272.4451. Because these two hospital-based PHP providers remained in the data when we calculated the boundaries of the OPPS ±3 standard deviation trim, the upper limit of the trim boundaries was fairly high, at 28.3446. As such, some aberrant CCRs for cost center 9000 were not trimmed out, and still had high values ranging from 6.3840 to 19.996. We note in section II.D. of the CY 2016 OPPS/ASC proposed rule that OPPS defines a biased CCR as one that falls outside the predetermined ceiling threshold for a valid CCR; using CY 2014 cost report data, that threshold is 1.5. The hospital CCR ceiling thresholds or upper limits are available online at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files-Items/2015-Annual-Policy-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.*

In the CY 2016 OPPS/ASC proposed rule (80 FR 39293), we stated that we are concerned that including aberrant data in the calculation of the hospital-based PHP per diem payment rates would inappropriately skew these payment rates. When we included these aberrant CCRs, which ranged from 6.3840 to 19.996, in hospital-based PHP cost modeling, the geometric mean per diem costs were $267.04 for Level 1 services and $223.39 for Level 2 services. We noted that the geometric mean per diem cost of the hospital-based PHP Level 1 APC was greater than that of the hospital-based PHP Level 2 APC, despite fewer services being provided. This occurred because a relatively higher share of high-CCR service days was reported for hospital-based PHP Level 1 services compared to hospital-based PHP Level 2 services. Due to the low volume of hospital-based PHP Level 1 services, the effect of the high-CCR service days on the resulting proposed geometric mean per diem costs was relatively greater than the effect of the high-CCR service days on the resulting proposed Level 2 geometric mean per diem costs. As such, the hospital-based Level 1 PHP APC geometric mean per diem costs were higher than the proposed geometric mean per diem costs for the hospital-based Level 2 PHP APC.

In order to reduce or eliminate the impact of including aberrant data received from a few CMHCs and hospital-based PHP providers in the claims data used for ratesetting, in the CY 2016 OPPS/ASC proposed rule (80 FR 39293), we proposed to use a ±2 standard deviation trim for CMHCs and to apply a CCR greater than five (CCR>5) hospital service day trim for hospital-based PHP providers for CY 2016 and subsequent years.

Under the ±2 standard deviation trim proposal, we proposed to exclude any CMHC when the CMHC's cost per day is more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. Our proposed trim on total CMHC costs per day is performed before stratifying the data by payment tiers (Level 1 and Level 2 CMHC PHP APCs), and affects both CMHC payment tiers. For example, based on our CY 2014 claims data used for the proposed CY 2016 ratesetting, the geometric mean cost per day for all CMHCs before trimming is $168.16. Using the ±2 standard deviation trim, three providers with geometric mean costs per day ranging from as low as $23.50 to as high as $996.71 were excluded from the ratesetting for CY 2016. Excluding providers with extremely low or extremely high costs per day protects CMHCs from having those extreme costs per day inappropriately skew the CMHC PHP APC geometric mean per diem costs. In addition, we proposed to use a ±2 standard deviation trim because, when we used this methodology, it aligned the geometric mean and median per diem costs for the CMHC Level 2 PHP APC payment tier, which also indicates that the trim removed the skewing in the data caused by the inclusion of aberrant data received from the three providers. We stated that we believe that the ±2 standard deviation trim would exclude CMHCs with aberrant data from the ratesetting process while allowing for the use of as much data as possible. In addition, we stated that implementing a ±2 standard deviation trim on CMHCs would target these aberrancies without limiting overall per diem cost increases. A ±2 standard deviation trim also is an accepted statistical approach for objectively mitigating extreme data. For normally distributed data, ±2 standard deviations from the mean capture approximately 95 percent of the data.

In the proposed rule, we applied the ±2 standard deviation trim to the geometric mean costs per day at the CMHC level. This application would exclude those CMHCs with costs per

day ±2 standard deviations from the geometric mean cost per day for all CMHCs. Under this proposal, three CMHCs with aberrant data would be removed from the ratesetting calculations. The exclusion of these three CMHCs removed from modeling 2,296 CMHC claims out of 25,383 total CMHC claims. We believe that removing aberrant data from modeling helps prevent inappropriate fluctuations in the payment rates. The resulting proposed CMHC Level 2 PHP APC geometric mean per diem costs would be $147.51. The CMHC Level 1 PHP APC geometric mean per diem costs actually increased slightly when the trim was applied, from $103.10 to $105.82.

We determined that proposing to use a higher trim level, such as ±2.5 or ±3 standard deviations from the geometric mean, did not reduce the skewing caused by the inclusion of data from a few CMHC providers. In other words, using a higher trim level did not remove the CMHCs with aberrant data from the ratesetting process. Further, we stated that we believe that using a trim level lower than ±2 standard deviations would remove too much data. If a data distribution is approximately normally distributed, approximately 68 percent of the data fall within ±1 standard deviation of the mean, and approximately 95 percent of the data fall within ±2 standard deviations of the mean. Our goal was to remove outliers while using as much of the CMHC data as possible.

We did not propose the CCR>5 service day trim for CMHCs, because longstanding PHP OPPS methodology defaults any CMHC CCR>1 to the statewide hospital ancillary CCR (we refer readers to the following section for a review of the PHP OPPS ratesetting methodology). Hospital statewide CCRs have been less than 1 and are available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files-Items/2015-Annual-Policy-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*. In our CY 2016 proposed ratesetting process, we identified only one CMHC that had a CCR>1. This CMHC's CCR was 1.019, and was defaulted to its appropriate hospital statewide CCR for CY 2016 ratesetting purposes.

We considered applying the ±2 standard deviation trim to hospital-based PHP providers as well. However, the ±2 standard deviation trim would have removed 25 hospital-based PHP providers with aberrant data out of 387 hospital-based PHP providers. We were concerned about removing data from that many providers, and sought an alternative that allowed for use of more of the data. Therefore, we proposed a trim on CCRs, which we believe would be more effective in removing aberrant data and allowing the use or retention of more data. Trims on hospital and CMHC CCRs are already used with the OPPS system, but due to the two very extreme outlier CCRs for cost center 9000 previously mentioned, the OPPS ± 3 standard deviation trim on hospital cost center 9000 CCRs had a higher upper limit than usual, and therefore did not trim all the claims with aberrant CCRs. As such, claims with aberrant data remained for some hospital-based PHPs. Therefore, for hospital-based PHPs, we proposed to apply a trim on hospital service days when the CCR>5 at the cost center level.

Under our proposal, the CCR>5 hospital service day trim would remove hospital-based PHP service days that use a CCR>5 to calculate costs for at least one of their component services. Unlike the ±2 standard deviation trim, which excludes CMHC providers that fail the trim, the CCR>5 trim would exclude any hospital-based PHP service day where any of the services on that day are associated with a CCR>5. For example, assume a hospital-based PHP had a claim with a service day with one individual therapy service, two group therapy services, and one occupational therapy service. Assume that the hospital-based PHP's cost center CCRs associated with these services were 0.6, 0.6, 0.6, and 6.7, respectively. Because the CCR associated with the occupational therapy service is greater than 5, this particular day, and all other days for this provider where occupational therapy services were provided, would be excluded from the data used in ratesetting. Applying this trim removed service days from seven hospital-based PHP providers. After applying the CCR>5 trim, the Level 1 hospital-based PHP APC geometric mean per diem cost changed from $267.04 to $195.73, and the Level 2 hospital-based PHP geometric mean per diem cost changed from $223.39 to $218.93. Without including the aberrant CCR service days in the data used to calculate the proposed hospital-based PHP APC geometric mean per diem costs, the Level 1 hospital-based PHP APC geometric mean per diem cost is less than the Level 2 hospital-based PHP APC geometric mean per diem cost.

As an alternative to these proposals for CMHCs and hospital-based PHPs, we considered proposing a 15-percent cap on changes in the geometric mean per diem costs. This cap would limit the increase or the decrease in the geometric mean per diem costs from one year to the next by capping the change at 15 percent. This cap also would protect providers from fluctuations in PHP APC per diem payment rates due to large increases or declines in the geometric mean per diem costs. However, we did not propose this alternative because we believe that establishing such a cap would not specifically target aberrant data from a minority of providers, which was the purpose of our proposals.

Targeting aberrant data is important in order to help stabilize the PHP APC geometric mean per diem costs for both CMHCs and hospital-based PHP services. As we receive updated claims and cost files, and as we continue analyzing PHP data, it is possible that the PHP trims that we proposed may need refinement. We stated in the CY 2016 OPPS/ASC proposed rule (80 FR 39294) that we would propose any changes to the methodology that we finalize later this year through future notice-and-comment rulemaking.

Therefore, for CY 2016 and subsequent years, we proposed to exclude any CMHC when the CMHC's costs per day are more than ±2 standard deviations from the geometric mean cost per day for all CMHCs (Level 1 and Level 2), and to exclude hospital-based PHP service days when a CCR>5 is used to calculate costs for at least one of their component services (Level 1 and Level 2).

The CY 2016 proposed PHP APC geometric mean per diem costs for CMHCs calculated under the proposed CY 2016 methodology using CY 2014 claims data and the most recent cost data were $105.82 for Level 1 (3 services per day) CMHC PHP services, and were $147.51 for Level 2 (4 or more services per day) CMHC PHP services.

The CY 2016 proposed PHP APC geometric mean per diem costs for hospital-based PHPs calculated under the proposed CY 2016 methodology using CY 2014 claims data and the most recent cost report data were $195.73 for Level 1 (3 services per day) hospital-based PHP services, and were $218.93 for Level 2 (4 or more services per day) hospital-based PHP services. As we stated in the CY 2016 OPPS/ASC proposed rule (80 FR 39295), we recognize that several factors may cause a fluctuation in the PHP APC per diem payment rates, including direct changes to the PHP APC per diem costs (for example, establishing separate APCs and associated per diem payment rates for CMHCs and hospital-based providers based on the provider type's costs), changes to the OPPS (for example, basing the relative payment weights on

geometric mean costs), and provider-driven changes (for example, a provider's decision to change its mix of services or to change its charges and clinical practice for some services). We refer readers to a more complete discussion of this issue in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75049).

The proposed CY 2016 PHP APC geometric mean per diem costs for the CMHC and hospital-based PHP APCs were shown in Tables 50 and 51 of the CY 2016 OPPS/ASC proposed rule (80 FR 39295). We noted that Tables 50 and 51 of the proposed rule displayed the proposed PHP APC renumbering that is part of the proposed reorganization of OPPS APCs described in section III.D. of the proposed rule. Specifically, we proposed to renumber the four PHP APCs, that is, APCs 0172, 0173, 0175, and 0176, as APCs 5851, 5852, 5861, and 5862, respectively. As noted earlier in this section, we referred readers to Addendum A to the proposed rule (which is available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*) for the proposed PHP APC payment rates. We invited public comments on these proposals.

Comment: Commenters supported the proposed increase in the PHP payment rates based on the geometric mean per diem costs calculated using CY 2014 claims data. One commenter validated the accuracy of the payment rates by replicating CMS' cost calculations using the CY 2014 claims data. The commenter agreed with the proposed trimming methodologies to remove aberrant data and believed that these methodologies would help mitigate inappropriate fluctuations in payment rates which have occurred in recent years. One commenter noted that service utilization seems to have stabilized after several years of decrease, and thanked CMS for the work it has done on PHP payment policies. Another commenter supported removing aberrant data, but believed that the same trims should have been used for determining the geometric mean per diem costs for both CMHCs and hospital-based PHPs.

Response: We appreciate the commenters' support of the proposed PHP APC payment rates based on the geometric mean per diem costs calculated using the most recent claims and cost report data and the proposed trimming methodologies. As discussed below, we are finalizing our proposed trimming methodologies without modification for CY 2016 and subsequent years. We also are finalizing our methodology for calculating the two CMHC PHP APC geometric mean per diem costs without modification, but are finalizing our methodology for calculating the two hospital-based PHP APC geometric mean per diem costs with modification so that we pay a higher payment rate for the PHP APC for Level 2 services than the PHP APC for Level 1 services, as discussed below.

We agree with the commenter that PHP utilization has stabilized, and that the trimming methodologies we proposed and are finalizing in this final rule with comment period may help to stabilize the PHP APC payment rates by mitigating fluctuations in payment rates caused by extremely low or high costs that inappropriately skew the geometric mean per diem costs. We believe that our inclusion of the detailed PHP ratesetting methodology in the CY 2016 OPPS/ASC proposed rule (80 FR 39295 through 39299) and in this final rule with comment period will lead to greater accuracy in provider reporting of claims and cost data, and thereby lead to greater accuracy in ratesetting and more stability in the PHP APC per diem costs. We encourage all PHP providers to review their accounting and billing processes to ensure that their costs are included in the data used for PHP ratesetting.

With regard to the commenter's concern that the same trims should be used for both CMHCs and hospital-based PHPs, in the CY 2016 OPPS/ASC proposed rule (80 FR 39293), we proposed to use a ±2 standard deviation trim for CMHCs and to apply a CCR>5 hospital service day trim for hospital-based PHP providers for CY 2016 and subsequent years. As noted in section VIII.B.2. of this final rule with comment period, there are differences in the ratesetting process between hospital-based PHPs and CMHCs, which are largely due to differences between the hospital cost reports and the CMHC cost reports, and we believe that having different trims more appropriately targets aberrant data for each provider type. We did not propose the CCR>5 service day trim for CMHCs because the longstanding PHP OPPS methodology defaults any CMHC CCR>1 to the statewide hospital ancillary CCR, and hospital statewide CCRs have been less than 1. In our CY 2016 final ratesetting process, we identified only one CMHC that had a CCR>1. This CMHC's CCR was 1.019, and was defaulted to its appropriate hospital statewide CCR for CY 2016 ratesetting purposes. We considered applying the ±2 standard deviation trim to hospital-based PHP providers. However, as stated in the CY 2016 OPPS/ASC proposed rule (80 FR 39294), the ±2 standard deviation trim would have removed 25 hospital-based PHP providers with aberrant data out of 387 hospital-based PHP providers. Using updated data for this final rule with comment period, this ±2 standard deviation trim would have removed 22 hospital-based PHP providers with aberrant data out of 388 hospital-based PHP providers. We are concerned about removing data from that many providers, and the alternative we proposed and are finalizing allows for use of more data from hospital-based providers. We believe the trim on CCRs will be more effective in removing aberrant data and will allow for the use and retention of more data. For these reasons, we continue to believe the trims that we proposed and are finalizing in this final rule with comment period are appropriate and effective for each provider type. We plan to review the trims annually, and would propose any changes to the trimming methodologies in future rulemaking as needed.

For this CY 2016 OPPS/ASC final rule with comment period, we used updated claims and cost data from the final June 2015 update of the CY 2014 Standard Analytic File (SAF) outpatient claims, the June 2015 update of the HCRIS (for development of hospital and statewide CCRs), and the July 2015 update of the OPSF (for development of CMHC CCRs). There were 66 CMHCs based on updated CY 2014 claims data in these files, and all 66 of these providers had CCR data reported in the July 2015 OPSF. We used each CMHC's most recent CCR from the OPSF. As stated previously, only one CMHC was defaulted to its statewide ancillary CCR because it had a CCR greater than 1. Two CMHCs were excluded from modeling because their CCRs failed the OPPS-wide ±3 standard deviation trim. These two providers had CCRs that were extremely low (CCRs of 0.001 and 0).

The CMHC per diem cost calculations were based upon the actual charges CMHCs reported on their claims, multiplied by the CCRs calculated from the actual costs reported on their cost reports. The data showed that there were some extreme costs per day that ranged from a low of $10.50 per day to a high of $2,213.83 per day. The ±2 standard deviation trim removed CMHCs with costs below $39.47 per day or above $640.29 per day from the cost calculations, resulting in the exclusion of two CMHCs. In addition, three CMHCs were removed because all of these CMHCs' service days had zero payments reported. The final CY 2016 geometric mean per diem costs are

$98.88 for CMHCs Level 1 PHP services and $149.64 for CMHC Level 2 PHP services, after we apply the ±2 standard deviation trim and follow the existing OPPS ratesetting procedures.

For this CY 2016 OPPS/ASC final rule with comment period, there were 400 hospital-based PHPs based on updated claims and cost data. We used the CCRs calculated at the departmental level from the most recent hospital cost reports, following the revenue-code-to-cost-center crosswalk described in section VIII.B.2 of the CY 2016 OPPS/ASC proposed rule and of this final rule with comment period. Hospital-based PHPs without a valid CCR calculated from costs in the primary, secondary, or tertiary cost centers of the crosswalk were defaulted to their hospital's overall ancillary CCR. Ninety-eight hospital-based PHPs had at least one PHP revenue center CCR defaulted to the overall ancillary CCR. We excluded service days for 6 hospital-based PHPs that failed the proposed CCR>5 trim (before the trim, the CCRs ranged between 0.0116 and 19.9996), which resulted in excluding all of these 6 providers' service days. We also excluded service days for 2 hospital-based PHPs that failed the longstanding OPPS trim based on service days with costs per day greater than ±3 standard deviations from the geometric mean. Again, this resulted in excluding all the service days for 2 hospital-based PHPs. Finally, 12 hospital-based PHPs were excluded because all their service days had zero payments reported, reducing the total population by 20 providers. As a result, 380 total hospital-based PHPs were used for modeling.

The hospital-based PHP per diem cost calculations were based upon the actual charges hospital-based PHPs reported on their claims, multiplied by the CCRs calculated from the actual costs reported on their cost reports, after applying the proposed trim based on service days with a CCR>5 and following the usual OPPS ratesetting procedures. Using the most updated data, the resulting hospital-based PHP geometric mean per diem costs showed an inversion, with the hospital-based PHP Level 1 geometric mean per diem costs equaling $218.46 and the hospital-based PHP Level 2 geometric mean per diem costs equaling $198.43. While our proposed trim of service days with a CCR>5 was effective in removing service days associated with aberrant CCRs, it does not address low or high costs per day that result when a non-aberrant CCR is multiplied by low or high charges. The inverted geometric mean per diem costs were influenced by two large-volume hospital-based PHP providers of Level 2 PHP services, which had low costs of $93 per day, and three large-volume hospital-based PHP providers of Level 1 PHP services, which had high costs ranging between $631 and $1,732 per day. We evaluated the hospital-based Level 1 and Level 2 service day utilization to determine if Level 1 services included more individual therapy, which is more costly than group therapy, and which could explain higher Level 1 costs in spite of providing fewer services. However, based on updated data, we found that hospital-based PHP Level 2 services had a slightly higher percentage of more costly individual therapy days than hospital-based PHP Level 1 services. The percentage of hospital-based PHP Level 1 group therapy days was nearly identical to the percentage of hospital-based PHP Level 2 group therapy days. Therefore, we believe that the inversion is due to the influence of a few large volume providers.

We also examined the data without applying any trim and after applying the ±2 standard deviation trim to the updated hospital-based PHP data as we did for CMHCs. Under both of these scenarios, the inversion existed. When we did not apply any trim, we continued to have a problem with aberrant data significantly skewing the geometric mean per diem costs. When we applied the ±2 standard deviation trim, the resulting geometric mean per diem costs were not as extreme, but the trim would have removed 22 hospital-based PHPs from the data, which we believe would have removed too many providers. Further, the five large volume providers discussed above with low or high costs were still present in the data after these adjustments had been made.

Therefore, we believe that our proposed CCR>5 trim is the most appropriate and effective methodology for removing aberrant data while allowing for the use and retention of data from hospital-based PHP providers. Although the inversion in the rates exists with this trim, we believe it was due to five hospital-based PHPs that had costs per day that were either low or high relative to other providers, but these costs are not what we would consider aberrant. Therefore, we are finalizing this policy without modification. We encourage all hospital-based PHP providers to review the revenue to cost-center crosswalk to ensure accurate recording of their PHP costs and to ensure that the relationship between hospital-based PHP charges and hospital-based PHP costs is accurately reflected in the hospital-based PHP CCRs.

However, we are concerned about the PHP APC geometric mean per diem costs, which are the basis for the PHP APC payment rates, being lower for the provision of more services. As such, we are making an adjustment to the hospital-based PHP APC geometric mean per diem costs to more equitably and appropriately pay for hospital-based PHP services. Section 1833(t)(2)(E) of the Act states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments. The authority granted to the Secretary under this provision is broad. We believe that it is not appropriate or equitable to pay a lower payment rate for the hospital-based PHP APC for Level 2 services, under which 4 or more services are provided, than for the hospital-based PHP APC for Level 1 services, under which 3 PHP services are provided. Using the authority set forth in section 1833(t)(2)(E) of the Act, we are making an equitable adjustment to correct the inversion in the data for CY 2016.

While we considered various methods to equitably adjust these rates, we ultimately decided to adjust the inverted per diem costs by first calculating the average percent difference between Level 1 and Level 2 per diem costs for the last 3 years. The method we chose is equitable in that it adjusts the inverted Level 1 and Level 2 per diem costs by the same factor, to result in a percent difference between these two per diem costs that is the same as the historical 3-year average. To make the adjustment, we first calculated the average percent difference between the hospital-based PHP APC per diem costs for Level 1 and Level 2 services from CY 2013 to CY 2015. We believe a 3-year timeframe is sufficient to reflect recent cost trends. We calculated the percent difference in hospital-based per diem costs for Level 1 and for Level 2 services using the per diem costs presented in the CY 2013, CY 2014, and CY 2015 OPPS/ASC final rules with comment period. For each of these 3 calendar years, we subtracted the hospital-based PHP Level 1 per diem cost from the hospital-based PHP Level 2 per diem cost, and then divided that result by the hospital-based PHP Level 1 per diem cost to calculate the percent difference. We then took the average of these three percent differences, which equaled 15.96 percent, based on the CY 2013 to CY 2015 final per diem costs. We then decreased the actual CY 2016 hospital-based PHP APC geometric mean per diem costs for Level 1 and increased the actual CY 2016 hospital-

based PHP APC geometric mean per diem costs for Level 2 hospital-based by the same factor, to result in a 15.96 percent difference.

To equitably adjust the inverted per diem costs, we calculate this unknown factor by which to increase or decrease the inverted per diem costs to result in a 15.96 percent difference between those per diem costs. We used the following formula to solve for this factor:

$$\frac{\text{(Level 2 Per Diem Cost)(1+ Factor)} - \text{(Level 1 Per Diem Cost)(1-Factor)}}{\text{(Level 1 Per Diem Cost) (1-Factor)}} = 15.96\%$$

When we use the above formula with the hospital-based PHP APC geometric mean per diem costs with the inversion and the equitable adjustment factor ''x'' to correct the inversion, the formula and resulting calculation become:

$$\frac{198.43(1+x) - 218.46(1-x)}{218.46(1-x)} = 0.1596$$

We then solve for the value of ''x'' using algebra, to result in a factor of 12.1525 percent. If we increase the CY 2016 inverted hospital-based PHP APC geometric mean per diem costs for Level 2 services by 12.1525 percent, and decrease the CY 2016 hospital-based PHP hospital-based PHP APC geometric mean per diem costs for Level 1 services by 12.1525 percent, the resulting CY 2016 hospital-based PHP APC per diem cost for Level 1 services is $191.91 and the resulting CY 2016 hospital-based PHP APC per diem cost for Level 2 services is $222.54. The percentage difference between these two equitably adjusted per diem costs is 15.96 percent. We are finalizing these equitably adjusted hospital-based PHP APC per diem costs for CY 2016.

Comment: One commenter was concerned about the small sample size of CMHCs and data used for calculating the geometric mean per diem costs, and noted that CMHCs with annual revenues of less than $100,000 are not required to file a full cost report. The commenter also stated that CMS does not collect salary information from CMHCs on their cost reports. One commenter believed that CMHCs are being unfairly penalized for providing more cost effective services than hospital-based PHPs. Another commenter expressed concern regarding the continued establishment of CMHC payment rates at levels that are below average geometric mean costs.

Response: As discussed previously in this final rule with comment period, there were 66 CMHCs based on updated CY 2014 claims data in these files, and all 66 of these providers had entries with CCR data reported in the July 2015 OPSF. We used each CMHC's most recent CCR from the OPSF. As stated previously, only one CMHC was defaulted to its statewide ancillary CCR because it had a CCR greater than 1. Two CMHCs were excluded from modeling because their CCRs failed the OPPS-wide ±3 standard deviation trim. These two providers had CCRs that were extremely low (CCRs of 0.001 and 0). The ±2 standard deviation trim removed CMHCs with costs below $39.47 per day or above $640.29 per day from the cost calculations, resulting in the exclusion of two CMHCs. In addition, three CMHCs were removed because all of the CMHCs' service days had zero payments reported. Therefore, we removed a total of seven CMHCs from the ratesetting modeling. We do not believe that the exclusion of these seven providers with aberrant data excessively reduced the CMHC population, but rather it allowed for the per diem cost determination to be based upon reasonable costs from nearly all CMHCs. Further, only two of these CMHCs were excluded based on the ±2 standard deviation trim; the others were removed under our current policies.

We acknowledge that, although all facilities must file a cost report, MACs have established thresholds that they use in determining a facility's eligibility to file less than a full cost report. MACs may authorize a CMHC to file less than a full cost report when they experience low or no Medicare utilization in a reporting period and receive correspondingly low interim payment which, in the aggregate, appears to justify making a final settlement for that period based on less than a normally required full cost report. In these instances, the MAC will require the CMHC to furnish the applicable information in accordance with 42 CFR 413.24(h) and Section 110, Chapter 1 of the Provider Reimbursement Manual—Part 2 (CMS Pub. 15–2). However, because CMHC geometric mean per diem costs are the basis for CMHC ratesetting, we encourage any CMHC that has been authorized by its MAC to file less than a full cost report to instead file a full cost report.

In response to the comment that CMHCs are being unfairly penalized for providing more cost effective services than hospital-based PHPs, we disagree. We consider the effects of exclusions on the modeling population for both CMHCs and hospital-based PHPs, and we review the data that we receive to ensure that we pay appropriately for PHP services furnished by both types of providers. We do not favor either provider type. Our cost determinations are based upon the data provided by hospitals and CMHCs using objective mathematical methods. The PHP APC per diem rates based on PHP APC per diem costs, and because CMHC PHP APC costs are lower than hospital-based PHP APC costs, CMHC geometric mean per diem rates are lower than hospital-based PHP geometric mean per diem rates.

With respect to the commenters' concerns that the CMHC per diem payment rates are below the geometric mean per diem costs, the CMHC calculated per diem rates are based on the actual reported costs of CMHCs used in modeling. Those actual reported costs are used to calculate the CMHC CCRs, which are applied to the charges CMHCs report on their claims, and that result in estimated CMHC costs. Therefore, the rates reflect the data provided by CMHCs. Those costs should include allowable salary costs. The commenter who stated that CMS does not collect salary costs on CMHC cost reports is mistaken. The CMHC cost report provides a column for salaries for the following categories: Drugs & Biologicals; Occupational Therapy; Psychiatric/Psychological Services; Individual Therapy; Group Therapy; Individualized Activity Therapies; Family Counseling; Diagnostic Services; Patient Training & Education; and Other. These categories may include salaries for a nurse or social worker, but we do not identify these specific

practitioners with their own cost centers. However, the CMHC cost report must not include the professional services of physicians, physician assistants, or clinical psychologists if those services are separately billable. CMHCs should review the cost reporting instructions, which are available online in CMS Pub. 15–2, Chapter 18, at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals.html*.

Our review of the updated data for calculating the final geometric mean per diem costs highlights the importance of all PHPs following the cost reporting and claims accounting procedures discussed in section VIII.B.2. of this final rule with comment period. CMHCs that do not include allowable salary costs in their cost reports are inadvertently removing appropriate costs from the ratesetting process. Likewise, hospital-based PHPs that do not follow the revenue-code-to-cost-center crosswalk when determining their costs may inadvertently remove appropriate costs from the ratesetting process, as the OPPS modeling for hospitals follows the crosswalk hierarchy. Finally, we note that errors in revenue and HCPCS coding on claims, which occurred almost exclusively on hospital-based PHP claims, also may result in removing appropriate costs from ratesetting. We estimate that, overall, hospital-based PHP costs were approximately $1.50 per day less than the costs would have been if PHP providers had used the proper coding as specified in the Claims Processing Manual.

Comment: Several commenters expressed concern regarding beneficiary access to PHP services. One commenter questioned whether the proposed changes would ensure continued beneficiary access and strengthen the PHP benefit when most CMHCs have ceased providing PHP services and many CMHCs have ceased doing business altogether. Two commenters stated that CMS' expressed concern for paying hospital-based PHPs at a lower rate than their cost structure could lead to closures and possible access problems. These two providers stated that CMS statement about hospital-based PHPs offering the widest access to PHP services because they are located throughout the country implies a strong bias on behalf of hospitals and a discriminatory stance towards CMHCs.

Response: We acknowledge the commenters' concerns regarding beneficiary access to PHP services. The final PHP APC per diem costs for CY 2016 reflect the costs of what providers expend to maintain such programs, as reported on their claims and cost reports. In comparison to the CY 2015 geometric mean per diem costs, the final CY 2016 geometric mean per diem costs decreased by 1.3 percent for Level 1 PHP services provided by CMHCs. However, only 5 percent of CMHC service days are billed as Level 1 PHP services. The final CY 2016 geometric mean per diem costs increased substantially for Level 2 PHP services provided by CMHCs, by 26.2 percent. Compared to the CY 2015 geometric mean per diem costs for hospital-based PHPs, the final CY 2016 equitably adjusted hospital-based PHP per diem costs increased by 3.2 percent for Level 1 PHP services, and increased by 9.6 percent for Level 2 PHP services. We believe that these per diem costs, which are the basis for the payment rates, support continued beneficiary access and strengthen the PHP benefit. Our PHP methodology provides for a stable rate structure, and we do not believe that it favors one provider type over another or diminishes access to PHP services. While we recognize that CMHCs and hospital-based PHPs provide the same services, our payment methodology requires that we make payments based upon provider costs. Hospital-based PHPs have higher costs than CMHCs, as evidenced by their cost report data, which is the reason hospital-based PHPs have higher geometric mean per diem costs than CMHCs.

We disagree with the commenters who believed CMS is demonstrating bias against CMHCs with respect to access to PHP services by referencing CMS' language in the proposed rule regarding hospital-based PHPs offering the widest access to care because they are located across the country. While it is true that hospital-based PHPs offer the widest access to PHP services because they are located across the country, we greatly value the access to PHP services provided by CMHCs as well. We want to ensure that CMHCs remain a viable option as providers of mental health care. We are concerned if any payment rate would contribute to providers ceasing operations. We have demonstrated our commitment to stabilize and ensure accuracy in payment for PHP services in part by our extensive analysis of the PHP payment data, and our publishing a detailed review of the PHP payment methodology for both CMHCs and hospital-based PHPs. We appreciate the services that all PHPs provide to those individuals with mental health issues, and remain committed to strengthening access to both CMHC PHP services and hospital-based PHP services.

Comment: One commenter expressed concern and objections regarding the continuing use of four PHP APC per diem payment rates based on geometric mean per diem costs for each provider type, and the adverse impact the proposed rates for CY 2016 will have again on few remaining CMHC providers across the country.

Response: The OPPS system pays for outpatient services provided, such as and including partial hospitalization services. This system bases payment on the geometric mean costs of providing services using provider data from claims and cost reports. We calculate the PHP APC per diem payment rates based on the data provided for each type of provider in order to pay for services. We believe this system provides appropriate payment for partial hospitalization services based on provider costs. The final PHP APC per diem costs for CY 2016 reflect the costs of what providers expend to maintain such programs, as reported on their claims and cost reports. With regard to CMHC rates specifically, as stated previously, in comparison to the CY 2015 geometric mean per diem costs, the final CY 2016 geometric mean per diem costs decreased by 1.3 percent for Level 1 PHP services provided by CMHCs. However, only 5 percent of CMHC service days are billed as Level 1 PHP services. The final CY 2016 geometric mean per diem costs increased substantially for Level 2 PHP services provided by CMHCs, by 26.2 percent. Therefore, we believe that the CY 2016 rates will be viewed positively by CMHCs across the country.

With respect to the continued use of four PHP APC per diem payment rates, we refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) where we implemented this policy. Because the cost of providing PHP services differs significantly by site of service, we implemented differing PHP payment rates for hospital-based PHPs and CMHCs. The resulting rates reflect the cost of what providers expend to maintain such programs based on data provided by these types of providers, which we believe is an improvement over the two-tiered methodology calculated using only hospital-based data.

With respect to rates based on geometric mean per diem costs, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412) where we established the geometric mean rather than the median as the measure upon which to

base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs. We believe that the use of geometric mean costs represents an improvement to our cost estimation process compared to the median. The geometric mean compared to the median allows inclusion of some extreme but not aberrant observations in developing the relative payment weights and captures a wider range of service costs, which we believe leads to more accurate relative payment weights. In addition to better incorporating those cost values that surround the median and, therefore, describing a broader range of cost patterns, basing the relative payment weight on geometric mean costs also may promote better stability in the payment system by making OPPS payments more reflective of the range of costs associated with providing services. Further, applying the geometric mean to the PHP APCs helps ensure that the relativity of the OPPS payment weights is properly aligned.

Comment: One commenter suggested that CMS consider paying PHPs using a quality-based payment system, and that CMS use value-based purchasing.

Response: We responded to a similar public comment in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66906) and refer readers to a summary of that comment and our response. Sections 1833(t)(2) and 1833(t)(9) of the Act set forth the requirements for establishing and adjusting OPPS rates, which include PHP rates. Section 1833(t)(17) of the Act authorizes the Hospital OQR Program, which applies a payment reduction to subsection (d) hospitals that fail to meet program requirements. In the CY 2015 OPPS/ASC proposed rule (79 FR 41040), we considered future inclusion of, and requested comments on, the following quality measures addressing PHP issues that would apply in the hospital outpatient setting: (1) 30-Day Readmissions; (2) Group Therapy; and (3) No Individual Therapy. We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66957 through 66959) for a more detailed discussion of PHP measures considered for inclusion in the Hospital OQR Program in future years. The Hospital OQR Program does not apply to CMHCs. Further, currently, there is no statutory language explicitly authorizing a value-based purchasing program for PHPs.

After consideration of the public comments we received, we are finalizing our proposals to update the four PHP APC per diem costs and payment rates based on geometric mean cost levels calculated using the most recent claims and cost data for each provider type. However, for hospital-based PHP APCs, we are making an equitable adjustment to the actual geometric mean per diem costs by increasing the Level 2 per diem costs and decreasing the Level 1 per diem costs by the same factor, to result in a percentage difference equal to the average percent difference between hospital-based PHP Level 1 and Level 2 services from CY 2013 through CY 2015. For CY 2016 and subsequent years, we also are finalizing the proposed trimming methodologies. Specifically, we are excluding any CMHC when the CMHC's costs per day are more than ±2 standard deviations from the geometric mean cost per day (Level 1 and Level 2), and excluding hospital-based PHP service days when a CCR>5 is used to calculate costs for at least one of their component services (Level 1 and Level 2). We plan to review the trims annually, and would propose any changes to the trimming methodologies in future rulemaking as needed.

The CMHC PHP Level 1 geometric mean per diem costs are $98.88, and the CMHC PHP Level 2 geometric mean per diem costs are $149.64, after applying the ±2 standard deviation trim to CMHCs. The equitably adjusted hospital-based PHP Level 1 per diem costs are $191.91, and the equitably adjusted hospital-based PHP Level 2 per diem costs are $222.54, after applying the CCR>5 trim to affected service days.

Table 54 below displays the final CY 2016 PHP APC geometric mean per diem costs for CMHC PHP services, and Table 55 below displays the final PHP APC equitably adjusted geometric mean per diem costs for hospital-based PHP services.

TABLE 54—CY 2016 PHP APC GEOMETRIC MEAN PER DIEM COSTS FOR CMHC PHP SERVICES

Renumbered CY 2016 APC	Group title	PHP APC geometric mean per diem costs
5851	Level 1 Partial Hospitalization (3 services) for CMHCs	$98.88
5852	Level 2 Partial Hospitalization (4 or more services) for CMHCs	149.64

TABLE 55—CY 2016 PHP APC EQUITABLY ADJUSTED GEOMETRIC MEAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

Renumbered CY 2016 APC	Group title	PHP APC equitably adjusted geometric mean per diem costs
5861	Level 1 Partial Hospitalization (3 services) for hospital-based PHPs	$191.91
5862	Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs	222.54

2. PHP Ratesetting Process

While PHP services are part of the OPPS, PHP ratesetting has some unique aspects. To foster understanding and transparency, as we did in the CY 2016 OPPS/ASC proposed rule (80 FR 39295 through 39299), we are providing the following detailed explanation of the PHP APC ratesetting process. The OPPS ratesetting process includes various steps as part of its data development process, such as CCR determination and calculation of geometric mean per diem costs, identification of allowable charges, development of the APC relative payment weights, calculation of the APC payment rates, and establishment of outlier thresholds. We refer readers to section II. of the proposed rule and this final rule with

comment period and encourage readers to review these discussions to increase their overall understanding of the entire OPPS ratesetting process. We also refer readers to the OPPS Claims Accounting narrative, which is a supporting document to the CY 2016 OPPS/ASC proposed rule and this final rule with comment period, available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html;* click on the link to the CY 2016 OPPS/ASC proposed rule or the final rule with comment period to find the Claims Accounting narrative. We encourage CMHCs and hospital-based PHPs to review their accounting and billing processes to ensure that they are following these procedures, which should result in greater accuracy in setting the PHP payment rates.

We limit our discussion here primarily to the data development process and calculation of PHP APC geometric mean per diem costs used for PHP ratesetting. Our discussions focus on five major phases in modeling the data, which result in the development of PHP APC geometric mean per diem costs, and on the importance of correct coding and reasonable charges for PHP services, and include: (a) Development of PHP claims; (b) determination of CCRs for CMHCs and hospital-based PHPs; (c) identification of PHP allowable charges; (d) determination of PHP APC per diem costs; (e) development of service days and cost modeling; and (f) issues regarding correct coding and reasonable charges.

a. Development of PHP Claims

We use outpatient claims from the national claims history file for the most recent available calendar year that were processed through December 31 of that year (that is, the calendar year that is 2 years before the calendar year at issue) to calculate the geometric mean per diem costs of APCs that underpin the relative payment weights for the calendar year at issue. It is important to note that this is not the population of claims paid under the OPPS, but all outpatient claims as explained in further detail in section II.A.2.a. of this final rule with comment period.

We then exclude the following claims from OPPS ratesetting. These are claims where:

- No payment is made;
- There are more than 300 lines; or
- Services were furnished in Maryland, Guam, the U.S. Virgin Islands, American Samoa, or the Northern Mariana Islands (these providers are not paid under the OPPS).

From these outpatient claims, we extract all hospital outpatient PHP claims and all CMHC claims. PHP claims are extracted based on their specific bill types: 12X or 13X, with condition code 41, for hospital-based PHPs; and 76X for CMHCs. For example, for the CY 2016 OPPS/ASC proposed rule, we used data from the CY 2014 hospital outpatient PHP and CMHC PHP claims from the national claims history file that were processed through December 31, 2014, to calculate the PHP APC geometric mean per diem costs that underpin the proposed PHP APC relative payment weights for CY 2016. For this final rule with comment period, we used the final CY 2014 SAF outpatient claims as of June 2015, the June 2015 update of HCRIS (for development of hospital and statewide CCRs), and the July 2015 update of the OPSF (for the development of CMHC CCRs).

As noted in section II.A.2.c. of the CY 2016 OPPS/ASC proposed rule and this final rule with comment period and in the Claims Accounting narrative, we exclude hospital-based PHP claims if—

- They were submitted by critical access hospitals;
- They reported obviously erroneous units (for example, more than 100,000 units for a single service);
- They reported charge amounts equal to the payment received;
- They did not report at least one HCPCS code, because OPPS APCs are based upon HCPCS codes; or
- They only contained flu or pneumonia vaccine services, which are paid separately outside of OPPS.

At the end of this process, we identified the PHP claims that are appropriate and available to use to calculate PHP APC geometric mean per diem costs. These claims include data on dates of service, revenue codes, HCPCS codes for services provided, charges, and the payments Medicare made (the PHP APC geometric mean per diem rates).

b. Determination of CCRs for CMHCs and Hospital-Based PHPs

Next, we determine and assess each provider's CCR. This ratio, along with the charges from the claims, is used to estimate the costs, which are then used to determine the geometric mean per diem costs. There are specific policies we follow in determining which CCR to use in estimating costs, which differ for CMHCs and for hospital-based PHPs, largely due to differences in the data required for claims and cost reports for these two types of PHP providers. We encourage PHP providers to review section II.A.1.c. of the CY 2016 OPPS/ASC proposed rule and this final rule with comment period rule and section 10.11, Chapter 4, of the Medicare Claims Processing Manual (internet-only manual (IOM), Pub. 100–04), which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*) for more specific discussion of CCRs used in PHP ratesetting.

(1) Calculation and Assessment of CMHC CCRs

As noted in section VIII.A. of the CY 2016 OPPS/ASC proposed rule and this final rule with comment period and section 10.11.9, Chapter 4 of the Medicare Claims Processing Manual (Pub. 100–04), the CMHC CCR is calculated using the provider's most recent full year cost report, Form CMS 2088–92, and Medicare cost and charges from Worksheet C, Page 2. We divide costs from line 39.01, Column 3 by charges from line 39.02, Column 3 to calculate an overall CMHC CCR. The CMHC cost report forms and cost reporting instructions are available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html?DLPage=1&DLSort=0&DLSortDir=ascending*.

The most recent CMHC CCRs are posted to the OPSF. We assess those CMHC CCRs within that file in preparation for use in cost estimation in the following manner:

- We use the most recent CMHC-specific CCR from the OPSF. If the CCR is not available (for example, the CMHC is a new provider with less than 12 months data), we use the hospital ancillary CCR associated with the provider's urban/rural designation and their state location. The statewide urban and rural hospital CCRs are available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html*.
- As described in Section 10.11.9, Chapter 4, of the Medicare Claims Processing Manual, for any CMHC with a CCR greater than 1, we use the hospital ancillary CCR associated with its urban/rural designation and its State location.

Once we have a CCR for each CMHC, we calculate the geometric mean of all CMHC CCRs. As described in the OPPS Claims Accounting narrative, we apply the existing OPPS ±3 standard deviation trim to the CMHC CCRs; this trim excludes any CMHC with a CCR that is ± 3 standard deviations from the geometric mean of all CMHC CCRs. At

the end of this process, we identified a CCR for all CMHCs that have not been excluded.

(2) Calculation and Assessment of Hospital-Based PHP CCRs

Unlike CMHCs where there is one CCR calculated for each CMHC, hospital-based PHPs have CCRs for each cost center that is associated with PHP services. For hospital-based PHPs, we use the provider's most recent full year hospital cost report, whether tentatively settled or final settled, to identify CCRs, using the HCRIS file. The CCRs for hospital-based PHPs are calculated by cost center on hospital cost report Worksheet C, Part I, Column 9. The overall hospital CCR is calculated by the MAC, and is posted in the Provider-Specific File. The hospital cost report form CMS–2552–10 and cost reporting instructions are in Chapter 40 of the Provider Reimbursement Manual—Part 2, which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html?DLPage=1&DLSort=0&DLSortDir=ascending*.

We assess the hospital-based PHP CCRs as described in section II.A.2.a. of the CY 2016 OPPS/ASC proposed rule and this final rule with comment period and in the OPPS Claims Accounting narrative, by applying the existing OPPS ±3 standard deviation trim to hospital-based PHP CCRs within each cost center and to the overall hospital ancillary CCR. To perform this ±3 standard deviation trim, we follow the following process. Each PHP revenue code is associated with particular cost centers on the cost report. The revenue-to-cost center crosswalk identifies the primary, secondary (if any), and tertiary (if any) cost centers that are associated with each PHP revenue code, and which are the source for the CCRs used in PHP ratesetting. The PHP portion of that OPPS crosswalk is shown in Table 56 below (Table 52 of the proposed rule). Based on the revenue code, we first look for a CCR calculated from the primary cost center; if none exists or the CCR fails the ±3 standard deviation trim, we look for a CCR calculated from the secondary cost center. If there is no CCR calculated from the secondary cost center or the CCR fails the ±3 standard deviation trim, we look for a CCR calculated from the tertiary cost center. If there is no CCR calculated from the tertiary cost center or the CCR fails the ±3 standard deviation trim, we look to the hospital's overall ancillary CCR. If the hospital's overall ancillary CCR fails the ±3 standard deviation trim, we exclude the hospital from ratesetting.

For example, for revenue code 0900, the primary cost center is 3550 ''Psychiatric/Psychological Services.'' If the CCR associated with this cost center passes the ±3 standard deviation trim, we retain that CCR for use in ratesetting. If the CCR associated with primary cost center 3550 fails the trim, it is deleted, and we then move to cost center 9000 ''Clinic'' to assess the provider's CCR. If that CCR passes the ±3 standard deviation trim, it is retained for use in ratesetting. If the CCR fails the ±3 standard deviation trim, it is deleted, and we then would consider the CCR calculated from the tertiary cost center. However, for revenue code 0900, there is no tertiary cost center. If the primary, secondary (if any), and tertiary (if any) cost centers' CCRs fail the trim, we assess the hospital's overall ancillary CCR. If that overall ancillary CCR passes the ±3 standard deviation trim, we retain it for use in ratesetting. If the overall ancillary CCR fails the ±3 standard deviation trim, we exclude the provider from ratesetting. This process of assessing the CCRs with a ±3 standard deviation trim is repeated for each revenue code's associated cost centers. After applying this ±3 standard deviation trim, we obtain a file with trimmed CCRs for use in ratesetting.

The revenue-to-cost center crosswalk for all services paid under the OPPS is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html*. We are providing an excerpt of the PHP portion of the OPPS crosswalk below.

TABLE 56—REVENUE-TO-COST CENTER CROSSWALK FOR PHP ALLOWABLE REVENUE CODES

Revenue code	Description	Primary cost center source for CCR	Primary cost center name	Secondary cost center source for CCR	Secondary cost center name
0250	Pharmacy	7300	Drugs Charged to Patients.		
0430	Occupational Therapy	6700	Occupational Therapy.		
0900, 0914, 0915, 0916, or 0918.	Psychiatric/Psychological Treatment: Individual, Group, and Family Therapy; Psychological testing.	3550	Psychiatric/ Psychological Services	9000	Clinic.
0904 *	Psychiatric/Psychological Treatment: Activity Therapy.	3580	Recreational Therapy	3550	Psychiatric/ Psychological Services.
0942	Other Therapeutic Services: Education/Training.	9000	Clinic.		

* Although not listed in this table, revenue code 0904 is the only PHP revenue code with a tertiary cost center serving as a source for the CCR, which is cost center 9000, ''Clinic.''

c. Identification of PHP Allowable Charges

We use the PHP claims derived under the methodology discussed in section VIII.B.2.a. of this final rule with comment period to identify which charges are allowable for PHP ratesetting. Each revenue code line on the PHP claim must report a HCPCS code and a charge (except for revenue code 0250, which only requires that the charge be reported). Allowable charges are those charges for the HCPCS codes which are associated with PHP allowable revenue codes; PHP allowable revenue codes are revenue codes allowable for OPPS PHP ratesetting purposes. As discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68412 to 68418), we updated the PHP allowable revenue codes and PHP allowable HCPCS codes for CY 2013 and subsequent years. The allowable revenue and PHP HCPCS codes are included in Section 260, Chapter 4, of the Medicare Claims Processing Manual (IOM Pub. 100–04), which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*) and are shown in Table 57 below (Table 53 of the proposed rule, 80 FR 39297):

TABLE 57—PHP ALLOWABLE REVENUE AND HCPCS CODES

Revenue code	Description	HCPCS code
0250	Drugs and Biologicals	Not required.
043X	Occupational Therapy	G0129.
0900	Behavioral Health Treatment/Services	90791 or 90792.
0904	Activity Therapy (Partial Hospitalization)	G0176.
0914	Individual Psychotherapy	90785, 90832, 90833, 90834, 90836, 90837, 90838, 90845, 90865, or 90880.
0915	Group Therapy	G0410 or G0411.
0916	Family Psychotherapy	90846 or 90847.
0918	Psychiatric Testing	96101, 96102, 96103, 96116, 96118, 96119, or 96120.
0942	Education Training	G0177.

The HCPCS codes shown in Table 56 above are those which are used in the four renumbered PHP APCs 5851, 5852, 5861, and 5862 (existing APCs 0172, 0173, 0175, and 0176), and are also shown in Appendix C–a and Appendix P of the Integrated Outpatient Code Editor (IOCE) Specifications. As described in section III.D. of this final rule with comment period, as we proposed, we are finalizing our proposal to renumber some of the OPPS APCs, and have shown both the renumbered APCs and the existing APCs for partial hospitalization services above. The IOCE is available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/OCEQtrReleaseSpecs.html*.

d. Determination of PHP APC Per Diem Costs

The PHP CCRs described in section VIII.B.2.b. of this final rule with comment period are applied to the PHP claim charges described in section VIII.B.2.c. of this final rule with comment period to determine the PHP APC geometric mean per diem costs. Costs for each service line reported on CMHC claims are calculated by multiplying each service line charge by the CCR associated with the claim's provider. Costs for each service line reported on the hospital-based PHP claims are calculated by multiplying the service line charge by the CCR associated with the provider's service line's revenue code (using the revenue-to-cost center crosswalk hierarchy described in section VIII.B.2.b. of this final rule with comment period). For both CMHCs and hospital-based PHPs, charges are set to zero for services reporting revenue codes, which are not included in the listing of PHP allowable revenue codes shown in Table 57 above (Table 53 of the proposed rule (80 FR 39297)).

e. Development of Service Days and Cost Modeling

Only the claims service lines containing PHP allowable HCPCS codes (shown in Table 57 above; Table 53 of the proposed rule (80 FR 39297)) from the remaining hospital-based PHP and CMHC claims are retained for PHP cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed to calculate the PHP APC geometric mean per diem cost, per diem payment rate, and per diem service volume for each PHP service day. Any service days with zero per diem payments are removed.

Because the PHP costs calculated above include the effects of geographic variation in wages, we use the wage index data to wage neutralize PHP APC per diem costs prior to the APC geometric mean per diem cost calculation. This removes the effects of geographic variation in costs used in the OPPS APC ratesetting process. Service days with no per diem costs or with no wage index values are removed. PHP service days with fewer than 3 service units are deleted and not considered for PHP cost modeling.

As discussed in section VIII.B.1. of the CY 2016 OPPS/ASC proposed rule and this final rule with comment period, there were several PHP providers with aberrant data. As such, we proposed and are finalizing a trimming methodology to exclude CMHCs that have a per diem cost that is ±2 standard deviations from the overall CMHC geometric mean per diem cost, beginning in CY 2016. This trim excluded from the ratesetting process any CMHCs with extreme costs per day. We also proposed and are finalizing a trimming methodology to exclude service days with extreme hospital-based PHP CCR values which were not removed by the ± 3 standard deviation trim discussed above, if those service days have a CCR>5, beginning in CY 2016. Therefore, we excluded hospital-based PHP service days where the CCR>5.

PHP service days from CMHCs and from hospital-based PHPs with exactly 3 service units, or with 4 or more service units (based on allowable HCPCS codes shown in Table 53 of the proposed rule (80 FR 39297); Table 57 of this final rule with comment period) are assigned to Level 1 or Level 2 PHP APCs as follows: (We note that we are finalizing our proposal to renumber some of the OPPS APCs, and are showing both the renumbered APCs and the existing APCs for partial hospitalization services below.)

- Level 1 Partial Hospitalization, renumbered APC 5851 (existing APC 0172): CMHC service days with exactly 3 service units;
- Level 2 Partial Hospitalization, renumbered APC 5852 (existing APC 0173): CMHC service days with 4 or more service units;
- Level 1 Partial Hospitalization, renumbered APC 5861 (existing APC 0175): hospital-based PHP service days with exactly 3 service units; and
- Level 2 Partial Hospitalization, renumbered APC 5862 (existing APC 0176): hospital-based PHP service days with 4 or more service units.

PHP service days with costs ±3 standard deviations from the geometric mean costs within each APC are deleted and removed from modeling. The remaining PHP service days are used to calculate the geometric mean per diem cost for each PHP APC.

For CY 2016, we also made an equitable adjustment to the hospital-based PHP geometric mean per diem costs, to remove an inversion in the per diem costs. The finalized PHP APC geometric mean per diem costs or PHP APC equitably adjusted per diem costs undergo several more steps, as noted below, before becoming budget neutral PHP APC per diem payment rates. The PHP APCs are part of the larger OPPS. As discussed in section II.A. of the CY 2016 OPPS/ASC proposed rule and this final rule with comment period, OPPS APC geometric mean per diem costs

(including PHP APC geometric mean per diem costs) are divided by the geometric mean per diem costs for renumbered APC 5012 (Level 2 Examinations and Related Services) to calculate each PHP APC's unscaled relative payment weight. An unscaled relative payment weight is one that is not yet adjusted for budget neutrality. Budget neutrality is required under section 1833(t)(9)(B) of the Act, and ensures that the estimated aggregate weight under the OPPS for a calendar year is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To adjust for budget neutrality (that is, to scale the weights), we compare the estimated aggregated weight using the scaled relative payment weights from the previous calendar year at issue. For example, to adjust for budget neutrality (that is, to scale the weights) in the CY 2016 OPPS/ASC proposed rule and this final rule with comment period, we compared the estimated aggregated weight using the CY 2015 scaled relative payment weights to the estimated aggregate weight using the CY 2016 unscaled relative payment weights. We refer readers to the ratesetting procedures described in Part 2 of the OPPS Claims Accounting narrative and in section II. of this final rule with comment period for more information on scaling the weights, and for details on the final steps of the process that lead to PHP APC per diem payment rates.

f. Issues Regarding Correct Coding and Reasonable Charges

PHP claims with revenue codes other than those listed as allowable in Table 57 above (Table 53 of the proposed rule (80 FR 39297)), but which are associated with allowable PHP HCPCS codes, may still be paid, as described in the OPPS Claims Accounting narrative. The OPPS does not include charges associated with revenue codes that are not allowable for ratesetting purposes. In reviewing CY 2013 and CY 2014 claims, we noticed CMHCs were using correct revenue coding for nearly all claims, but hospital-based PHPs were occasionally using other revenue codes, particularly revenue codes 0912 and 0913. Revenue codes 0912 and 0913 are not on the allowable list of PHP revenue codes. As such, the charges associated with those two revenue codes are not included in ratesetting, even when revenue code 0912 or 0913 is associated with a PHP allowable HCPCS code. For the most accurate ratesetting, it is imperative that providers follow coding guidelines for all revenue codes and all CPT and Level 2 HCPCS codes in a manner consistent with their descriptors, instructions, and correct coding principles. We also refer readers to the coding instructions given in the Claims Processing Manual. Following the correct coding guidelines will help ensure that we include all PHP costs in ratesetting.

Finally, it appears that a few PHPs may not be reporting reasonable charges for their services on their claims. When this occurs with CMHCs or hospital-based PHPs that provide a high number of services during the year, the data used for ratesetting may be inappropriately skewed. Therefore, we remind PHPs of the regulations at 42 CFR 413.53 and existing CMS guidance related to charges, which is found in Chapter 22 of the Provider Reimbursement Manual, Part 1, which is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.html?DLPage=1&DLSort=0&DLSortDir=ascending*.

In section 2202.4, we define ''Charges,'' as the regular rates established by the provider for services rendered to both beneficiaries and to other paying patients. Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient. We also state in section 2204, ''Medicare Charges,'' that the Medicare charge for a specific service must be the same as the charge made to non-Medicare patients (including Medicaid, CHAMPUS, private, etc.) must be recorded in the respective income accounts of the facility, and must be related to the cost of the service. In section 2203, ''Provider Charge Structure as Basis for Apportionment,'' we state that each facility should have an established charge structure which is applied uniformly to each patient as services are furnished to the patient, and which is reasonably and consistently related to the cost of providing the services, so that its charges may be allowable for use in apportioning costs under the program. The Medicare program cannot dictate to a provider what its charges or charge structure may be. However, the program may determine whether or not the charges are allowable for use in apportioning costs under the program. We received one comment regarding the ratesetting process.

Comment: One commenter supported the CMS recommendation that CMHCs and hospital-based PHPs review their accounting and billing processes to ensure that they are following procedures properly, with the goal of obtaining greater accuracy in setting PHP payment rates. The commenter committed to working with its members to help ensure correct recording of costs and claims coding.

Response: We appreciate the commenter's support and commitment.

C. Separate Threshold for Outlier Payments to CMHCs

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), after examining the costs, charges, and outlier payments for CMHCs, we believed that establishing a separate OPPS outlier policy for CMHCs would be appropriate. A CMHC-specific outlier policy would direct OPPS outlier payments towards the genuine cost of outlier cases, and address situations where charges were being artificially increased to enhance outlier payments.

We created a separate outlier policy that would be specific to the estimated costs and OPPS payments provided to CMHCs. We note that, in the CY 2009 OPPS/ASC final rule with comment period, we established an outlier reconciliation policy to comprehensively address charging aberrations related to OPPS outlier payments (73 FR 68594 through 68599). Therefore, beginning in CY 2004, we designated a portion of the estimated OPPS outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

The separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004, and $0.5 million in outlier payments to CMHCs in CY 2005. In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments. We believe that this difference in outlier payments indicates that the separate outlier threshold for CMHCs has been successful in keeping outlier payments to CMHCs in line with the percentage of OPPS payments made to CMHCs.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39299), we proposed to continue to designate a portion of the estimated 1.0 percent outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS in CY 2016, excluding outlier payments. In the CY 2016 OPPS/ASC proposed rule, we stated that CMHCs are projected to receive 0.04 percent of total OPPS payments in CY 2016, excluding outlier payments. Therefore, we proposed to designate 0.49 percent of the estimated 1.0 percent outlier

target amount for CMHCs, and establish a threshold to achieve that level of outlier payment. Based on our simulations of CMHC payments for CY 2016, in the CY 2016 OPPS/ASC proposed rule (80 FR 39299), we proposed to continue to set the threshold for CY 2016 at 3.40 times the highest CMHC PHP APC payment rate (that is, renumbered APC 5852 (Level 2 Partial Hospitalization) (existing APC 0173). We continue to believe that this approach would neutralize the impact of inflated CMHC charges on outlier payments and better target outlier payments to those truly exceptionally high-cost cases that might otherwise limit beneficiary access.

In addition, we proposed to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2016, we proposed to continue to pay 50 percent of CMHC APC geometric mean per diem costs over the threshold. In section II.G. of the CY 2016 OPPS/ASC proposed rule, for the hospital outpatient outlier payment policy, we proposed to set a dollar threshold in addition to an APC multiplier threshold. Because the PHP APCs are the only APCs for which CMHCs may receive payment under the OPPS, we would not expect to redirect outlier payments by imposing a dollar threshold. Therefore, we did not propose to set a dollar threshold for CMHC outlier payments.

In summary, in the CY 2016 OPPS/ASC proposed rule, we proposed to establish that if a CMHC's cost for partial hospitalization services, paid under either renumbered APC 5851 (existing APC 0172) or renumbered APC 5852 (existing APC 0173), exceeds 3.40 times the payment rate for renumbered APC 5852, the outlier payment is calculated as 50 percent of the amount by which the cost exceeds 3.40 times the renumbered APC 5852 payment rate. We invited public comments on these proposals.

We did not receive any public comments on our proposed outlier policy. Therefore, we are finalizing our proposal for CY 2016 to set a separate outlier threshold for CMHCs without modification. As discussed in section II.G. of this final rule with comment period, using more recent data for this final rule with comment period, we set the target for hospital outpatient outlier payments at 1.00 percent of total estimated OPPS payments. We allocated a portion of the 1.00 percent, an amount equal to 0.36 percent of outlier payments, or 0.0036 percent of total estimated OPPS payment, to CMHCs for PHP outlier payments. For CY 2016, as proposed, we are setting the CMHC outlier threshold at 3.40 multiplied by renumbered APC 5852 (existing APC 0173) payment rate and the CY 2016 outlier percentage applicable to costs in excess of the threshold at 50 percent. In other words, if a CMHC's cost for partial hospitalization services paid under either renumbered APC 5851 (existing APC 0172) or APC 5852 (existing APC 0173) exceeds 3.40 times the payment rate for renumbered APC 5852 (existing APC 0173), the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the renumbered APC 5852 (existing APC 0173) payment rate.

IX. Procedures That Will Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full historical discussion of our longstanding policies on how we identify procedures that are typically provided only in an inpatient setting (referred to as the inpatient only list) and, therefore, will not be paid by Medicare under the OPPS, and on the criteria that we use to review the inpatient only list each year to determine whether or not any procedures should be removed from the list.

B. Changes to the Inpatient Only List

In the CY 2016 OPPS/ASC proposed rule (80 FR 39299 through 39300), for the CY 2016 OPPS, we proposed to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65834)) of reviewing the current list of procedures on the inpatient only list to identify any procedures that may be removed from the list. The established criteria upon which we make such a determination are as follows:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that we have already removed from the inpatient only list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

Using this methodology, for the proposed rule, we identified seven procedures that could potentially be removed from the inpatient only list for CY 2016. We reviewed the clinical characteristics and related evidence for these procedures for removal from the inpatient only list and found them to be appropriate candidates.

In the CY 2016 OPPS/ASC proposed rule, for CY 2016, we proposed to remove the following procedures from the inpatient only list:

- CPT code 0312T (Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming);
- CPT code 20936 (Autograft for spine surgery only (includes harvesting the graft); local (*e.g.,* ribs, spinous process, or laminar fragments) obtained from the same incision);
- CPT code 20937 (Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision));
- CPT code 20938 (Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricotical (through separate skin or fascial incision));
- CPT code 22552 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace);
- CPT code 54411(Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including the irrigation and debridement of infected tissue); and
- CPT code 54417 (Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative sessions, including irrigation and debridement of infected tissue).

The seven procedures that we proposed to remove from the inpatient only list for CY 2016 and their CPT codes, long descriptors, proposed APC assignments, and proposed status indictors were displayed in Table 54 of the proposed rule (80 FR 39300). We invited public comments on the proposed removal of these seven procedures from the inpatient only list.

Comment: Several commenters supported CMS' proposal to remove CPT codes 0312T, 20936, 20937, 20938,

22552, 54411, and 54417 from the inpatient only list.

Response: We appreciate the commenters' support.

Comment: One commenter requested that the procedures described by CPT codes 27477 (Arrest, epiphyseal, any method (*e.g.,* epiphysiodesis); tibia and fibula, proximal) and 27485 (Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (*e.g.,* genu varus or valgus)) also be removed from the inpatient only list based on the similarity of these procedures to CPT codes 27475 (Arrest, epiphyseal, any method (*e.g.,* epiphysiodesis); distal femur) and 27479 (Arrest, epiphyseal, any method (*e.g.,* epiphysiodesis); combined distal femur, proximal tibia and fibula), which are not on the inpatient only list.

Response: We agree with the commenter that procedures described by CPT codes 27477 and 27485 are similar to the procedures described by CPT codes 27475 and 27479. CPT codes 27477 and 27485 also describe procedures that stop leg growth. However, these procedures either are performed on a different part of the leg (CPT code 27477) or utilize a variation of the surgical method used to perform this type of procedure (CPT code 27485). The differences between these two procedures do not prevent either of the procedures from being performed safely in the outpatient setting. Therefore, we agree with the commenter that the procedures described by CPT codes 27477 and 27485 meet the criterion of being a procedure that is related to codes that we have already removed from the inpatient only list (criterion 3 listed above) and are removing these two codes from the inpatient only list for CY 2016.

Comment: Another commenter requested that the procedures described by CPT codes 22630 (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar), 22633 (Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar), and 63267 (Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; lumber) be removed from the inpatient only list. The commenter stated that, based on its experience with these three procedures, the three procedures can be safely performed in the outpatient setting and therefore should be removed from the inpatient only list.

Response: While the commenters asserted that the procedures can be safely performed in the outpatient setting, we are not confident that an inpatient hospitalization would not be required for these procedures. We examined the clinical characteristics of the procedures described by CPT codes 63267, 22630, and 22633 and compared them to other procedures both included on the inpatient only list and not included on the inpatient only list. For the procedures described by CPT codes 22630 and 22633, the interbody technique is more extensive than the posterior or posterolateral described by CPT code 22612, which is not on the inpatient only list. We believe that the associated recovery and monitoring would also be more extensive for procedures described by CPT codes 22630 and 22633 than for the procedure described by CPT code 22612 and, therefore, the procedures described by CPT codes 22630 and 22633 should be retained on the inpatient only list for CY 2016. For the procedure described by CPT code 63267, we believe that patients would likely require inpatient monitoring for possible postoperative bleeding in the spinal canal, which could result in paralysis (a devastating complication). We examined recent Medicare utilization data for these codes by site of service. Based on our examinations, we have determined that these three procedures do not meet any of the criteria listed above for removal from the inpatient only list. Therefore, we are not removing them from the inpatient only list for CY 2016.

Comment: One commenter opposed the removal of the procedures described by CPT codes 54411 and 54417 from the inpatient only list based on the indication of the presence of an ''infected field'' in the code description and the commenter's belief that patients on which these procedures are performed will require close monitoring and a period of IV antibiotics, and will likely need cultures obtained at the time of surgery that require a minimum of 48 hours to return with the sensitivity report to know the appropriate IV antibiotic(s). The commenter believed that, for patient safety, the procedures described by these two codes should not be performed in the outpatient setting.

Response: We disagree with the commenter that the procedures described by CPT codes 54411 and 54417 should be retained on the inpatient only list. After consulting with physicians who routinely perform these procedures, we believe that properly trained surgeons can safely perform these procedures in the outpatient setting. In addition, the term ''infected field'' as used in the code descriptors encompasses a range of infections from mild to severe. We remind the commenter and the public that removal of a code from the inpatient only list does not mean that all procedures described by the code or even a majority of procedures must or should be performed in the outpatient setting. Removal of a procedure from the inpatient only list only means that the procedure is no longer precluded from being paid under the OPPS if it is performed in the outpatient setting. Not all procedures described by a code are the same, and we want to afford physicians and hospitals the maximum flexibility in choosing the most clinically appropriate site of service for the procedure, as long as the characteristics of the procedure are consistent with the criteria listed above. In the case of the procedures described by CPT codes 54411 and 54417, we believe that it is possible for surgeons to perform them in the less severe cases in the HOPD.

After consideration of the public comments we received, we are finalizing our proposal to remove procedures described by CPT codes 0312T, 20936, 20937, 20938, 22552, 54411, and 54417 from the inpatient only list for CY 2016. In addition, we are removing the procedures described by CPT codes 27477 and 27485 from the inpatient only list for CY 2016, as recommended by the commenter. The nine procedures and their CPT codes, long descriptors, APC assignments, and status indictors for CY 2016 are displayed in Table 58 below.

The complete list of codes that will be paid by Medicare in CY 2016 only as inpatient procedures is included as Addendum E to this final rule with comment period (which is available via the Internet on the CMS Web site).

TABLE 58—PROCEDURES REMOVED FROM THE INPATIENT ONLY LIST FOR CY 2016

CPT/HCPCS code	Long descriptor	CY 2016 APC assignment	CY 2016 status indicator
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming.	5464	J1
20936	Autograft for spine surgery only (includes harvesting the graft); local (e.g., ribs, spinous process, or laminar fragments) obtained from same incision.	N/A	N
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision).	N/A	N
20938	Autograft for spine surgery only (includes harvesting the graft); structural bicortical or tricortical (through separate skin or fascial incision).	N/A	N
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace.	N/A	N
27477	Arrest epiphyseal, any method (*e.g.,* epiphysiodesis); tibia and fibula, proximal	5122	T
27485	Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (*e.g.,* genu varus or valgus)	5122	T
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue.	5377	J1
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue.	5377	J1

X. Nonrecurring Policy Changes

A. Advance Care Planning Services

For CY 2015, the CPT Editorial Panel created two new codes describing advance care planning (ACP) services: CPT code 99497 (Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; first 30 minutes, face-to-face with the patient, family member(s) and/or surrogate) and an add-on CPT code 99498 (Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; each additional 30 minutes (List separately in addition to code for primary procedure)). In Addendum B of the CY 2015 OPPS/ASC final rule with comment period, we assigned CPT codes 99497 and 99498 an OPPS interim final status indicator of ''N'' (Paid under OPPS; payment is packaged into payment for other services. Therefore, there is no separate APC payment.). In Addendum B of the CY 2016 OPPS/ASC proposed rule (which is available via the Internet on the CMS Web site), we also proposed to continue assignment of status indicator ''N'' to CPT codes 99497 and 99498 for CY 2016.

Comment: Several commenters asked that separate OPPS payment be made for the services described by CPT codes 99497 and 99498 when these services are provided in the HOPD by auxiliary hospital staff. The commenters noted that separate payment for services described by these codes was proposed under the MPFS for CY 2016 (80 FR 41773). The commenters believed that nurses and other medical staff currently provide these services to hospital outpatients and that separate OPPS payment is warranted because the hospital incurs additional costs when it provides this counseling. The commenters also reported that some hospitals are currently coding this service with HCPCS code G0463 (Hospital outpatient clinic visit for the assessment and management of a patient). In addition, the Panel recommended at its summer 2015 meeting that CMS separately pay for advance care planning in the OPPS and assign the service to an APC. The Panel agreed with a presenter that if hospitals are providing this service to patients, separate payment for the service is warranted.

Response: We agree in part with the commenters that separate OPPS payment should be made for the service described by CPT code 99497, but only under limited circumstances. We believe that payment for the service described by CPT code 99497 is appropriately packaged in the OPPS except when the service is the only service provided to the patient. Therefore, we are modifying our proposal to unconditionally package payment for CPT code 99497 and instead are conditionally packaging payment for the service described by this code and assign it status indicator ''Q1'' (instead of status indicator ''N''). The service described by CPT code 99497 is assigned to APC 5011 (Level 1 Examinations and Related Services) based on expected similarity in resource use to other services assigned to this APC. CPT code 99498 is an add-on code and therefore payment for the service described by this code is unconditionally packaged (assigned status indicator ''N'') in the OPPS in accordance with 42 CFR 419.2(b)(18). We also note that the CPT code descriptors for CPT code 99497 and 99498 describe advance care planning as services provided by a ''physician or other qualified health professional.'' Therefore, based on the code descriptors, we expect that physicians or qualified nonphysician practitioners (as defined at 42 CFR 410.27(g)) will be involved (beyond just providing direct supervision of hospital staff) in providing these services to patients in the hospital outpatient setting.

In the CY 2016 MPFS final rule, advance care planning (described by CPT codes 99497 and 99498) is being added as an optional element of the Annual Wellness Visit (AWV). We refer readers to the CY 2016 MPFS final rule with comment period for a discussion of this policy. Payment for the AWV, and the advance care planning described by CPT codes CPT codes 99497 and 99498 when furnished as a part of the AWV, is excluded under the OPPS in accordance with 42 CFR 419.22(t). However, payment for the AWV, and the advance care planning described by CPT codes 99497 and 99498 when furnished as a part of the AWV, is made under the MPFS when these services are furnished in a hospital outpatient

department (75 FR 72016). (We refer readers to section 1833(a)(2)(H) of the Act.)

B. Changes for Payment for Computed Tomography (CT)

Section 218(a)(1) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) amended section 1834 of the Act by establishing a new subsection 1834(p). Effective for services furnished on or after January 1, 2016, section 1834(p) of the Act reduces payment for the technical component (TC) of applicable computed tomography (CT) services paid under the MPFS and applicable CT services paid under the OPPS (a 5-percent reduction in 2016 and a 15-percent reduction in 2017 and subsequent years). The applicable CT services are identified by HCPCS codes 70450 through 70498; 71250 through 71275; 72125 through 72133; 72191 through 72194; 73200 through 73206; 73700 through 73706; 74150 through 74178; 74261 through 74263; and 75571 through 75574 (and any succeeding codes) for services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled ''Standard Attributes on CT Equipment Related to Dose Optimization and Management.'' Section 1834(p)(4) of the Act specifies that the Secretary may apply successor standards through rulemaking.

Section 1834(p)(6)(A) of the Act requires that information be provided and attested to by a supplier and an HOPD that indicates whether an applicable CT service was furnished using equipment that was not consistent with the standard set forth in section 1834(p)(6) of the Act (currently the NEMA CT equipment standard) and that such information may be included on a claim and may be a modifier. Section 1834(p)(6)(A) of the Act also provides that such information must be verified, as appropriate, as part of the periodic accreditation of suppliers under section 1834(e) of the Act and hospitals under section 1865(a) of the Act. Section 218(a)(2) of the PAMA made a conforming amendment to section 1833(t) of the Act by adding a new paragraph (20), which provides that the Secretary shall not take into account reduced expenditures that result from the application of section 1834(p) of the Act in making any budget neutral adjustments under the OPPS.

To implement this provision, in the CY 2016 OPPS/ASC proposed rule (80 FR 39300 through 39301), we proposed to establish a new modifier to be used on claims that include CT services furnished using equipment that does not meet each of the attributes of the NEMA Standard XR–29–2013. We proposed that, beginning January 1, 2016, hospitals and suppliers would be required to use this modifier on claims for CT scans described by any of the HCPCS codes identified above (and any successor codes) that are furnished on non-NEMA Standard XR–29–2013-compliant CT scans. We stated that the use of the proposed modifier would result in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act.

We invited public comments on our proposal.

Comment: Many commenters endorsed the use of quality incentives to improve patient safety and optimize the use of radiation when providing CT diagnostic imaging services. Several commenters supported CMS' proposal to establish a modifier to identify services furnished using equipment that does not meet each of the attributes of the NEMA Standard XR–29–2013.

Response: We appreciate the commenters' support.

Comment: Several commenters asked that CMS delay implementation of section 1834(p)(2) of the Act to allow hospitals additional time to comply with the statutory provision before the payment reduction becomes effective.

Response: The statutory provision under section 1834(p)(2) of the Act refers to computed tomography services that are furnished on or after January 1, 2016. Given this statutory date, we believe that we must implement this provision beginning January 1, 2016. Health care providers have identified radiation overdose from CT scanners as a public health problem. The payment reduction is 5 percent in CY 2016 and increases to 15 percent in subsequent years. Hospitals providing services that are noncompliant as of January 1, 2016, will be subject to a 5-percent payment reduction for those services during CY 2016, and have the opportunity to upgrade their CT scanners before the 15-percent reduction takes effect in CY 2017.

Comment: Several commenters requested clarification regarding the reduction in the payment amount for CT services furnished with equipment that does not meet the CT equipment standard. Commenters specifically inquired about the application of the payment reduction to CT services that are packaged into comprehensive or composite APCs.

Response: We will be applying the payment reduction to the services described by the CT scan CPT codes (and any successor codes) listed in the statutory provision when the modifier is included on the claim. We cannot apply the payment reduction when the service described by an applicable CT scan code is packaged because there is no payment amount associated with the packaged CT scan code. Therefore, the payment reduction will only be applied when the service for a code is paid separately.

Comment: One commenter cited section 1834 (p)(4) of the Act, which specifies that, through rulemaking, the Secretary may apply successor standards for CT equipment and requested that CMS develop successor standards that exempt CT scans performed on cone beam CT (CBCT) scanners that are FDA cleared only for imaging of the head from the requirement for Automatic Exposure Control (AEC) capability. The commenter indicated that its request was based on the fact that AEC capability is unavailable on CBCT scanners.

Response: Section 1834(p) of the Act is a new provision. Our proposal was for the initial implementation of the NEMA Standard XR–29–2013. We would like to gain some experience with the statutory standard before adopting a successor standard. Therefore, we are not currently planning to adopt a successor standard to the NEMA Standard XR–29–2013.

After consideration of the public comments we received, we are finalizing the establishment of the new CT modifier. This 2-digit modifier will be added to the HCPCS annual file as of January 1, 2016, with the label ''CT'' and the long descriptor ''Computed tomography services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) XR–29–2013 standard''.

Beginning January 1, 2016, hospitals and suppliers will be required to report the ''CT'' modifier on claims for CT scans described by any of the HCPCS codes identified above (and any successor codes) that are furnished on non-NEMA Standard XR–29–2013-compliant CT scanners. The use of this modifier will result in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act.

C. Lung Cancer Screening With Low Dose Computed Tomography

On February 5, 2015, CMS issued a National Coverage Determination (NCD) for the coverage of lung cancer screening with low dose computed tomography (LDCT) under Medicare.

This coverage includes a lung cancer screening counseling and shared decision-making visit, and, for appropriate beneficiaries, annual screening for lung cancer with LDCT as an additional preventive service under Medicare if certain criteria are met. The decision memorandum announcing the NCD is available on the CMS Web site at: *http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274*.

The HCPCS codes that describe these services are HCPCS code G0296 (Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and share decision making)) (listed as HCPCS code GXXX1 in the proposed rule) and HCPCS code G0297 (Low dose CT scan (LDCT) for lung cancer screening) (listed as HCPCS code GXXX2 in the proposed rule). In the CY 2016 OPPS/ASC proposed rule (80 FR 39301), for the CY 2016 OPPS, we proposed to assign HCPCS code G0296 to APC 5822 (Level 2 Health and Behavior Services) and HCPCS code G0297 to APC 5570 (Computed Tomography without Contrast).

Comment: Commenters supported CMS' February 2015 NCD regarding coverage of lung cancer screening with LDCT and the counseling visit to discuss the need for lung cancer screening using LDCT, as well as CMS' proposal to establish HCPCS codes for payment of these services under the OPPS. However, the majority of the commenters recommended that CMS make the new HCPCS G-codes for lung cancer screening effective on February 5, 2015 (the effective date of the NCD) and extend the 1-year claims filing deadline by at least an additional quarter in CY 2016 to allow hospitals adequate time to file the claims.

One commenter supported CMS' proposed assignment of HCPCS code G0297 to APC 5570. Other commenters believed that the proposed payment rate amounts for the counseling visit and for LDCT lung cancer screening were insufficient to cover the costs of this new preventive health service. One commenter recommended that CMS assign the services described by HCPCS code G0296 to APC 5012 (Level 2 Examinations and Related Services), similar to the APC assignment of the services described by HCPCS code G0402 (Initial preventive exam, 30 minute intra-serve time).

Response: We appreciate the commenters' support. We agree that new HCPCS codes G0296 and G0297 should be effective for services furnished on or after the February 5, 2015 NCD effective date. We believe that hospitals will have sufficient time to file claims prior to the 1-year deadline.

We also appreciate the commenter's support of our proposed assignment of HCPCS code G0297 to APC 5570, and continue to believe that HCPCS codes G0296 and G0297 are appropriately assigned to APCs 5822 and 5570, respectively, based on clinical and expected resource similarity with the procedures currently assigned to those APCs. As is our standard practice, when claims data become available for these two codes, we will evaluate the claims data in relation to the APC assignment for services described by these codes and will propose a different APC through future rulemaking if such a change is warranted based on the claims data.

Comment: A few commenters asked CMS to clarify that a medically necessary evaluation and management (E/M) service on the same day as a shared counseling visit for lung cancer screening with LDCT is allowed when it is clinically appropriate. Another commenter urged CMS to clarify that, similar to the policy that cost-sharing does not apply to lung cancer screening, the policy on cost-sharing will not apply to the shared decision-making discussion on screening.

Response: We note that a medically necessary E/M service on the same day as a shared counseling visit for lung cancer screening with LDCT is allowed when it is clinically appropriate and the same day E/M service should be separately reportable with modifier ''25'' to identify a significant, separately identifiable E/M service on the same day. We also note that OPPS cost-sharing (that is, the coinsurance or deductible) does not apply to either the lung cancer screening with LDCT or the counseling visit to discuss the need for lung cancer screening using LDCT.

Comment: A few commenters also addressed issues on the following subject-matter areas: Telemedicine; post-payment review; acceptable provider types; practitioners who can provide the counseling services; frequency limitations; and documentation requirements.

Response: These comments pertain to issues for which we did not include any proposals in the proposed rule. Therefore, we believe these comments are outside the scope of the proposed rule, and we are not addressing them in this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposal to assign HCPCS code G0296 (Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making)), to APC 5822 (Level 2 Health and Behavior Services) and HCPCS code G0297 (Low dose CT scan (LDCT) for lung cancer screening), to APC 5570 (Computed Tomography without Contrast). These new codes and APC assignments are effective as of the February 5, 2015 NCD effective date and may be billed under the OPPS beginning January 1, 2016. A waiver of the coinsurance and deductible applies to HCPCS codes G0296 and G0297 because the services described by these codes are identified as additional preventive services, as stated in the NCD.

D. Payment for Procurement of Corneal Tissue Used in Procedures Performed in the HOPD and the ASC

1. Background

We have a longstanding policy of making separate payment for the acquisition or procurement of corneal tissue used in procedures performed in both the HOPD and the ASC. When corneal tissue is used in procedures performed in the HOPD, we make separate payment outside of the OPPS based on hospitals' reasonable costs to procure corneal tissue (65 FR 18448 through 18449). When corneal tissue is used in procedures performed in the ASC, we pay separately for corneal tissue procurement as a covered ancillary service when it is furnished integral to the performance of an ASC-covered surgical procedure based on invoiced costs for the acquisition costs of corneal tissue (72 FR 42508 through 42509 and 42 CFR 416.164(b)(3)). HCPCS code V2785 (Processing, preserving and transporting corneal tissue) is used to report the acquisition or procurement of corneal tissue used in procedures performed in both the HOPD and the ASC.

The original use (and currently the primary use) of corneal tissue is in corneal transplant surgery. Because corneal transplants are the primary procedures in which corneal tissue is used, in prior rulemaking discussions of the corneal tissue payment policy in both the HOPD and the ASC, we focused on the costs associated with corneal tissue when used in corneal transplants (65 FR 18448 through 18449 and 72 FR 42508 through 42509). However, we have not expressly limited the corneal tissue payment policy to only corneal tissue used in corneal transplants. When corneal tissue is used in procedures in the HOPD, we have stated that we will make separate payment, based on the hospital's reasonable costs incurred to acquire

corneal tissue (65 FR 18450). Moreover, corneal tissue acquisition costs are excluded from the determination of OPPS payment rates under 42 CFR 419.2(c)(8). Section 419.2(c)(8) of the regulation was amended in the CY 2002 OPPS final rule (66 FR 59922) and the phrase ''incurred by hospitals that are paid on a reasonable cost basis'' was deleted. For corneal tissue used in procedures performed in the ASC, as stated above, we include corneal tissue procurement in the scope of ASC services as a covered ancillary service when it is furnished integral to the performance of an ASC covered surgical procedure and pay separately for this service. Therefore, payment is not packaged into the ASC payment for the associated covered surgical procedure (72 FR 42509).

In early 2015, a stakeholder asked whether the acquisition of corneal tissue used as grafting material in glaucoma shunt surgery could be reported with HCPCS code V2785 and separately paid under the ASC payment system. In reviewing our longstanding policy on separate payment for corneal tissue acquisition when furnished integral to a covered ASC surgical procedure, we determined that the current language does not limit separate payment for the acquisition of corneal tissue to corneal transplants. Accordingly, we included an instruction in the April 2015 ASC quarterly update (Transmittal 3234, Change Request 9100) that states that ASCs can bill for the acquisition of corneal allograft tissue used for coverage (using CPT code 66180) or revision (using CPT code 66185) of a glaucoma aqueous shunt with HCPCS code V2785. In Change Request 9100, we also stated that contractors pay for corneal tissue acquisition reported with HCPCS code V2785 based on acquisition/invoice cost. The April 2015 ASC Change Request is available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3234CP.pdf*. Since the publication of the April 2015 ASC instruction, stakeholders have disagreed with the different payment policies for corneal tissue used for patch grafting (which is paid separately) versus noncorneal tissue (sclera and pericardium, among others) used for patch grafting (which is packaged).

2. CY 2016 Change to Corneal Tissue Payment Policy in the HOPD and the ASC

In the CY 2016 OPPS/ASC proposed rule (80 FR 39301 through 39302), for CY 2016, we proposed to limit the separate payment policy for acquisition costs of corneal tissue used in procedures performed in the HOPD and the ASC to only corneal tissue that is used in a corneal transplant procedure. Under our proposal, the acquisition costs for corneal tissue used in procedures performed in the HOPD setting would be separately paid only when the corneal tissue is used in a corneal transplant procedure. Otherwise, the corneal tissue would be a packaged surgical supply in the OPPS under the regulation at 42 CFR 419.2(b)(4). We proposed that corneal tissue procurement for use in procedures performed in the ASC would be included as a covered ancillary service only when it is furnished integral to the performance of a corneal transplant procedure that is an ASC covered surgical procedure, and we pay separately for covered ancillary services under the ASC payment system. We also stated that we would provide a specific list of corneal transplant procedure HCPCS codes with which HCPCS code V2785 may be reported in the January 2016 OPPS and ASC updates through change requests. We stated that this would mean that, for corneal tissue used in procedures performed in the HOPD and the ASC, we would not make separate payment for corneal tissue when it is used in any nontransplant procedure (payment for the corneal tissue in that instance would be packaged with the surgical procedure). We also stated that we would make packaged payment for all tissues used as patch grafts in glaucoma shunt surgery. We did not propose to change any other aspect of the policy for payment for corneal tissue used in procedures performed in either the HOPD or the ASC.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39302), we stated that we believe limiting separate payment for corneal tissue to corneal transplants only is warranted for the following reasons:

- The public comments summarized in the CY 2000 OPPS final rule with comment period (65 FR 18448 through 18449) and referenced in the CY 2008 ASC final rule (72 FR 42508 through 42509) by the Eye Bank Association of America (EBAA) and the study report submitted by the EBAA focused on corneal tissue acquisition for corneal transplants. These comments and the study were significant factors in the finalized corneal tissue separate payment policy that addressed corneal tissue acquisition costs associated with corneal tissue used in corneal transplants.
- Corneal tissue for transplantation requires more specialized and more costly processing than corneal tissue used as glaucoma shunt-tube patch grafts because of the fragility and importance of the corneal endothelium, of which the health and preservation are necessary for successful transplantation but not for scleral patch grafting.
- Unlike corneas used for corneal transplantation, in which there is currently no substitute, there are multiple different tissue types, each with their own costs and relative benefits and detriments, available for glaucoma shunt surgery patch grafting.
- Given the numerous tissue options for patch grafting, we believe that Medicare beneficiaries will continue to have access to patch grafting in glaucoma shunt surgery in both the hospital setting and the ASC setting.

In the proposed rule, we also proposed to revise the related regulations at 42 CFR 416.164(b)(3) and 419.2(c)(8) to specify that payment would be made for corneal tissue acquisition or procurement costs for corneal transplant procedures.

We invited public comments on these proposals.

Comment: Many commenters supported the proposals. The commenters believed that the payment for the glaucoma surgery described by HCPCS code 66180 (Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft) with any/all of the various grafting materials (corneal tissue, sclera, or pericardium) that is packaged into the payment for the surgery is adequate for payment for procedures performed in both the HOPD and the ASC.

Response: We appreciate the commenters' support.

Comment: Several other commenters opposed the proposals. The commenters urged CMS to continue separate payment for corneal tissue. They believed that, without separate payment for corneal tissue for use as a graft in glaucoma surgery, ASCs would not permit glaucoma surgeons to perform this procedure in the ASC because the total cost of the procedure, including the shunt and the grafting material, would exceed the payment (if any or all grafting materials are packaged into the surgical procedure).

Response: We disagree with these commenters. We believe that the total payment for the procedure described by HCPCS 66180 (with any or all grafting materials packaged) is adequate when procedures are performed in both the HOPD and the ASC. Therefore, for CY 2016, we are packaging payment for corneal tissue used in all applicable procedures except when used in corneal transplant surgery. In addition, we believe that our reassignment of some of

the intraocular procedures from APC 5492 (Level 2 Intraocular Procedures) to APC 5491 (Level 1 Intraocular Procedures), as described in section III.D.5 of this final rule with comment period, should help alleviate the concerns of the commenters relating to the sufficiency of payment for glaucoma surgery with patch grafting because this change will result in an increase in the payment for this procedure.

After consideration of the public comments we received, we are finalizing our proposals, without modification. Under the ASC payment system, procurement or acquisition of corneal tissue for use in procedures performed in the ASC will be included as a covered ancillary service only when it is furnished integral to the performance of a corneal transplant procedure that is an ASC covered surgical procedure. Under the OPPS, procurement or acquisition of corneal tissue will be paid separately only when it is used in corneal transplant procedures. Specifically, corneal tissue will be separately paid when used in procedures performed in the HOPD and the ASC only when the corneal tissue is used in a corneal transplant procedure described by one of the following CPT codes: 65710 (Keratoplasty (corneal transplant); anterior lamellar); 65730 (Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia)); 65750 (Keratoplasty (corneal transplant); penetrating (in aphakia)); 65755 (Keratoplasty (corneal transplant); penetrating (in pseudophakia)); 65756 (Keratoplasty (corneal transplant); endothelial); 65765 (Keratophakia); 65767 (Epikeratoplasty); and any successor code or new code describing a new type of corneal transplant procedure that uses eye banked corneal tissue. This list of corneal transplant procedures with which corneal tissue is separately payable also will appear in the January 2016 OPPS and ASC updates through change requests. We also are finalizing the proposed changes to §§ 416.164(b)(3) and 419.2(c)(8) of the regulations, without modification.

XI. CY 2016 OPPS Payment Status and Comment Indicators

A. CY 2016 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. The complete list of the payment status indicators and their definitions for CY 2016 is displayed in Addendum D1 to this final rule with comment period, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The CY 2016 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this final rule with comment period, which are available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39302), for CY 2016, we proposed to create two new status indicators:

- ''J2'' to identify certain combinations of services that we proposed to pay through new proposed C–APC 8011 (Comprehensive Observation Services). We refer readers to section II.A.2.e. of this final rule with comment period for a detailed discussion of this change and any public comments that we received.
- ''Q4'' to identify conditionally packaged laboratory tests. We refer readers to section II.A.3. of this final rule with comment period for a detailed discussion of this new status indicator and any public comments that we received.

We note that, as discussed in sections II.A.2.e. and II.A.3. of this final rule with comment period, we are finalizing the two new status indicators ''J2'' and ''Q4''.

B. CY 2016 Comment Indicator Definitions

In the CY 2016 OPPS/ASC proposed rule (80 FR 39302), for the CY 2016 OPPS, we proposed to use three comment indicators. Two comment indicators, ''CH'' and ''NI,'' which were in effect in CY 2015, would continue in CY 2016. In the proposed rule, we proposed to create new comment indicator ''NP'' that would be used in the proposed rule to identify a new code for the next calendar year or an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year proposed APC assignment, and would also indicate that comments will be accepted on the proposed APC assignment for the new code.

- ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

We proposed to use the ''CH'' comment indicator in the CY 2016 OPPS/ASC proposed rule to indicate HCPCS codes for which the status indicator or APC assignment, or both, are proposed for change in CY 2016 compared to their assignment as of June 30, 2015. We stated that we believe using the ''CH'' indicator in the proposed rule would facilitate the public's review of the changes that we proposed for CY 2016. We proposed to use the ''CH'' comment indicator in the CY 2016 OPPS/ASC final rule with comment period to indicate HCPCS codes for which the status indicator or APC assignment, or both, would change in CY 2016 compared to their assignment as of December 31, 2015. Use of the comment indicator ''CH'' in association with a composite APC indicates that the configuration of the composite APC would be changed in the CY 2016 OPPS/ASC final rule with comment period.

For CY 2016, we proposed that any existing HCPCS codes with substantial revisions to the code descriptors for CY 2016 compared to the CY 2015 descriptors would be labeled with comment indicator ''NI'' in Addendum B to the CY 2016 OPPS/ASC final rule with comment period (80 FR 39302). However, in order to receive the comment indicator ''NI,'' the CY 2016 revision to the code descriptor (compared to the CY 2015 descriptor) must be significant such that the new code descriptor describes a new service or procedure for which the OPPS treatment may change. We proposed to use comment indicator ''NI'' to indicate that these HCPCS codes would be open for comment as part of the CY 2016 OPPS/ASC final rule with comment period. Like all codes labeled with comment indicator ''NI,'' we would respond to public comments and finalize their OPPS treatment in the CY 2017 OPPS/ASC final rule with comment period.

In accordance with our usual practice, we proposed that CPT and Level II HCPCS codes that are new for CY 2016 and that are included in Addendum B to the CY 2016 OPPS/ASC final rule with comment period also would be labeled with comment indicator ''NI'' in Addendum B to the CY 2016 OPPS/ASC final rule with comment period.

We proposed that CPT codes that are new for CY 2016 and any existing HCPCS codes with substantial revisions to the code descriptors for CY 2016 compared to the CY 2015 descriptors that were included in Addendum B to the CY 2016 OPPS/ASC proposed rule would be labeled with new comment indicator ''NP'' in Addendum B to indicate that these CPT codes would be open for comment as part of the CY 2016 OPPS/ASC proposed rule. We would respond to public comments and finalize their OPPS assignment in the CY 2016 OPPS/ASC final rule with comment period.

Comment: One commenter did not believe the comment indicator ''NP'' was necessary because CMS has already been using comment indicator ''NI.'' The commenter suggested that the two comment indicators were redundant. Moreover, the commenter recommended that CMS pare back the number of status and comment indicators, given the complexity that they add to the claims process.

Response: We appreciate the commenter's recommendation to simplify the claims process. However, we disagree that comment indicators ''NP'' and ''NI'' are redundant and complicate claims processing. The ''NP'' comment indicator was proposed to be used in OPPS Addendum B, which also includes the proposed APC assignment of the code, to identify a new code or an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year. The ''NP'' comment indicator is intended to notify the public in the proposed rule that public comments will be accepted on the proposed APC assignment for the new code and considered in that year's final rule. On the other hand, comment indicator ''NI'' is only used in the OPPS final rule with comment period Addendum B to identify a new code or existing code with substantial revision to its code descriptor in the next calendar year interim APC assignment for which comments will be accepted on the interim APC assignment for the new code. We believe that the creation of comment indicator ''NP'' will simplify the process of identification of new codes added in time for the proposed rule, as opposed to those that are new or substantially revised in the final rule with comment period.

After consideration of the public comments we received, we are finalizing, without modification, the proposed new comment indicator ''NP'' for CY 2016.

The CY 2015 definitions of comment indicators ''CH'' and ''NI'' continue to be appropriate, and we are continuing to use them for CY 2016.

The definitions of the OPPS comment indicators for CY 2016 are listed in Addendum D2 to this final rule with comment period, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

For further discussion on the treatment of new CY 2016 CPT codes that will be effective January 1, 2016, for which we solicited public comments in the CY 2016 OPPS/ASC proposed rule, we refer readers to section III. of this final rule with comment period.

XII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74378 through 74379), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68434 through 68467), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75064 through 75090), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66915 through 66940).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under 42 CFR 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate to be furnished to Medicare beneficiaries in ASCs. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS (72 FR 42478).

In the August 2, 2007 final rule (72 FR 42495), we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66932 through 66934), we expanded the scope of ASC covered ancillary services to include certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS when they are provided integral to an ASC covered surgical procedure. Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR

42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests to update services covered under the OPPS. We also provide quarterly update change requests (CRs) for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). CMS releases new and revised Level II HCPCS codes and recognizes the release of new and revised CPT codes by the AMA and makes these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. CMS releases new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payment and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process was used to update HCPCS and CPT codes (76 FR 42291).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS inpatient list), new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

B. Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised Category I and Category III CPT Codes and Level II HCPCS Codes

Category I CPT, Category III CPT, and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims: (1) Category I CPT codes, which describe surgical procedures and vaccine codes; (2) Category III CPT codes, which describe new and emerging technologies, services, and procedures; and (3) Level II HCPCS codes, which are used primarily to identify items, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes; however, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in the CY 2016 OPPS/ASC proposed rule and this final rule with comment period.

We have separated our discussion below based on when the codes are released and whether we proposed to solicit public comments in the proposed rule (and respond to those comments in this CY 2016 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in this CY 2016 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2017 OPPS/ASC final rule with comment period).

We note that we sought public comments in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66918) on the new and revised Category I and III CPT and Level II HCPCS codes that were effective January 1, 2015. We also sought public comments in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66918) on the new and revised Level II HCPCS codes effective October 1, 2014. These new and revised codes, with an effective date of October 1, 2014 or January 1, 2015, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2015 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2015 OPPS/ASC final rule with comment period. In the proposed rule (80 FR 39304), we stated that we will respond to public comments and finalize the treatment of these codes under the ASC payment system in this CY 2016 OPPS/ASC final rule with comment period.

2. Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April 2015 and July 2015 for Which We Solicited Public Comments in the CY 2016 OPPS/ASC Proposed Rule

In the April 2015 and July 2015 Change Requests (CRs), we made effective for April 1, 2015 and July 1, 2015, respectively, a total of 13 new Level II HCPCS codes and two new Category III CPT codes that describe covered ASC services that were not addressed in the CY 2015 OPPS/ASC final rule with comment period.

In the April 2015 ASC quarterly update (Transmittal 3234, CR 9100, dated April 15, 2015), we added one new device Level II HCPCS code and seven new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 55 of the CY 2016 OPPS/ASC proposed rule (80 FR 39304) listed the new Level II HCPCS codes that were implemented April 1, 2015, along with their proposed payment indicators for CY 2016.

In the July 2015 ASC quarterly update (Transmittal 3279, CR 9207, dated June 5, 2015), we added one new device Level II HCPCS code and four new drug and biological Level II HCPCS codes to the list of covered ancillary services. Table 56 of the CY 2016 OPPS/ASC proposed rule (80 FR 39305) listed the new Level II HCPCS codes that were implemented July 1, 2015. The proposed payment rates, where applicable, for these April and July codes can be found in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site).

Through the July 2015 quarterly update CR, we also implemented ASC payment for two new Category III CPT

codes as ASC covered surgical procedures, effective July 1, 2015. These codes are listed in Table 57 of the CY 2016 OPPS/ASC proposed rule (80 FR 39305), along with their proposed payment indicators. The proposed payment rates for these new Category III CPT codes can be found in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

In the CY 2016 OPPS/ASC proposed rule (80 FR 39304), we invited public comments on these proposed payment indicators and the proposed payment rates for the new Category III CPT code and Level II HCPCS codes that were newly recognized as ASC covered surgical procedures or covered ancillary services in April 2015 and July 2015 through the quarterly update CRs, as listed in Tables 55, 56, and 57 of the proposed rule. We proposed to finalize their payment indicators and their payment rates in this CY 2016 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding the proposed ASC payment indicators and payment rates. Therefore, we are adopting as final the CY 2016 proposed ASC payment indicators and payment rates for the ASC covered surgical procedures and covered ancillary services described by the new Level II HCPCS codes implemented in April 2015 and July 2015 through the quarterly update CRs as shown below, in Tables 59, 60 and 61, respectively. The final CY 2016 ASC payment rates for these codes can be found in ASC Addendum AA and BB of this OPPS/ASC final rule with comment period.

TABLE 59—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2015

CY 2015 HCPCS code	CY 2016 HCPCS code	CY 2016 Long descriptor	Final CY 2016 payment indicator
C2623	C2623	Catheter, transluminal angioplasty, drug-coated, non-laser	J7
C9445	J0596	Injection, c1 esterase inhibitor (recombinant), Ruconest, 10 units	K2
C9448*	J8655	Netupitant 300 mg and palonosetron 0.5 mg	K2
C9449	J9039	Injection, blinatumomab, 1 microgram	K2
C9450	J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	K2
C9451	J2547	Injection, peramivir, 1 mg	K2
C9452	J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	K2
Q9975	J7205	Injection, factor viii fc fusion (recombinant), per iu	K2

*HCPCS code C9448 was deleted June 30, 2015 and replaced with HCPCS code Q9978 effective July 1, 2015.

TABLE 60—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2015

CY 2015 HCPCS code	CY 2016 HCPCS code	CY 2016 Long descriptor	Final CY 2016 payment indicator
C2613	C2613	Lung biopsy plug with delivery system	J7
C9453	J9299	Injection, nivolumab, 1 mg	K2
C9454	J2502	Injection, pasireotide long acting, 1 mg	K2
C9455	J2860	Injection, siltuximab, 10 mg	K2
Q9978*	J8655	Netupitant 300 mg and palonosetron 0.5 mg	K2

*HCPCS code Q9978 replaced HCPCS code C9448 effective July 1, 2015.

TABLE 61—NEW CATEGORY III CPT CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2015

CY 2015 CPT code	CY 2016 CPT code	CY 2016 Long descriptor	Final CY 2016 payment indicator
0392T	0392T	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band).	G2
0393T	0393T	Removal of esophageal sphincter augmentation device	G2

3. Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2016

a. Current Process for Accepting Comments on New and Revised CPT Codes That Are Effective January 1

Historically, we have not received new and revised Category I and Category III CPT codes that take effect at the beginning of a calendar year in time to include them in the proposed rule for that calendar year. Therefore, under the ASC payment system, the current process we have used is to incorporate new and revised Category I and Category III CPT codes that are effective January 1 in the final rule with comment period thereby updating the ASC payment system for the following calendar year. These codes are released to the public by the AMA via the annual CPT code books and electronic CPT code file. In addition, we include these codes in the January ASC quarterly update CR, and we list the codes in ASC Addendum AA and BB of the OPPS/ASC final rule with comment period. All of the new codes are flagged with comment indicator ''NI'' in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. In addition, existing CPT codes that have substantial revision

to their code descriptors that necessitate a change in the current ASC payment indicator are assigned to comment indicator ''NI.'' The payment indicator and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the OPPS/ASC final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year's OPPS/ASC update. For example, the new CPT codes that were effective January 1, 2014 were assigned to comment indicator ''NI'' in Addendum AA and Addendum BB to the CY 2014 OPPS/ASC final rule with comment period. We responded to public comments received on the CY 2014 OPPS/ASC final rule with comment period and finalized the payment indicator assignments for these codes in the CY 2015 OPPS/ASC final rule with comment period; and we included the final ASC payment indicator assignments in Addendum AA and Addendum BB to that final rule with comment period.

Several stakeholders, including consultants, device manufacturers, drug manufacturers, as well as specialty societies and hospitals, have expressed concern with the process we use to recognize new and revised CPT codes. They believe that we should publish proposed ASC payment indicators for the new and revised CPT codes that will be effective January 1 in the OPPS/ASC proposed rule for the prior year, and request public comments prior to finalizing them for the January 1 implementation date. Further, the stakeholders believe that seeking public input on the ASC payment indicator assignments for these new and revised codes would assist CMS in assigning the CPT codes to appropriate payments under the ASC payment system. We were informed of similar concerns regarding our process for assigning interim payment values for revalued and new and revised codes under the MPFS and the OPPS. Consequently, we included proposed policies to address those concerns in the CY 2015 MPFS proposed rule (79 FR 40359 through 40364), and in the CY 2015 OPPS/ASC proposed rule (79 FR 40977 through 40979). Based on the comments that we received to the proposed rules, we finalized the policies in the CY 2015 MPFS final rule (79 FR 67602 through 67609) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844).

Like the MPFS and the OPPS, the ASC payment system relies principally upon the Current Procedural Terminology (CPT®) coding system maintained by the AMA for billing. CPT® is the standard code set adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for outpatient services. The AMA CPT Editorial Panel's coding cycle occurs concurrently with our calendar year rulemaking cycle for the OPPS and the ASC payment system. The OPPS/ASC proposed rules have historically been published prior to the publication of the CPT codes that are generally made public in the fall, with a January 1 effective date, and therefore, we have not historically been able to include these codes in the OPPS/ASC proposed rules.

b. Modification of the Current Process for Accepting Comments on New and Revised Category I and III CPT Codes That Are Effective January 1

In the CY 2016 OPPS/ASC proposed rule (80 FR 39305 through 39307), we proposed to make changes in the process we use to establish ASC payment indicators for new and revised Category I and Category III CPT codes. As discussed above, we finalized similar revisions under the MPFS and the OPPS for establishing payment indicators for new and revised CPT codes that take effect each January 1. Because we are following this new process for the OPPS where new and revised codes that are received in time for the proposed rule are assigned proposed payment indicators and proposed APC assignments in the OPPS, we also needed to propose a corresponding process for payment rates and payment indicators in the ASC for those codes that are ASC covered surgical procedures and covered ancillary services. The proposed revised process would eliminate our current practice of assigning interim payment indicators for the vast majority of new and revised CPT codes that take effect on January 1 each year.

Consequently, in the CY 2016 OPPS/ASC proposed rule (80 FR 39305 through 39307), we proposed that we would include new and revised Category I and III CPT codes that we receive from the AMA CPT Editorial Panel in time for the proposed rule and their proposed ASC payment indicators in the OPPS/ASC proposed rule and finalize the ASC payment indicator assignments in the OPPS/ASC final rule with comment period. We proposed that, for new and revised Category I and III CPT codes that can be cross-walked to current codes for which ASC payment assignments are already established that we receive from the AMA CPT Editorial Panel too late for inclusion in the proposed rule for a year, we would delay adoption of these new and revised codes for that year and, instead, adopt coding policies and payment rates that conform, to the extent possible, to the policies and payment rates in place for the previous year. We proposed to adopt these conforming coding and payment policies (by creating G codes that mirror existing codes that are the predecessor codes to the untimely new and revised CPT codes) on an interim basis pending the result of our specific proposals for these new and revised codes through notice—and—comment rulemaking in the OPPS/ASC proposed rule for the following year. However, if certain CPT codes are revised in a manner that would not affect the cost of inputs (for example, a grammatical change to CPT code descriptors), we would use these revised codes and continue to assign those codes to their current ASC payment indicator and APC unless a policy change was being proposed for the codes. For example, under this proposed process, if a single CPT code was separated into two codes and we did not receive those codes until May 2016, we would assign each of those codes to interim payment indicator ''B5'' (Alternative code may be available; no payment made) in the final rule with comment period, to indicate that an alternate code is recognized under the ASC payment system. ASCs could not use those two new CPT codes to bill Medicare for ASC services the first year after the effective date of the codes. Instead, we would create a HCPCS G-code with the same descriptor as the single predecessor CPT code, and continue to use the same ASC payment indicator for that code during the year. We would propose payment indicators for the two new CPT codes during rulemaking in CY 2017 for payment beginning in CY 2018. We recognize that the use of HCPCS G-codes may place an administrative burden on those ASCs that bill for services under the ASC payment system. We are optimistic based on what has occurred in CY 2015 that the AMA CPT Editorial Panel ultimately will be able to adjust its timelines and processes so that most, if not all, of the annual coding changes can be addressed in the OPPS/ASC proposed rule.

As stated previously, for new or revised codes, including new codes that describe wholly new services, we would make every effort to work with the AMA CPT Editorial Panel to ensure that we received the codes in time to propose payment rates in the proposed rule. However, if we do not receive the code for a wholly new service in time to

include proposed ASC payment indicator assignments in the proposed rule for a year, we would establish interim ASC payment indicator assignments for the initial year. We proposed to establish the initial ASC payment indicator assignments for wholly new services as interim final assignments, and to follow our current process to solicit and respond to public comments and finalize the ASC payment indicator assignments in the subsequent year. We proposed to finalize and implement the revised CMS process for establishing ASC payment indicator assignments for new and revised codes for CY 2016.

In summary, we proposed to include in the OPPS/ASC proposed rule the proposed ASC payment indicators for the vast majority of new and revised CPT codes before they are used for payment purposes under the ASC payment system. We would address new and revised CPT codes for the upcoming year that are available in time for the proposed rule by proposing ASC payment indicators for the codes. Otherwise, we would delay adoption of the new and revised codes that can be cross-walked to current codes for which ASC payment assignments are already established for a year while using methods (including creating G-codes that describe the predecessor codes) to maintain the existing ASC payment indicators until the following year when we would include proposed assignments for the new and revised codes in the proposed rule. In the case of a new CPT code that describes a wholly new service (such as a new technology or new surgical procedure) that has not previously been addressed under the ASC payment system for which we do not receive timely information from the AMA, we proposed to establish interim ASC payment indicators in that year's OPPS/ASC final rule with comment period, as is our current process, and to follow our current process to respond to public comments and finalize the ASC payment indicator assignments in the OPPS/ASC final rule with comment period for the subsequent year. The proposed revised process would eliminate our current practice of assigning interim ASC payment indicators for the vast majority of new and revised CPT codes that take effect on January 1 each year. We invited public comment on these proposals.

As stated in the CY 2016 OPPS/ASC proposed rule (80 FR 39306), for the CY 2016 ASC update, we received the CY 2016 Category I and III CPT codes from the AMA in time for inclusion in the CY 2016 OPPS/ASC proposed rule. The new and revised CY 2016 Category I and III CPT codes were included in ASC Addenda AA and BB to the CY 2016 OPPS/ASC proposed rule (which are available via the Internet on the CMS Web site) and were assigned to proposed new comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed ASC payment indicator and that comments will be accepted on the proposed payment indicator. In the CY 2016 OPPS/ASC proposed rule, we solicited public comments on the proposed CY 2016 ASC payment indicators for the new and revised Category I and III CPT codes that would be effective January 1, 2016.

Comment: One commenter recommended that CMS refrain from creating temporary HCPCS G-codes when CPT codes are available in order to avoid confusion and parallel coding inconsistencies. The commenter further recommended that CMS rely solely on the use of CPT codes for procedures and services under both the OPPS and the ASC payment system.

Response: We appreciate the commenter's recommendations. However, we do not agree that we should refrain from creating temporary HCPCS G-codes when CPT codes are available or that we should rely solely on the use of CPT codes for procedures and services under both the OPPS and the ASC payment system. We intend to the extent possible to include new and revised Category I and III CPT codes and their proposed payment indicators in a proposed rule and finalize the payment indicators in the final rule with comment period for the same year. We will delay the adoption of new and revised Category I and III CPT codes that can be cross-walked to current codes for which ASC payment assignments are already established that are available too late for a current proposed rule for a year. Instead, we will use G-codes that mirror the predecessor CPT codes that are scheduled for deletion in the upcoming year to maintain the existing ASC payment indicators until the following year. In the following year, we will include proposed assignments for these new and revised Category I and III CPT codes in the OPPS/ASC proposed rule, and finalize the payment indicators for these codes in the OPPS/ASC final rule with comment period. In the case of a new Category I or III CPT code that describes a wholly new service (such as a new technology or new surgical procedure) that has not previously been addressed under the ASC payment system for which we do not receive timely information from the AMA, we will establish interim ASC payment indicators in that year's OPPS/ASC final rule with comment period, as is our current process, and follow our current process to respond to public comments and finalize the ASC payment indicator assignments in the OPPS/ASC final rule with comment period for the subsequent year. We believe this new process aligns the reporting requirements for the same codes under all three payment systems: MPFS, OPPS, and the ASC payment system. This creates coding consistency and less confusion amongst all three Medicare payment systems.

Comment: Some commenters supported and commended CMS for proposing a comment period for new CPT codes before they are used for payment purposes under the ASC payment system. The commenters stated that requesting public input prior to use of new and revised codes will encourage reliable and accurate payments. One commenter believed that the inclusion of new and revised CPT codes in the proposed rule represents a significant improvement. The commenters requested that CMS adopt its proposal to allow for comments on new and revised CPT codes prior to usage for payment purposes.

Response: We appreciate the commenters support for our proposal. We believe that publishing our proposed ASC payment indicators for the new and revised Category I and III CPT codes prior to their implementation on January 1 whenever possible will help ensure that correct ASC payment indicators for new and revised codes are effective January 1, and that ASCs are paid appropriately when the codes are implemented.

After consideration of the public comments we received, we are finalizing our proposal without any modification. First, for new and revised Category I and III CPT codes that we receive timely from the AMA CPT Editorial Panel, we are finalizing our proposal to include these codes that will be effective January 1 in the OPPS/ASC proposed rules with proposed ASC payment indicators, and finalize their assignments in the OPPS/ASC final rules with comment period. Secondly, for those new and revised Category I and III CPT codes that can be cross-walked to current codes for which ASC payment assignments are already established that cannot be included in the OPPS/ASC proposed rules, we are finalizing our proposal to delay adoption of these codes for a year while

using methods, including creating G-codes that describe the predecessor codes, to maintain the existing ASC payment indicators as interim ASC payment indicator assignments until the following year when we will include proposed payment indicator assignments for the codes in the OPPS/ASC proposed rule, and finalize these payment indicator assignments in the OPPS/ASC final rule with comment period. We note that we will assign the HCPCS G-codes to interim ASC payment indicator assignments for one year, and assign the Category I and III CPT codes to ASC payment indicator ''B5'' to indicate that another HCPCS code should be reported to Medicare. However, if certain Category I and III CPT codes are revised in a manner that would not affect the cost of inputs (for example, a grammatical change to CPT code descriptors), we will use these revised codes and continue to assign those codes to their current ASC payment indicator and APC unless a policy change was being proposed for the codes. Thirdly, for Category I and III CPT codes that describe wholly new services that have not previously been addressed under the ASC payment system for which we do not receive timely information from the AMA, we will establish interim ASC payment indicators for these CPT codes for the initial year in the OPPS/ASC final rule with comment period in which we will solicit public comments on these interim payment indicators, and respond to those comments and finalize the ASC payment indicator assignments in the subsequent year OPPS/ASC final rule with comment period, as is our current practice.

4. Process for New and Revised Level II HCPCS Codes That Are Effective October 1, 2015 and January 1, 2016 for Which We Are Soliciting Public Comments in This CY 2016 OPPS/ASC Final Rule With Comment Period

In the CY 2016 OPPS/ASC proposed rule (80 FR 39307), although we proposed to revise our process for requesting public comments on the new and revised Category I and III CPT codes, we did not propose any change to the process for requesting public comments on the new and revised Level II HCPCS codes that would be effective October 1 and January 1.

As has been our practice in the past, we incorporate those new and revised Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS Web site, and also through the January ASC quarterly update CRs. In the past, we also released new and revised Level II HCPCS codes that are effective October 1 through the October ASC quarterly update CRs and incorporated these new and revised codes in the final rule with comment period, thereby updating the ASC for the following calendar year. All of these codes are flagged with comment indicator ''NI'' in Addenda AA and BB to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. The payment indicator and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the OPPS/ASC final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year's OPPS/ASC update.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39307), we proposed to continue this process for CY 2016. Specifically, the Level II HCPCS codes that will be effective October 1, 2015 and January 1, 2016 would be flagged with comment indicator ''NI'' in Addendum AA and BB to the CY 2016 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment status for CY 2016. We also stated that we will be inviting public comments on the proposed payment indicators and payment rates for these codes, if applicable, that would be finalized in the CY 2017 OPPS/ASC final rule with comment period.

In Table 62 below, we summarize the CY 2016 process described in section XII.B. of the proposed rule for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new and revised codes under the ASC payment system.

TABLE 62—PROPOSED COMMENT TIMEFRAME FOR CY 2016 FOR NEW OR REVISED CATEGORY I AND III CPT CODES AND LEVEL II HCPCS CODES

ASC quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April 1, 2015	Level II HCPCS Codes	April 1, 2015	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.
July 1, 2015	Level II HCPCS Codes	July 1, 2015	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.
	Category I (certain vaccine codes) and III CPT codes.	July 1, 2015	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.
October 1, 2015	Level II HCPCS Codes	October 1, 2015	CY 2016 OPPS/ASC final rule with comment period.	CY 2017 OPPS/ASC final rule with comment period.
January 1, 2016	Level II HCPCS Codes	January 1, 2016	CY 2016 OPPS/ASC final rule with comment period.	CY 2017 OPPS/ASC final rule with comment period.
	Category I and III CPT Codes.	January 1, 2016	CY 2016 OPPS/ASC proposed rule.	CY 2016 OPPS/ASC final rule with comment period.

We invited public comments on this proposed process. We did not receive any public comments related to our proposal. Therefore, we are finalizing our proposal to assign the Level II HCPCS codes that will be effective October 1, 2015 and January 1, 2016 to comment indicator ''NI'' in Addendum AA and BB of this CY 2016 OPPS/ASC

final rule with comment period to indicate that we have assigned the codes an interim ASC payment indicator for CY 2016. We note that the payment indicator and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the OPPS/ASC final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year's OPPS/ASC update.

C. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC list of covered surgical procedures beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the list of covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

(2) Changes for CY 2016 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2016 OPPS/ASC proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2014 volume and utilization data and the clinical characteristics for all covered surgical procedures that are assigned payment indicator ''G2'' (Nonoffice-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2015, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2,'' ''P3,'' or ''R2'' in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66921 through 66923).

Our review of the CY 2014 volume and utilization data resulted in our identification of two covered surgical procedures, CPT codes 43197 (Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)) and 43198 (Esophagoscopy, flexible, transnasal; with biopsy, single or multiple) that we believe meet the criteria for designation as office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices and we believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The two CPT codes we proposed to permanently designate as office-based are listed in Table 59 of the CY 2016 OPPS/ASC proposed rule (80 FR 39308).

We invited public comment on this proposal.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal, without modification, to designate the procedures described by CPT codes 43197 and 43198 as permanently office-based for CY 2016, as set forth in Table 63 below.

TABLE 63—ASC COVERED SURGICAL PROCEDURES NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2016

CY 2016 CPT code	CY 2016 long descriptor	CY 2015 ASC payment indicator	Proposed CY 2016 ASC payment indicator	Final CY 2016 ASC payment indicator *
43197	Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	G2	P3	P3
43198	Esophagoscopy, flexible, transnasal; with biopsy, single or multiple	G2	P3	P3

* Final payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2016. For a discussion of the MPFS rates, we refer readers to the CY 2016 MPFS final rule with comment period.

We also reviewed CY 2014 volume and utilization data and other information for six procedures finalized for temporary office-based status in Table 47 in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66922 through 66923). Among these six procedures, there were very few claims in our data or no claims data for five procedures: CPT code 0099T (Implantation of intrastromal corneal ring segments); CPT code 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound); CPT code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies); CPT

code 10030 (Image-guided fluid collection drainage by catheter (*e.g.,* abscess, hematoma, seroma, lymphocele, cyst), soft tissue (*e.g.,* extremity, abdominal wall, neck), percutaneous); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (*e.g.,* retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, in the CY 2016 OPPS/ASC proposed rule (80 FR 39308 through 39309) we proposed to maintain the temporary office-based designations for these five codes for CY 2016. We listed all of these codes in Table 60 of the proposed rule (80 FR 39309), except for HCPCS code 0099T. HCPCS code 0099T was assigned payment indicator ''R2'' in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66922), but this code is being replaced with a new CPT code currently identified with a CMS 5-digit placeholder code of 657XG. Table 61 of the proposed rule (80 FR 39309) reflected the new CY 2016 codes for ASC covered surgical procedures with proposed temporary office-based designations.

For CPT code 64617 (Chemodenervation of muscle(s); larynx, unilateral, percutaneous (*e.g.,* for spasmodic dysphonia), includes guidance by needle electromyography, when performed), claims data indicate these procedures are performed more than 50 percent of the time in physicians' offices, and we believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. Therefore, we proposed to make the office-based designation for CPT code 64617 permanent.

The proposed CY 2016 payment indicator designations for the procedures that were temporarily designated as office-based in CY 2015 were displayed in Table 60 of the proposed rule. The procedures for which the proposed office-based designations for CY 2016 are temporary also are indicated by asterisks in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

We invited public comment of these proposals.

Comment: One commenter supported CMS' proposal to designate HCPCS code C9800 as temporarily rather than permanently office-based, allowing for additional utilization data to be collected.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, for CY 2016 we are finalizing our proposal, without modification, to designate the four procedures listed in Table 64 as temporarily office-based and one procedure listed in Table 64 as permanently office-based.

TABLE 64—CY 2016 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2015 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2016 CPT code	CY 2016 long descriptor	CY 2015 ASC payment indicator	CY 2016 ASC payment indicator **
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound.	R2 *	R2 *
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies.	R2 *	R2 *
10030	Image-guided fluid collection drainage by catheter (*e.g.,* abscess, hematoma, seroma, lymphocele, cyst), soft tissue (*e.g.,* extremity abdominal wall, neck), percutaneous.	P2 *	P2 *
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (*e.g.,* for spasmodic dysphonia), includes guidance by needle electromyography, when performed.	P3 *	P3
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (*e.g.,* retinopathy of prematurity), photocoagulation or cryotherapy.	R2 *	R2 *

* If designation is temporary.

** Final payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2016. For a discussion of the MPFS rates, we refer readers to the CY 2016 MPFS final rule with comment period.

For CY 2016, we also proposed to designate certain new CY 2016 codes for ASC covered surgical procedures as temporary office-based, displayed in Table 61 of the proposed rule (80 FR 39309). After reviewing the clinical characteristics, utilization, and volume of related codes, we determined that the procedures described by these new CPT codes would be predominantly performed in physicians' offices. However, because we had no utilization data for the procedures specifically described by these new CPT codes, we proposed that the office-based designations be temporary rather than permanent and we will reevaluate the procedures when data become available. The procedures for which the proposed office-based designations for CY 2016 are temporary also are indicated by asterisks in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

We invited public comment on these proposals.

We did not receive any public comment on our proposal. Therefore, for CY 2016, we are finalizing our proposal without modification to designate the four procedures listed in Table 65 as temporarily office-based.

TABLE 65—CY 2016 PAYMENT INDICATORS FOR NEW CY 2016 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

Final CY 2016 OPPS/ASC Proposed Rule 5-digit CMS placeholder code ***	CY 2016 CPT code	Final CY 2016 long descriptor	Final CY 2016 ASC payment indicator **
6446A	64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	P3 *
6446C	64463	Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed).	P3 *
03XXB	0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed).	R2 *
657XG	65785	Implantation of intrastromal corneal ring segments	R2 *

* If designation is temporary.
** Final payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the MPFS final rates. Current law specifies a 0.5 percent update to the MPFS payment rates for CY 2016. For a discussion of the MPFS rates, we refer readers to the CY 2016 MPFS final rule with comment period.
*** New CPT codes (with CMS 5-digit placeholder codes) that will be effective January 1, 2016. The final ASC payment rate for this code can be found in ASC Addendum AA, which is available via the Internet on the CMS Web site.

b. ASC Covered Surgical Procedures Designated as Device-Intensive—Finalized Policy for CY 2015 and Finalized Policy for CY 2016

(1) Background

As discussed in the August 2, 2007 final rule (72 FR 42503 through 42508), we adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, in order to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures. According to that modified ASC payment methodology, we apply the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We then calculate the service portion of the ASC payment for device-intensive procedures by applying the uniform ASC conversion factor to the service (nondevice) portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the revised ASC payment system. For CY 2015, we implemented a comprehensive APC policy under the OPPS under which we created C–APCs to replace most of the then-current device-dependent APCs and a few nondevice-dependent APCs under the OPPS, which discontinued the device-dependent APC policy (79 FR 66798 through 66810). We did not implement C–APCs in the ASC payment system.

Therefore, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66925), we provided that all separately paid covered ancillary services that are provided integral to covered surgical procedures that mapped to C–APCs continue to be separately paid under the ASC payment system instead of being packaged into the payment for the C–APC as under the OPPS. To avoid duplicating payment, we provided that the CY 2015 ASC payment rates for these C–APCs are based on the CY 2015 OPPS relative payments weights that had been calculated using the standard APC ratesetting methodology for the primary service instead of the relative payment weights that are based on the comprehensive bundled service. For the same reason, under the ASC payment system, we also used the standard OPPS APC ratesetting methodology instead of the comprehensive methodology to calculate the device offset percentage for C–APCs for purposes of identifying device-intensive procedures and to calculate payment rates for device-intensive procedures assigned to C–APCs. Because we implemented the C–APC policy and, therefore, eliminated device-dependent APCs under the OPPS in CY 2015, we revised our definition of ASC device-intensive procedures to be those procedures that are assigned to any APC (not only an APC formerly designated as device-dependent) with a device offset percentage greater than 40 percent based on the standard OPPS APC ratesetting methodology.

We also provided that we would update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with our modified definition of device-intensive procedures, reflecting the APC assignments of procedures and APC device offset percentages based on the CY 2013 OPPS claims and cost report data available for the CY 2015 OPPS/ASC proposed rule and final rule with comment period.

(2) Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2016

In the CY 2016 OPPS/ASC proposed rule (80 FR 39310), for CY 2016, we proposed to continue our CY 2015 policies. Specifically, for CY 2016, we proposed to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with our proposed modified definition of device-intensive procedures, reflecting the proposed APC assignments of procedures and APC device offset percentages based on the CY 2014 OPPS claims and cost report data available for the proposed rule.

The ASC covered surgical procedures that we proposed to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology for CY 2016 are listed in Table 62 of the proposed rule (80 FR 39311 through 39314). The CPT code, the CPT code short descriptor, the proposed CY 2016 ASC payment indicator, the proposed CY 2016 OPPS

APC assignment, the proposed CY 2016 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy would apply are also listed in Table 62 of the proposed rule. All of these procedures are included in Addendum AA to the proposed rule (which is available via the Internet on the CMS Web site).

We invited public comment on these proposals.

Comment: One commenter requested that CMS make ASC payment for CPT code 19296 (Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy) under a device-intensive designation. The commenter noted that the code, due to prior designation as an office-based procedure, continued to be assigned an office-based ASC payment indicator, even though the other procedures assigned to the same OPPS APC would qualify for device-intensive status in CY 2016. The commenter further requested that codes that qualify for both device-intensive and office-based status be designated as device-intensive prior to application of the office-based payment comparison.

Response: Our current policy, as described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74409), is for the device-intensive status to supersede the assignment of the office-based designation. Therefore, CPT code 19296 will be a device-intensive procedure and will be assigned ASC payment indicator ''J8'' (device-intensive procedure; paid at adjusted rate) for CY 2016 under the ASC payment system.

Comment: Commenters supported CMS' assignment of the procedure described by CPT code C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) to a device-intensive APC, which they believed would lead to more appropriate payment. One commenter also requested that the procedure described by CPT code C9739 be designated a device-intensive procedure.

Response: We appreciate the commenters' support. An ASC device-intensive procedure is a procedure that is assigned to any APC (not only an APC formerly designated as device-dependent) with a device offset percentage greater than 40 percent based on the standard OPPS APC ratesetting methodology. CPT code C9739 is not assigned to an APC with a device offset percentage greater than 40 percent based on the standard OPPS APC ratesetting methodology. Therefore, it will not be considered a device-intensive procedure for CY 2016 under the ASC payment system. For a more detailed discussion of these codes, we refer readers to section III.D.13. of this final rule with comment period.

Comment: Commenters noted that APC 0105 (Level 1 Pacemaker and Similar Procedures), which was proposed to be renumbered to APC 5221, was designated as a device-intensive APC even though the APC only consists of device removal, revision, or repair procedures and, therefore, would not necessarily include a device. The commenters believed that the designation was inaccurately applied because it would inaccurately apply edits for device codes to procedures that would not require them. The commenters requested that the device designation for the APC and its procedure be removed.

Response: As stated previously, an ASC device-intensive procedure is a procedure that is assigned to any APC (not only an APC formerly designated as device-dependent) with a device offset percentage greater than 40 percent based on the standard OPPS APC ratesetting methodology. For the CY 2016 OPPS/ASC proposed rule, APC 5221 had a device offset percentage greater than 40 percent. Using CY 2016 OPPS/ASC final rule claims and cost report data, APC 5221 does not have a final device offset percentage of greater than 40 percent. Therefore, any procedure assigned to APC 5221 will not be an ASC device-intensive procedure. For a discussion of device-intensive procedures under the OPPS, we refer readers to section IV.B. of this final rule with comment period.

After consideration of the public comments we received, we are designating the ASC covered surgical procedures displayed in Table 66 below as device-intensive and subject to the device-intensive procedure payment methodology for CY 2016. The CPT code, the CPT code short descriptor, the final CY 2016 ASC payment indicator (PI), the final CY 2016 OPPS APC assignment, the final CY 2016 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy will apply also are listed in Table 66 below. All of these procedures are included in Addendum AA to this final rule with comment period (which is available via the Internet on the CMS Web site).

(3) Solicitation of Comments on Device-Intensive Policy for ASCs

As discussed previously, prior to CY 2015, ASC device-intensive procedures were defined as those procedures that are assigned to device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS. Because we implemented the comprehensive APC policy and, therefore, eliminated device-dependent APCs under the OPPS in CY 2015, we redefined ASC device-intensive procedures for CY 2015 as those procedures that are assigned to any APC with a device offset percentage greater than 40 percent based on the standard OPPS APC ratesetting methodology (79 FR 66923 through 66925).

Payment rates for ASC device-intensive procedures are based on a modified payment methodology. As described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829), under that modified payment methodology, we apply the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment to determine the device cost included in the noncomprehensive OPPS unadjusted payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We then calculate the service portion of the ASC payment for device-intensive procedures by applying the uniform ASC conversion factor to the service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure, which is then scaled for ASC budget neutrality. Finally, we sum the ASC device portion and the ASC service portion to establish the full payment for the device-intensive procedure under the revised ASC payment system.

We recognize that, in some instances, there may be a procedure that contains high-cost devices but is not assigned to a device-intensive APC. Where an ASC covered surgical procedure is not designated as device-intensive, the procedure would be paid under the ASC methodology established for that covered surgical procedure, through either an MPFS nonfacility PE RVU-based amount or an OPPS relative payment weight based methodology, depending on the ASC status indicator assignment.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39310), in response to stakeholder concerns regarding the situation where procedures with high-cost devices are not classified as device-

intensive under the ASC payment system, we solicited public comments for alternative methodologies for establishing device-intensive status for ASC covered surgical procedures.

Comment: Several commenters requested that CMS calculate device intensity at the HCPCS level. The commenters believed that designating device intensity at the HCPCS level would be appropriate because the current method of calculating device intensity at the APC level does not take into account device similarity within an APC. Other commenters requested that CMS adopt additional changes to the device-intensive policy to encourage the migration of services to ASCs from other settings. Another commenter requested that CMS lower the threshold for device intensity such that the estimated device cost of 30 percent or greater of the procedural cost. One commenter suggested that correctly coded claims be used to calculate device intensity, codes assigned to New Tech APCs be allowed designation of an interim device-intensity percentage, and comments be solicited on codes with fluctuations of greater than 10 percent in device intensity from year-to-year as measured by the estimated device cost relative to the estimated APC cost.

Response: We appreciate the thoughtful comments that stakeholders have provided and will take them into consideration for future rulemaking.

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC policy with regard to payment for costly devices implanted in ASCs at no cost/full credit or partial credit, as set forth in § 416.179, is consistent with the OPPS policy that was in effect until CY 2014. The established ASC policy reduces payment to ASCs when a specified device is furnished without cost or with full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices (73 FR 68742 through 68744).

As discussed in section IV.B. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPPS, our policy was to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more (but less than 100 percent) of the cost for the specified device. In the CY 2014 OPPS/ASC final rule with comment period, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a replaced device, capped at the device offset amount.

Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in that final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual amount received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal in the CY 2014 OPPS/ASC final rule with comment period to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39310 through 39314), we proposed to update the list of ASC covered device-intensive procedures, based on the revised device-intensive definition finalized last year, which would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2016. Table 62 of the proposed rule (80 FR 39311 through 39314) displayed the ASC covered device-intensive procedures that we proposed would be subject to the no cost/full credit or partial credit device adjustment policy for CY 2016. Specifically, when a procedure that is listed in Table 62 is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost to the ASC or with full credit. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure being furnished by the ASC.

For partial credit, we proposed to reduce the payment for implantation procedures listed in Table 62 of the proposed rule that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC would append the HCPCS ''FC'' modifier to the HCPCS code for a surgical procedure listed in Table 62 that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. In order to report that they received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs would have the option of either: (1) Submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device. Beneficiary coinsurance would continue to be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period, in order to ensure that our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost/full credit or partial credit, we apply our FB/FC policy to all device-intensive procedures (79 FR 66926).

We invited public comment on these proposals.

We did not receive any public comments on these proposals. Therefore, we are finalizing our proposals without modification. Specifically, we will apply our FB/FC

policy to all device-intensive procedures in CY 2016. The device-intensive procedures for CY 2016 are listed in Table 66 below. For CY 2016, we will reduce the payment for the procedures listed in Table 66 by the full device offset amount if a device is furnished without cost or with full credit. ASCs must append the HCPCS modifier ''FB'' to the HCPCS code for a surgical procedure listed in Table 66 below when the device is furnished without cost or with full credit. In addition, for CY 2016, we will reduce the payment for the procedures listed in Table 66 below by one-half of the device offset amount if a device is provided with partial credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the device cost. The ASC must append the HCPCS ''FC'' modifier to the HCPCS code for a surgical procedure listed in Table 66 when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device.

TABLE 66—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE-INTENSIVE FOR CY 2016, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY

HCPCS code	Short descriptor	Final CY 2016 ASC payment indicator	Final CY 2016 OPPS APC	Final CY 2016 device offset percentage	Final FB/FC policy will apply
0100T	Prosth retina receive&gen	J8	1599	91.62	Y
0171T	Lumbar spine proces distract	J8	5125	53.97	Y
0238T	Trluml perip athrc iliac art	J8	5193	60.36	Y
0282T	Periph field stimul trial	J8	5462	56.19	Y
0283T	Periph field stimul perm	J8	5464	86.79	Y
0302T	Icar ischm mntrng sys compl	J8	5223	68.66	Y
0303T	Icar ischm mntrng sys eltrd	J8	5222	73.05	Y
0304T	Icar ischm mntrng sys device	J8	5222	73.05	Y
0308T	Insj ocular telescope prosth	J8	5494	84.55	Y
0316T	Replc vagus nerve pls gen	J8	5464	86.79	Y
0387T	Leadless c pm ins/rpl ventr	J8	5193	60.36	Y
0408T *	Insj/rplc cardiac modulj sys	J8	5231	77.67	Y
0409T *	Insj/rplc cardiac modulj pls gn	J8	5231	77.67	Y
0410T *	Insj/rplc car modulj atr elt	J8	5222	73.05	Y
0411T *	Insj/rplc car modulj vnt elt	J8	5222	73.05	Y
0414T *	Rmvl & rpl car modulj pls gn	J8	5231	77.67	Y
19296	Place po breast cath for rad	J8	5093	40.84	Y
19298	Place breast rad tube/caths	J8	5093	40.84	Y
19325	Enlarge breast with implant	J8	5093	40.84	Y
19342	Delayed breast prosthesis	J8	5093	40.84	Y
19357	Breast reconstruction	J8	5093	40.84	Y
20696	Comp multiplane ext fixation	J8	5125	53.97	Y
21243	Reconstruction of jaw joint	J8	5125	53.97	Y
22551	Neck spine fuse&remov bel c2	J8	5125	53.97	Y
22554	Neck spine fusion	J8	5125	53.97	Y
23616	Treat humerus fracture	J8	5125	53.97	Y
24361	Reconstruct elbow joint	J8	5125	53.97	Y
24362	Reconstruct elbow joint	J8	5125	53.97	Y
24363	Replace elbow joint	J8	5125	53.97	Y
24366	Reconstruct head of radius	J8	5125	53.97	Y
24370	Revise reconst elbow joint	J8	5125	53.97	Y
24371	Revise reconst elbow joint	J8	5125	53.97	Y
24410	Revision of humerus	J8	5125	53.97	Y
24435	Repair humerus with graft	J8	5125	53.97	Y
24545	Treat humerus fracture	J8	5125	53.97	Y
24546	Treat humerus fracture	J8	5125	53.97	Y
24587	Treat elbow fracture	J8	5125	53.97	Y
25441	Reconstruct wrist joint	J8	5125	53.97	Y
25442	Reconstruct wrist joint	J8	5125	53.97	Y
25444	Reconstruct wrist joint	J8	5125	53.97	Y
25446	Wrist replacement	J8	5125	53.97	Y
27279	Arthrodesis sacroiliac joint	J8	5125	53.97	Y
27356	Remove femur lesion/graft	J8	5125	53.97	Y
27438	Revise kneecap with implant	J8	5125	53.97	Y
27440	Revision of knee joint	J8	5125	53.97	Y
27441	Revision of knee joint	J8	5125	53.97	Y
27442	Revision of knee joint	J8	5125	53.97	Y
27446	Revision of knee joint	J8	5125	53.97	Y
27870	Fusion of ankle joint open	J8	5125	53.97	Y
28420	Treat/graft heel fracture	J8	5125	53.97	Y
28705	Fusion of foot bones	J8	5125	53.97	Y
28715	Fusion of foot bones	J8	5125	53.97	Y
28735	Fusion of foot bones	J8	5125	53.97	Y
29889	Knee arthroscopy/surgery	J8	5125	53.97	Y
33206	Insert heart pm atrial	J8	5223	68.66	Y
33207	Insert heart pm ventricular	J8	5223	68.66	Y
33208	Insrt heart pm atrial & vent	J8	5223	68.66	Y

TABLE 66—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE-INTENSIVE FOR CY 2016, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY—Continued

HCPCS code	Short descriptor	Final CY 2016 ASC payment indicator	Final CY 2016 OPPS APC	Final CY 2016 device offset percentage	Final FB/FC policy will apply
33210	Insert electrd/pm cath sngl	J8	5222	73.05	Y
33211	Insert card electrodes dual	J8	5222	73.05	Y
33212	Insert pulse gen sngl lead	J8	5222	73.05	Y
33213	Insert pulse gen dual leads	J8	5223	68.66	Y
33214	Upgrade of pacemaker system	J8	5223	68.66	Y
33216	Insert 1 electrode pm-defib	J8	5222	73.05	Y
33217	Insert 2 electrode pm-defib	J8	5222	73.05	Y
33221	Insert pulse gen mult leads	J8	5224	72.72	Y
33224	Insert pacing lead & connect	J8	5223	68.66	Y
33227	Remove&replace pm gen singl	J8	5222	73.05	Y
33228	Remv&replc pm gen dual lead	J8	5223	68.66	Y
33229	Remv&replc pm gen mult leads	J8	5224	72.72	Y
33230	Insrt pulse gen w/dual leads	J8	5231	77.67	Y
33231	Insrt pulse gen w/mult leads	J8	5232	80.72	Y
33233	Removal of pm generator	J8	5222	73.05	Y
33240	Insrt pulse gen w/singl lead	J8	5231	77.67	Y
33249	Insj/rplcmt defib w/lead(s)	J8	5232	80.72	Y
33262	Rmvl& replc pulse gen 1 lead	J8	5231	77.67	Y
33263	Rmvl & rplcmt dfb gen 2 lead	J8	5231	77.67	Y
33264	Rmvl & rplcmt dfb gen mlt ld	J8	5232	80.72	Y
33270	Ins/rep subq defibrillator	J8	5232	80.72	Y
33271	Insj subq impltbl dfb elctrd	J8	5222	73.05	Y
33282	Implant pat-active ht record	J8	5222	73.05	Y
37221	Iliac revasc w/stent	J8	5192	50.76	Y
37225	Fem/popl revas w/ather	J8	5192	50.76	Y
37226	Fem/popl revasc w/stent	J8	5192	50.76	Y
37227	Fem/popl revasc stnt & ather	J8	5193	60.36	Y
37228	Tib/per revasc w/tla	J8	5192	50.76	Y
37229	Tib/per revasc w/ather	J8	5193	60.36	Y
37230	Tib/per revasc w/stent	J8	5193	60.36	Y
37231	Tib/per revasc stent & ather	J8	5193	60.36	Y
37236	Open/perq place stent 1st	J8	5192	50.76	Y
37238	Open/perq place stent same	J8	5192	50.76	Y
37241	Vasc embolize/occlude venous	J8	5192	50.76	Y
37242	Vasc embolize/occlude artery	J8	5192	50.76	Y
37243	Vasc embolize/occlude organ	J8	5192	50.76	Y
50080	Removal of kidney stone	J8	5376	53.73	Y
50081	Removal of kidney stone	J8	5376	53.73	Y
50557	Kidney endoscopy & treatment	J8	5376	53.73	Y
53440	Male sling procedure	J8	5376	53.73	Y
53444	Insert tandem cuff	J8	5376	53.73	Y
53445	Insert uro/ves nck sphincter	J8	5377	69.61	Y
53447	Remove/replace ur sphincter	J8	5377	69.61	Y
54112	Treat penis lesion graft	J8	5376	53.73	Y
54400	Insert semi-rigid prosthesis	J8	5376	53.73	Y
54401	Insert self-contd prosthesis	J8	5377	69.61	Y
54405	Insert multi-comp penis pros	J8	5377	69.61	Y
54410	Remove/replace penis prosth	J8	5377	69.61	Y
54416	Remv/repl penis contain pros	J8	5377	69.61	Y
55873	Cryoablate prostate	J8	5376	53.73	Y
61885	Insrt/redo neurostim 1 array	J8	5463	85.68	Y
61886	Implant neurostim arrays	J8	5464	86.79	Y
61888	Revise/remove neuroreceiver	J8	5462	56.19	Y
62360	Insert spine infusion device	J8	5471	80.14	Y
62361	Implant spine infusion pump	J8	5471	80.14	Y
62362	Implant spine infusion pump	J8	5471	80.14	Y
63650	Implant neuroelectrodes	J8	5462	56.19	Y
63655	Implant neuroelectrodes	J8	5463	85.68	Y
63663	Revise spine eltrd perq aray	J8	5462	56.19	Y
63664	Revise spine eltrd plate	J8	5462	56.19	Y
63685	Insrt/redo spine n generator	J8	5464	86.79	Y
64553	Implant neuroelectrodes	J8	5462	56.19	Y
64555	Implant neuroelectrodes	J8	5462	56.19	Y
64561	Implant neuroelectrodes	J8	5462	56.19	Y
64565	Implant neuroelectrodes	J8	5462	56.19	Y
64568	Inc for vagus n elect impl	J8	5464	86.79	Y
64569	Revise/repl vagus n eltrd	J8	5462	56.19	Y
64575	Implant neuroelectrodes	J8	5462	56.19	Y

TABLE 66—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE-INTENSIVE FOR CY 2016, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WILL APPLY—Continued

HCPCS code	Short descriptor	Final CY 2016 ASC payment indicator	Final CY 2016 OPPS APC	Final CY 2016 device offset percentage	Final FB/FC policy will apply
64580	Implant neuroelectrodes	J8	5463	85.68	Y
64581	Implant neuroelectrodes	J8	5462	56.19	Y
64590	Insrt/redo pn/gastr stimul	J8	5463	85.68	Y
69714	Implant temple bone w/stimul	J8	5125	53.97	Y
69715	Temple bne implnt w/stimulat	J8	5125	53.97	Y
69930	Implant cochlear device	J8	5166	83.04	Y
C9740	Cysto impl 4 or more	J8	1565	65.18	Y

* New CPT codes that will be effective January 1, 2016.

d. Adjustment to ASC Payments for Discontinued Device-Intensive Procedures

As discussed in section IV.B.4. of this final rule with comment period, we proposed to modify the calculation of OPPS payment when modifiers on the claim indicate that the procedure was discontinued. When a procedure assigned to a device-intensive APC is discontinued either prior to administration of anesthesia or for a procedure that does not require anesthesia, we presume that, in the majority of cases, the device was not used and remains sterile such that it could be used for another case. In these circumstances, under current policy, providers are being paid twice by Medicare for the same device, once for the initial procedure that was discontinued and again when the device is actually used. We believe that, in cases where the procedure was not performed, it would be appropriate to remove the estimated cost of the device because the device would have presumably not been used.

We believe these same issues exist in the ASC setting. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39314 through 39315), we proposed that this alternative payment calculation, where the device offset is removed before applying any standard downward payment adjustments because a full procedure was not performed, would also apply to device-intensive procedures in the ASC payment system beginning in CY 2016, with modifiers ''52'' (reduced services) and ''73'' (Discontinued outpatient procedure prior to anesthesia administration). These are the same modifiers proposed for use in the OPPS. Modifier ''52'' is used to indicate certain circumstances in which a procedure is partially reduced or eliminated. Modifier ''73'' is used when a service is canceled prior to the surgical preparation due to circumstances that may threaten the well-being of a patient. Under this proposed methodology, any adjustment policies reducing payment would only apply to the procedural portion of the service, based on ASC payment after the device offset is removed. Use of modifiers ''52'' or ''73'' would thus result in 50 percent of ASC payment for the service, after the device offset has first been subtracted from the standard ASC payment amount. We proposed to restrict the policy to ASC device-intensive procedures so that the adjustment would not be triggered by the use of an inexpensive device whose cost would not constitute a significant portion of the total payment rate.

Similar to the OPPS, we did not propose to deduct the device offset amount from a procedure that was discontinued after anesthesia was administered (modifier ''74'') because we believe that it may be more likely that devices involved with such procedures are no longer sterile and could not be restocked and used for another case. However, we solicited public comments on how often the device becomes ineligible for use in a subsequent case and whether we should deduct the device offset amount from claims with modifier ''74'' as well. We proposed to revise 42 CFR 416.172 to reflect this proposal.

We invited public comment on this proposal and this proposed codification.

Comment: Commenters generally disagreed with the proposal to modify the calculation of payment when device intensive procedures with modifiers ''52'' and ''73.'' The commenters suggested that the current calculation or alternatives such as full payment of the device cost were preferable. One commenter also questioned the magnitude of the issue, noting that removing the estimated cost of the device would incentivize the continuation of a procedure at possible risk to the beneficiaries.

Response: We have a longstanding policy of appending modifiers to track discontinued procedures and reducing payment. We believe that the payment adjustment that we proposed for these discontinued device intensive procedures is appropriate for expenses incurred in these cases. While we note that these occur in special circumstances and therefore the frequency with which they occur is limited, we would expect that providers who furnish services to Medicare beneficiaries would not expose beneficiaries to health risk due to financial incentives related to this policy. We believe that the ASC payment adjustment we have proposed better represents the estimated cost of these procedures.

However, in the case of procedures involving modifier ''52'' where anesthesia is not planned, we now believe that it would be rare that an implantable device would be used based on the feedback commenters have provided and an examination of the claims data. Accordingly, we are not finalizing our proposal to remove the device offset from services furnished in the ASC that are billed with modifier ''52.''

After consideration of the public comments we received, we are finalizing our proposed policy with modification. For device-intensive procedures (defined as those APCs with a device offset greater than 40 percent), we will reduce the ASC payment amount for discontinued device-intensive procedures billed with modifier ''73,'' where anesthesia is planned but is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed but before anesthesia is induced, by 100 percent of the device offset amount prior to application of any additional payment adjustments associated with discontinued procedures. We are revising 42 CFR

416.172 to reflect this policy. We also note that we inadvertently used the word ''copayment'' instead of ''coinsurance'' in the proposed codification of 42 CFR 416.172(f)(2) and have made this technical change to the final regulation.

e. Additions to the List of ASC Covered Surgical Procedures

We conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, we proposed to update the list of ASC covered surgical procedures by adding 11 procedures to the list for CY 2016. We determined that these 11 procedures would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. Therefore, we proposed to include them on the list of ASC covered surgical procedures for CY 2016.

The 11 procedures that we proposed to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2016 payment indicators, were displayed in Table 63 of the proposed rule (80 FR 39315).

We invited public comment on this proposal.

Comment: Several commenters supported the proposal to add 11 procedures to the CY 2016 list of ASC covered surgical procedures.

Response: We appreciate the commenters' support. As indicated later in this section, we are finalizing our proposal to add these procedure codes to the list of ASC covered procedures in addition to six other procedure codes requested by commenters.

Comment: One commenter requested that CMS include all surgical and ancillary procedures that are currently paid in the HOPD setting on the ASC covered surgical procedures list.

Response: We are not adopting this commenter's request. As stated in our final policy, which is discussed in detail in the August 2, 2007 final rule (72 FR 42476 through 42486; 42 CFR 416.2 and 416.166), we believe that it is inappropriate to exclude only those surgical procedures on the OPPS inpatient list from ASC payment and have established criteria to determine whether a procedure should be excluded from the ASC covered surgical procedures list (42 CFR 416.2 and 416.166). Including all of the procedures that are currently paid in the HOPD setting on the ASC covered surgical procedures list is inconsistent with our goal of only excluding those procedures from ASC payment that are unsafe for performance in ASCs or are expected to require an overnight stay. Typically, HOPDs are able to provide much higher acuity care than ASCs. ASCs have neither patient safety standards consistent with those in place for hospitals, nor are they required to have the trained staff and equipment needed to provide the breadth and intensity of care that hospitals are required to maintain. Therefore, there are some procedures that we believe may be appropriately provided in the HOPD setting that are unsafe for the performance in ASCs. Thus, we did not adopt a final policy to exclude only those surgical procedures on the OPPS inpatient list from ASC payment under the ASC payment system.

Comment: Some commenters requested that CMS include several additional CPT/HCPCS codes on the list of ASC covered surgical procedures that were not proposed to be added to the list. The commenters stated that codes that describe instrumentation and bone grafting are key components of many spine procedures that have been added to the ASC covered surgical procedures list in recent years and requested that those codes be added to the list as well. The commenters also stated that some of the procedures described by these codes were performed on non-Medicare patients in the ASC setting with positive outcomes. Some commenters believed that, because Medicare makes facility payments for unlisted CPT codes under the OPPS, CMS should also allow ASCs to use unlisted CPT codes to report procedures. The list of codes that commenters requested to be added in addition to those that were proposed to be added is shown in Table 67 below.

TABLE 67—PROCEDURES REQUESTED FOR ADDITION TO THE CY 2016 LIST OF ASC COVERED SURGICAL PROCEDURES

CY 2016 CPT/HCPCS code	Short descriptor
17999	Skin tissue procedure.
19307	Mast mod rad.
20999	Muscoskeletal surgery.
22840*	Insert spine fixation device.
22842*	Insert spine fixation device.
22845*	Insert spine fixation device.
22851	Apply spine prosth device.
22856	Cerv artific diskectomy.
23470	Reconstruct shoulder joint.
23473	Revis reconst shoulder joint.

TABLE 67—PROCEDURES REQUESTED FOR ADDITION TO THE CY 2016 LIST OF ASC COVERED SURGICAL PROCEDURES—Continued

CY 2016 CPT/HCPCS code	Short descriptor
28805	Amputation thru metatarsal.
28899	Foot/toes surgery procedure.
29799	Casting/strapping procedure.
29868	Meniscal trnspl knee w/scpe.
29999	Arthroscopy of joint.
31599	Larynx surgery procedure.
31600	Incision of windpipe.
32551	Insertion of chest tube.
33244	Remove eltrd transven.
35045	Repair defect of arm artery.
35471	Repair arterial blockage.
35903	Excision graft extremity.
37191	Ins endovas vena cava filtr.
37193	Rem endovas vena cava filter.
37241	Vasc embolize/occlude venous.
37242	Vasc embolize/occlude artery.
37243	Vasc embolize/occlude organ.
37799	Vascular surgery procedure.
38207	Cyropreserve stem cells.
38214	Volume deplete of harvest.
38999	Blood/lymph system procedure.
39400	Mediastinoscopy incl biopsy.
41899	Dental surgery procedure.
43280	Laparoscopy fundoplasty.
43281	Lap paraesophag hern repair.
43499	Esophagus surgery procedure.
43770	Lap place gastr adj device.
43999	Stomach surgery procedure.
44180	Lap enterolysis.
44799	Unlisted px small intestine.
44970	Laparoscopy appendectomy.
49659	Laparo proc hernia repair.
46999	Anus surgery procedure.
47379	Laparoscope procedure liver.
49329	Laparo proc abdm/per/oment.
49406	Image cath fluid peri/retro.
49999	Abdomen surgery procedure.
53899	Urology surgery procedure.
54332	Revise penis/urethra.
54336	Revise penis/urethra.
54535	Extensive testis surgery.
54650	Orchiopexy (Fowler-Stephens).
55899	Genital surgery procedure.
57282	Colpopexy intraperitoneal.
57283	Colpopexy extraperitoneal.
57425	Laparoscopy surg colpopexy.
60252	Removal of thyroid.
60260	Repeat thyroid surgery.
60271	Removal of thyroid.
63011	Removal of spinal lamina.
63012	Removal of spinal lamina.
63015	Removal of spinal lamina.
63016	Removal of spinal lamina.
63017	Removal of spinal lamina.
63035	Spinal disk surgery add-on.
63040	Laminotomy single cervical.
63046	Remove spine lamina 1 thrc.
63048	Remove spinal lamina add-on.
63055	Decompress spinal cord thrc.
63057	Decompress spine cord add-on.

TABLE 67—PROCEDURES REQUESTED FOR ADDITION TO THE CY 2016 LIST OF ASC COVERED SURGICAL PROCEDURES—Continued

CY 2016 CPT/HCPCS code	Short descriptor
63064	Decompress spinal cord thrc.
63075	Neck spine disk surgery.
63076	Neck spine disk surgery.
64999	Nervous system surgery.
66999	Eye surgery procedure.

*CPT codes on the OPPS inpatient list for CY 2015

We reviewed all of the codes that commenters requested for addition to the ASC list of covered surgical procedures. Of the 75 codes requested for addition to the ASC list, we did not consider the three procedures that are reported by CPT codes (22840, 22842, and 22845) that are on the inpatient-only list (identified with one asterisk in Table 67). The three codes that are currently on the inpatient-only list are not eligible for addition to the ASC list of covered surgical procedures (72 FR 42476 through 42486; 42 CFR 416.166). We have, however, evaluated these three codes for removal from the inpatient-only list, and we do not believe that any of the codes meet the criteria to be safely performed in the hospital outpatient setting.

Of the remaining 72 procedures described by codes in Table 67 that commenters requested be added to the list of ASC covered surgical procedures, there are procedures described by six codes (CPT codes 37241, 37242, 37243, 49406, 63046, and 63055) that we agree should be added to the list for CY 2016. These procedures are similar to other procedures that we have previously added to the ASC list and are described below.

We are adding the procedures described by: (1) CPT code 37241 (Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (*e.g.,* congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)); (2) CPT code 37242 (Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (*e.g.,* congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)); and (3) CPT code 37243 (Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction) to the ASC list of covered procedures for CY 2016. The procedures described by these codes are similar to the stent placement procedures described by codes in the CPT code 372XX series that are payable in the ASC setting. We are adding the procedure described by CPT code 49406 (Image-guided fluid collection drainage by catheter (*e.g.,* abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, percutaneous) because of this procedure's similarity to the procedure described by CPT code 49407 (Image-guided fluid collection drainage by catheter (*e.g.,* abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, transvaginal or transrectal), which is included on the ASC list of covered surgical procedures. We also believe that the procedure described by CPT code 63046 (Laminectomy, facetectomy, and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equine and/or nerve root(s), eg spinal or lateral recess stenosis, single vertebral segment; thoracic) should be included on the ASC list of covered surgical procedures. This procedure described by this code is similar to the procedures described by CPT code 63045 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [*e.g.,* spinal or lateral recess stenosis]), single vertebral segment; cervical) and CPT code 63047 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [*e.g.,* spinal or lateral recess stenosis]), single vertebral segment; lumbar), which are on the ASC covered procedures list. We also believe that the procedure described by CPT code 63055 (Transpedicular approach with decompression of spinal cord, equine and/or nerve root(s) (*e.g.,* herniated intervertebral disc), single segment; thoracic) should be added to the ASC list of covered surgical procedures because this procedure is similar to the procedure described by CPT code 63056 (Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (*e.g.,* herniatedintervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (*e.g.,* far lateral herniated intervertebral disc)), which is on the ASC covered procedures list.

Regarding the comment about unlisted codes being noncovered in the ASC, we have a longstanding ASC policy that procedures described by all unlisted codes are noncovered in the ASC because we are unable to determine (due to the nondescript nature of unlisted procedure codes) if a procedure that would be reported with an unlisted code would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. We continue to believe it would not be appropriate to provide ASC payment for procedures described by unlisted CPT codes in the surgical range, even if payment may be provided under the OPPS. ASCs do not possess the breadth and intensity of services that hospitals must maintain to care for patients of higher acuity, and we would have no way of knowing what specific procedures reported by unlisted CPT codes were provided to patients in order to ensure that they are safe for ASC performance. Therefore, we are not adding the procedures describe by the 22 unlisted CPT codes requested to the ASC list of covered surgical procedures.

We do not agree that any of the 44 remaining procedures described by these codes should be added to the list of ASC covered surgical procedures because they do not meet our criteria for inclusion on this list. Under 42 CFR 416.2 and 416.166, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. The criteria used under the revised ASC payment system to identify procedures that would be expected to pose a significant safety risk when performed in an ASC include, but are not limited to, those procedures that: Generally result in extensive blood loss; require major or prolonged invasion of body cavities; directly involve major blood vessels; are generally emergent or life threatening in nature; commonly require systemic thrombolytic therapy; are designated as requiring inpatient care under 42 CFR 419.22(n); can only be reported using a CPT unlisted surgical procedure code; or are otherwise excluded under 42 CFR 411.15 (we refer

readers to 42 CFR 416.166). Procedures that do not meet the criteria set forth in § 416.166 would not be added to the list of ASC covered surgical procedures. We note that we have evaluated many of these procedures in previous years (79 FR 66918 through 66921; 78 FR 75067 through 75070) and did not add the procedures to the ASC list due to similar concerns regarding beneficiary safety. The commenters provided no specific information regarding the safety of these procedures in the ASC setting.

After consideration of the public comments we received, we are finalizing our proposal to add the 11 procedures that we proposed to add to the ASC list of covered surgical procedures. In addition, we are adding six procedures recommended by commenters as discussed above. The HCPCS code long descriptors and CY 2016 payment indicators for these codes are displayed in Table 68.

TABLE 68—ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2016

Final CY 2016 HCPCS code	Final CY 2016 long descriptor	Final CY 2016 ASC payment indicator
0171T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level.	J8
0172T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level.	N1
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (*e.g.,* congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles).	J8
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (*e.g.,* congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms).	J8
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction.	J8
49406	Image-guided fluid collection drainage by catheter (e.g., abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, percutaneous.	G2
57120	Colpocleisis (Le Fort type)	G2
57310	Closure of urethrovaginal fistula	G2
58260	Vaginal hysterectomy, for uterus 250 g or less	G2
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)	G2
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g	G2
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	G2
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g	G2
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	G2
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	G2
63046	Laminectomy, facetectomy, and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equine and/or nerve root(s), eg spinal or lateral recess stenosis, single vertebral segment; thoracic.	G2
63055	Transpedicular approach with decompression of spinal cord, equine and/or nerve root(s) (*e.g.,* herniated intervertebral disc), single segment; thoracic.	G2

f. ASC Treatment of Surgical Procedures That Are Removed From the OPPS Inpatient List for CY 2016

As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68724), we adopted a policy to include, in our annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS inpatient-only list for possible inclusion on the ASC list of covered surgical procedures. We evaluated each of the seven procedures we proposed to remove from the OPPS inpatient-only list for CY 2016 according to the criteria for exclusion from the list of covered ASC surgical procedures. The CPT codes for these seven procedures and their long descriptors are listed in Table 64 of the proposed rule (80 FR 39315 through 39316). We invited public comment on the continued exclusion of these codes from the ASC list of covered surgical procedures. Based on commenters' requests, we are also removing CPT codes 27477 and 27485 found in Table 69 below from the CY 2016 inpatient-only list. We believe that these nine procedures should continue to be excluded from the ASC list of covered surgical procedures for CY 2016 because they would be expected to pose a significant risk to beneficiary safety or to require an overnight stay in ASCs.

Comment: Some commenters requested that CMS add CPT codes 0312T, 20936, 20937, 20938, 22552, 54411, and 54417 that were proposed to be removed from the inpatient-only list for CY 2016 to the CY 2016 list of ASC covered surgical procedures to allow these procedures to be performed in the ASC setting as well as the hospital outpatient setting. One commenter stated that the procedure described by CPT code 0312T can be compared to other laparoscopic procedures allowed to be performed in an ASC such as laparoscopic cholecystectomy (CPT 47562 or 47563) or laparoscopic adjustable gastric band placement (CPT 43770). In addition, the commenter mentioned that the majority of patients who participated in clinical trials of the device used in the procedure were discharged the same day they received their implant.

Response: We are not adding these CPT codes to the list of ASC covered surgical procedures. Under 42 CFR 416.2 and 416.166, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that

are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. Although we believe that the procedures proposed to be removed from the inpatient-only list for CY 2016 may be appropriately provided in the HOPD setting based on ability of HOPDs to provide extended monitoring and higher acuity care for the management of complications, based on our evaluation of these codes, we maintain the belief that these procedures are unsafe for performance in ASCs. Also, although the commenter noted that patients who participated in clinical trials of the device used in CPT code 0312T were discharged the same day they received their implant, this has not been replicated outside of the experimental setting. Further, CPT codes 20936, 20937, 20938, and 22552 are not separately payable under the OPPS, which also makes these procedures ineligible for payment under the ASC payment system.

After consideration of the public comments we received, we are finalizing our proposal without modification to continue to exclude these codes from the ASC list of covered surgical procedures.

TABLE 69—PROCEDURES EXCLUDED FROM THE ASC LIST OF COVERED SURGICAL PROCEDURES FOR CY 2016 THAT ARE REMOVED FROM THE CY 2016 OPPS INPATIENT LIST

CPT code	Long descriptors
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming.
20936	Autograft for spine surgery only (includes harvesting the graft); local (*e.g.,* ribs, spinous process, or laminar fragments) obtained from same incision.
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision).
20938	Autograft for spine surgery only (includes harvesting the graft); structural bicortical or tricortical (through separate skin or fascial incision).
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace.
27477	Arrest epiphyseal, any method (*e.g.,* epiphysiodesis); tibia and fibula, proximal.
27485	Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (*e.g.,* genu varus or valgus.
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue.
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue.

2. Covered Ancillary Services

a. List of Covered Ancillary Services

Consistent with the established ASC payment system policy, in the CY 2016 OPPS/ASC proposed rule (80 FR 39316), we proposed to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2016 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary services because of changes that are being proposed under the OPPS for CY 2016. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2015 may be proposed for packaged status under the CY 2016 OPPS and, therefore, also under the ASC payment system for CY 2016.

To maintain consistency with the OPPS, we proposed that these services also would be packaged under the ASC payment system for CY 2016. We proposed to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator ''CH,'' discussed in section XII.F. of the proposed rule, is used in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2016.

All ASC covered ancillary services and their proposed payment indicators for CY 2016 were included in Addendum BB to the proposed rule. We invited public comment on this proposal.

Comment: Commenters expressed appreciation for CMS' adding the service described by CPT code 91035 (Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation) to the list of covered ancillary services. The commenters also requested that pass-through payment status be granted to this device.

Response: We appreciate the commenters' support. The code is not a pass-through device under the OPPS and, therefore, is not assigned ASC payment indicator ''J7'' (OPPS pass-through device paid separately when provided integral to a surgical procedure on ASC list; payment contractor-priced). The designation of a device as having pass-through status only applies in the OPPS. We note that there is a process for applying for pass-through device payment under the OPPS, which is described in detail in section IV.A.2. of this final rule with comment period.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS. All CY 2016 ASC covered ancillary services and their final payment indicators are included in Addendum BB to this final rule with comment period (which is available via the Internet on the CMS Web site).

b. Exclusion of Corneal Tissue Procurement from the Covered Ancillary Services List When Used for Nontransplant Procedures

We refer readers to section X.D. of this final rule with comment period for a discussion of our final policy regarding the inclusion of corneal tissue procurement as a covered ancillary service only when it is provided integral to the performance of a corneal transplant procedure that is an ASC covered surgical procedure.

c. Removal of Certain Services from the Covered Ancillary Services List That Are Not Used as Ancillary and Integral To A Covered Surgical Procedure

As stated in 42 CFR 416.2 and 416.164(b), covered ancillary services

are ancillary items and services that are integral to a covered surgical procedure performed in an ASC for which separate payment may be made. It has come to our attention that we include codes for services on our covered ancillary services list that are not provided as ancillary and integral to an ASC covered surgical procedure. In some cases, codes on the ASC covered ancillary services list are not provided in the ASC setting due to clinical practice. In examining the current ancillary services list and claims data available to us for CY 2016 proposed ASC rulemaking, we noted several services that are not and have not been historically furnished in the ASC setting as integral and ancillary to an ASC covered surgical procedure. Several radiation therapy treatment services, including Co-60 stereotactic radiosurgery (SRS), are most frequently provided in the hospital outpatient setting and paid through the OPPS and also are furnished, but also somewhat less frequently, in freestanding radiation therapy centers and paid under the PFS. Only four claims for SRS treatment services were included in the CY 2014 ASC claims data. Two of these four claims were denied and the other two claims were paid in error. SRS delivery is a stand-alone radiation treatment and is not furnished integral and ancillary to an ASC covered surgical procedure. Thus, in the CY 2016 OPPS/ASC proposed rule (80 FR 39316), we proposed to remove radiation treatment codes for SRS treatment services from the list of ASC covered ancillary services. Specifically, we proposed to remove CPT codes 77371 (Radiation treatment delivery, stereotactic radiosurgery (srs), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source cobalt 60 based), 77372 (Radiation treatment delivery, stereotactic radiosurgery (srs), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based), and 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions) from the list of ASC covered ancillary services for CY 2016 and subsequent years.

We invited public comment on this proposal.

Comment: Commenters requested that CMS include the stereotactic radiosurgery codes on the covered ancillary services list, with one commenter specifically focusing on CPT code 77371. One commenter noted that several ASCs provide the service and requested that CMS reevaluate available data to confirm that the service was being provided in the ASC setting.

Response: We reviewed the available claims data and, as stated previously, only four claims for SRS treatment services were included in the CY 2014 ASC claims data—two of which were denied and two of which were paid in error. Based on these claims data, we continue to believe that SRS delivery is a standalone radiation treatment and is not furnished integral and ancillary to an ASC covered surgical procedure. Therefore, SRS treatment services should not be on the list of ASC covered ancillary services. With respect CPT code 77371, clinically, it is not performed integral to an ASC covered surgical procedure. It is a stand-alone form of radiation therapy. Therefore, it should not be on the ASC covered ancillary services list.

After consideration of the public comments we received, we are finalizing our proposed policy without modification to remove CPT codes 77371, 77372, and 77373 from the ASC covered ancillary services list for CY 2016 and subsequent years.

D. ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy for the revised ASC payment system, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2.'' Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator ''A2'' because it is used to identify procedures that are exempted from application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66915 through 66940), we updated the CY 2014 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2,'' ''G2,'' and ''J8'' using CY 2013 data, consistent with the CY 2015 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2015 OPPS device offset percentages calculated under the standard APC ratesetting methodology as discussed earlier in this section.

Payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') are the lower of the MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2016 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2015 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2015 rate for each of the office-based procedures, calculated according to the ASC standard ratesetting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2015 payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal codes under the OPPS. Under the OPPS, a conditionally packaged code (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment

system. There would be no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To address this concern, for the device removal procedures that are conditionally packaged in the OPPS (status indicator ''Q2''), we assigned the current ASC payment indicators associated with these procedures and continued to provide separate payment in CYs 2014 and 2015.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2016

In the CY 2016 OPPS/ASC proposed rule (80 FR 39317), we proposed to update ASC payment rates for CY 2016 and subsequent years using the established rate calculation methodologies under § 416.171 and using our established modified definition of device-intensive procedures, as discussed above. Because the proposed OPPS relative payment weights are based on geometric mean costs for CY 2016 and subsequent years, the ASC system will use geometric means to determine proposed relative payment weights under the ASC standard methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2.''

We proposed that payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') and device-intensive procedures (payment indicator ''J8'') be calculated according to our established policies and, for device-intensive procedures, using our established modified definition of device-intensive procedures, as discussed above. Therefore, we proposed to update the payment amount for the service portion of the device-intensive procedures using the ASC standard ratesetting methodology and the payment amount for the device portion based on the proposed CY 2016 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures would be at the lesser of the proposed CY 2016 MPFS nonfacility PE RVU-based amount or the proposed CY 2016 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 and 2015, for CY 2016 and subsequent years, we proposed to continue our policy for device removal procedures such that payment for device removal procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2'') would be assigned the current ASC payment indicators associated with these procedures and would continue to be paid separately under the ASC payment system.

We invited public comment on these proposals.

We did not receive any public comments on these proposals. Therefore, we are finalizing our proposed policies, without modification, to calculate the CY 2016 payment rates for ASC covered surgical procedures according to our established methodologies using the modified definition of device-intensive procedures. For those covered surgical procedures where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the MPFS final rates, the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the MPFS rates effective January 1, 2016. For a discussion of the MPFS rates, we refer readers to the CY 2016 MPFS final rule with comment period.

c. Waiver of Coinsurance and Deductible for Certain Preventive Services

Section 1833(a)(1) and section 1833(b)(1) of the Act waive the coinsurance and the Part B deductible for those preventive services under section 1861(ddd)(3)(A) of the Act as described in section 1861(ww)(2) of the Act (excluding electrocardiograms) that are recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. Section 1833(b) of the Act also waives the Part B deductible for colorectal cancer screening tests that become diagnostic. In the CY 2011 OPPS/ASC final rule with comment period, we finalized our policies with respect to these provisions and identified categories of services and the ASC covered surgical procedures and covered ancillary services that are preventive services that are recommended by the USPSTF with a grade of A or B for which the coinsurance and the deductible are waived. For a complete discussion of our policies and categories of services, we refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72047 through 72049). We did not propose any changes to our policies or the categories of services for CY 2016. We identify the specific services with a double asterisk in Addenda AA and BB to this final rule with comment period (which are available via the Internet on the CMS Web site).

d. Payment for Cardiac Resynchronization Therapy Services

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizes a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD). CRT performed by the implantation of an ICD along with a pacing electrode is referred to as ''CRT–D.'' In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2012 ASC payment rate for CRT–D services based on the OPPS payment rate applicable to APC 0108 when procedures described by CPT codes 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator (*e.g.,* for upgrade to dual chamber system) (list separately in addition to code for primary procedure)) and 33249 (Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber) are performed on the same date of service in an ASC.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66931), we finalized our proposals under the OPPS that the services described by CPT code 33249, the primary code for CRT–D services, continue to be assigned to APC 0108 (Level II ICD and Similar Procedures), and that payment for the services described by CPT code 33225 be packaged under the OPPS. We also finalized our proposals under the ASC payment system that services described by CPT code 33249, the primary code for CRT–D services, will continue to be assigned to APC 0108, and payment for services described by CPT code 33225 will be packaged into the payment for the primary covered surgical procedure (for example, CPT code 33249). In the CY 2016 OPPS/ASC proposed rule (80 FR 39317 through 39318), we did not propose any changes to our ASC payment policies for cardiac resynchronization therapy services for CY 2016. However, we note that, in the proposed rule, we proposed to renumber APC 0108 as APC 5232 (Level 2 ICD and Similar Procedures).

We did not receive any public comments on our proposal to renumber APC 0108 as APC 5232, and therefore as discussed in section II.A. of this final rule with comment period, are finalizing

the renumbering for the APC beginning in CY 2016.

e. Payment for Low Dose Rate (LDR) Prostate Brachytherapy Composite

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy); and CPT code 77778 (Interstitial radiation source application; complex). Generally, the component services represented by both codes are provided in the same operative session on the same date of service to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2013 ASC payment rate for LDR prostate brachytherapy services based on the OPPS relative payment weight applicable to APC 8001 when CPT codes 55875 and 77778 are performed on the same date of service in an ASC. ASCs use the corresponding HCPCS Level II G-code (G0458) for proper reporting when the procedures described by CPT codes 55875 and 77778 are performed on the same date of service, and therefore receive the appropriate LDR prostate brachytherapy composite payment. When not performed on the same day as the service described by CPT code 55875, the service described by CPT code 77778 will be assigned to APC 0651 (in the proposed rule, proposed to be renumbered APC 5641). When not performed on the same day as the service described by CPT code 77778, the service described by CPT code 55875 will be assigned to APC 0162 (in the proposed rule, proposed to be renumbered APC 5374). For a complete discussion of our policy regarding payment for LDR prostate brachytherapy services in ASCs, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68457). In the CY 2016 OPPS/ASC proposed rule (80 FR 39318), we did not propose any changes to our current policy regarding ASC payment for LDR prostate brachytherapy services for CY 2016. We did not receive any public comments on our proposal to renumber APC 0162 as APC 5374, and therefore as discussed in section II.A. of this final rule with comment period, are finalizing the renumbering for the APC beginning in CY 2016.

2. Payment for Covered Ancillary Services

a. Background

Our final payment policies under the revised ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N,'' ''Q1,'' and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169; 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged code describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indictor ''N1'') under the ASC payment system (except for device removal codes as discussed in section XII.D.1.a. of this final rule with comment period). Thus, our final policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates. We generally pay for separately payable radiology services at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount, regardless of which is lower.

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (42 CFR 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to the final policies for the revised ASC payment system (72 FR 42502 and 42508 through 42509; 42 CFR 416.164(b)). Under the revised ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (nondevice) portion of the

procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include reference to diagnostic services and those for which the payment is based on the MPFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include reference to diagnostic services.

b. Payment for Covered Ancillary Services for CY 2016

In the CY 2016 OPPS/ASC proposed rule (80 FR 39319 through 39320), for CY 2016 and subsequent years, we proposed to update the ASC payment rates and to make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2016 OPPS and ASC payment rates and subsequent year payment rates. We also proposed to continue to set the CY 2016 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the proposed OPPS payment rates for CY 2016.

Consistent with established ASC payment policy (72 FR 42497), we proposed that the CY 2016 payment for separately payable covered radiology services be based on a comparison of the proposed CY 2016 MPFS nonfacility PE RVU-based amounts (we refer readers to the CY 2016 MPFS proposed rule) and the CY 2016 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two amounts (except as discussed below for nuclear medicine procedures and radiology services that use contrast agents). We made this same proposal for subsequent years. For CY 2016 and subsequent years, we also proposed that payment for a radiology service would be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged or conditionally packaged under the OPPS. The payment indicators in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site) indicate whether the proposed payment rates for radiology services are based on the MPFS nonfacility PE RVU-based amount or the ASC standard ratesetting methodology, or whether payment for a radiology service is packaged into the payment for the covered surgical procedure (payment indicator ''N1''). Radiology services that we proposed to pay based on the ASC standard ratesetting methodology in CY 2016 and subsequent years are assigned payment indicator ''Z2'' (Radiology or diagnostic service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight), and those for which the proposed payment is based on the MPFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3'' (Radiology or diagnostic service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs).

As finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology (rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower) and, therefore, will include the cost for the diagnostic radiopharmaceutical. We proposed to continue this modification to the payment methodology for CY 2016 and subsequent years and, therefore, proposed to assign the payment indicator ''Z2'' to nuclear medicine procedures.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), payment indicators for radiology services that use contrast agents are set to ''Z2'' so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent. We proposed to continue this modification to the payment methodology for CY 2016 and subsequent years and, therefore, proposed to assign the payment indicator ''Z2'' to radiology services that use contrast agents.

We proposed to not make separate payment as a covered ancillary service for procurement of corneal tissue when used in any nontransplant procedure under the ASC payment system. For more detail on this CY 2016 proposal, we refer readers to section X.C. of the proposed rule and section X.D. of this final rule with comment period. We proposed, for CY 2016 ASC payment purposes, to continue to designate hepatitis B vaccines as contractor-priced based on the invoiced costs for the vaccine, and corneal tissue acquisition as contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplant.

Consistent with our established ASC payment policy, we proposed that the CY 2016 payment for devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and would be contractor-priced. Currently, the three devices that are eligible for pass-through payment in the OPPS are described by HCPCS code C1841 (Retinal prosthesis, includes all internal and external components), HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) and, beginning on July 1, HCPCS code C2613 (Lung biopsy plug with delivery system). As finalized in the CY 2015 OPPS/ASC final rule with comment period, HCPCS code C1841 will no longer be eligible for pass-through payment in the OPPS for CY 2016 (79 FR 66870 through 66871), and thus the costs for devices described by HCPCS code C1841 would be packaged into the costs of the procedures with which the devices are reported in the hospital claims data used in the development of the OPPS

relative payment weights that will be used to establish ASC payment rates for CY 2016. Payment amounts for HCPCS codes C2623 and C2613 under the ASC payment system would be contractor-priced for CY 2016. Consistent with our current policy, we proposed that payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (nondevice) portion of the procedure's OPPS relative payment weight, if the APC weight for the procedure includes similar packaged device costs.

Consistent with our current policy, we proposed that certain diagnostic tests within the medicine range of CPT codes (that is, all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT) for which separate payment is allowed under the OPPS are covered ancillary services when they are provided integral to an ASC covered surgical procedure. We would pay for these tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). As discussed in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66934), for CY 2015, we identified one diagnostic test that is within the medicine range of CPT codes and for which separate payment is allowed under the OPPS: CPT code 91035 (Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation). We added this code to the list of ASC covered ancillary services and finalized separate ASC payment as a covered ancillary service for this code beginning in CY 2015 when the test is provided integral to an ASC covered surgical procedure. We stated that we would expect the procedure described by CPT code 91035 to be integral to the endoscopic attachment of the electrode to the esophageal mucosa. There are no additional codes that meet this criterion for CY 2016.

In summary, for CY 2016, we proposed to continue the methodologies for paying for covered ancillary services established for CY 2015. Most covered ancillary services and their proposed payment indicators for CY 2016 are listed in Addendum BB to the proposed rule (which is available via the Internet on the CMS Web site).

We discuss our OPPS and ASC payment policies for nontransplant corneal tissue in section X.D. of this final rule with comment period.

We did not receive public comments on our policy proposals regarding payment for covered ancillary services (other than on the corneal tissue procurement policy, which we discuss and finalize in section X.D. of this final rule with comment period), and therefore are finalizing these policies as proposed for CY 2016 and subsequent years. For those covered ancillary services where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the MPFS final rates, the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the MPFS rates effective January 1, 2016. For a discussion of the MPFS rates, we refer readers to the CY 2016 MPFS final rule with comment period.

E. New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in 42 CFR 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

- Applicants submit their NTIOL requests for review to CMS by the annual deadline. For a request to be considered complete, we require submission of the information that is found in the guidance document entitled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an existing NTIOL Class'' posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.
- We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Pub. L. 103–432 and our regulations at 42 CFR 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.
- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments;

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2016

We did not receive any requests for review to establish a new NTIOL class for CY 2016 by March 2, 2015, the due date published in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66935).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we did not propose to revise the payment adjustment amount for CY 2016.

4. Newness Criterion

Since the inception of the NTIOL policy in 1999, there has not been any specific criterion provided to evaluate the newness of a candidate IOL for new technology payment under the ASC payment system. Absence of any specific criterion means that, regardless of when an IOL was originally FDA approved and available on the U.S. market, the IOL could be established as a new NTIOL class if it satisfies the requirements of 42 CFR 416.195. We believe that because the NTIOL payment adjustment under the statute was specifically created for IOLs that are ''new,'' the regulations at § 416.195 should include a newness criterion. Therefore, in the CY 2016 OPPS/ASC proposed rule (80 FR 39320), we proposed that, beginning in CY 2016,

any application for a new NTIOL class must fulfill an additional criterion. Specifically, we proposed that, beginning January 1, 2016, an NTIOL application will only be evaluated by CMS for a new IOL class if the IOL has received initial FDA premarket approval within the 3 years prior to the NTIOL application submission date. Without this proposed requirement, there is nothing in the existing regulations that would preclude an applicant from applying for and possibly being granted NTIOL status, despite U.S. market entry many years ago, which would be contrary to the plain meaning of ''new'' technology IOLs. We proposed to revise § 416.195(a)(1) of the regulations to reflect this proposal. We invited public comments on this proposal.

Comment: Two commenters supported the proposed newness criterion for NTIOL candidate lenses.

Response: We appreciate the commenters' support.

Comment: One commenter believed that the current regulations are sufficient and that this proposal was not necessary.

Response: We disagree with the commenter. Without the proposed newness criterion, old IOLs that have been on the market for many years could apply for NTIOL status. Furthermore, a lack of recent NTIOL applications does not obviate the need for this new regulation.

After consideration of the public comments we received, we are finalizing our proposal to establish a newness criterion for NTIOL applications. Beginning January 1, 2016, an NTIOL application will only be evaluated by CMS for a new NTIOL class if the IOL has received initial FDA approval within the 3 years prior to the NTIOL application submission date. We are revising 42 CFR 416.195 to reflect this change, and in this final rule with comment period we are deleting the unnecessary phrase ''under this provision'' from the proposed revised regulation text.

5. Announcement of CY 2016 Deadline for Submitting Requests for CMS Review of Applications for a New Class of NTIOLs

In accordance with 42 CFR 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective beginning in CY 2017, requests for review of applications for a new class of new technology IOLs must be received at CMS by 5 p.m. EST, on March 1, 2016. Send requests to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include the information requested on the CMS Web site at: *http://www.cms.gov/ASCPayment/downloads/NTIOLprocess.pdf*.

F. ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we also created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC list of covered services prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators used in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). We indicated that in the CY 2016 OPPS/ASC final rule with comment period, we will respond to public comments and finalize the ASC treatment of all codes that are labeled with comment indicator ''NI'' in Addenda AA and BB to the CY 2015 OPPS/ASC final rule with comment period.

The ''CH'' comment indicator is used in Addenda AA and BB to the proposed rule (which are available via the Internet on the CMS Web site) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year; an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

2. ASC Payment and Comment Indicators

In the CY 2016 OPPS/ASC proposed rule (80 FR 39321), for CY 2016 and subsequent years, we proposed to continue using the current comment indicators of ''NI'' and ''CH.'' For CY 2016, there are new and revised Category I and III CPT codes, as well as new and revised Level II HCPCS codes. Therefore, we proposed that Category I and III CPT codes that are new and revised for CY 2016 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2016 compared to the CY 2015 descriptors that are included in ASC Addendum AA and BB to the CY 2016 OPPS/ASC proposed rule would be labeled with proposed new comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes are open for comment as part of the CY 2016 OPPS/ASC proposed rule. Proposed new comment indicator ''NP'' means a new code for the next calendar year or an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year; comments will be accepted on the proposed ASC payment indicator for the new code.

For the CY 2016 update, we also proposed to add ASC payment indicator ''B5'' (Alternative code may be available; no payment made) to ASC Addendum DD1 to the proposed rule (which is available via the Internet on the CMS Web site). This code indicates that an alternative code is recognized under the ASC payment system. We proposed to add this payment indicator for situations where we receive new and revised Category I and Category III CPT codes too late for inclusion in a proposed rule, as discussed in section XII.B.3.b. of the proposed rule regarding

our proposed process for accepting comments on new and revised Category I and III CPT codes that are effective January 1. We stated that we would respond to public comments and finalize their ASC assignment in the CY 2016 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 to the proposed rule (which are available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2016 update.

We did not receive any public comments on the ASC payment and comment indicators and therefore are finalizing their use as proposed without modification.

G. Calculation of the ASC Conversion Factor and the ASC Payment Rates

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007 as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; 42 CFR 416.171(e)).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2. of the proposed rule), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor cost when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13–01 for the IPPS hospital wage index beginning in FY 2015. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66937), we finalized a 1-year transition policy that we applied in CY 2015 for all ASCs that experienced any decrease in their actual wage index exclusively due to the implementation of the new OMB delineations. This transition does not apply in CY 2016.

For CY 2016, the proposed CY 2016 ASC wage indexes fully reflect the new OMB labor market area delineations.

We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a

border). For example, for CY 2014, we applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA) and CBSA 08 (Rural Delaware).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). (In other situations, where there are no IPPS hospitals located in a relevant labor market area, we will continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.)

Comment: Several commenters made the same recommendation that was made in the CY 2010 (74 FR 60625), CY 2011 (75 FR 72059), CY 2012 (76 FR 74446), CY 2013 (77 FR 68463), and CY 2014 (78 FR 75086) rulemakings—that is, that CMS adopt for the ASC payment system the same wage index values used for hospital payment under the OPPS.

Response: We have responded to this comment in the past, and believe our prior rationale for using unadjusted wage indexes is still a sound one. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by almost all Medicare payment systems, appropriately account for geographic variance in labor costs for ASCs. We refer readers to our response to this comment in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72059). We discuss our budget neutrality adjustment for changes to the wage indices below in section XII.G.2.b. of this final rule with comment period.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2016 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). In the CY 2016 OPPS/ASC proposed rule (80 FR 39322 through 39323), consistent with our established policy, we proposed to scale the CY 2016 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2014, we proposed to compare the total payment using the CY 2015 ASC relative payment weights with the total payment using the CY 2016 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2015 and CY 2016. We proposed to use the ratio of CY 2015 to CY 2016 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2016. The proposed CY 2016 ASC scaler is 0.9180 and scaling would apply to the ASC relative payment weights of the covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of this final rule with comment period, we have available 98 percent of CY 2014 ASC claims data.

To create an analytic file to support calculation of the weight scaler and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2014 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2014 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for the proposed rule, is posted on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html*.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2016 ASC payment system and subsequent years, we proposed to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2016, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2014 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2016 ASC wage indexes. Specifically, holding CY 2014 ASC utilization and service-mix and the proposed CY 2016 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2015 ASC wage indexes (which reflect the new OMB delineations and include any applicable transition period) and the total adjusted payment using the proposed CY 2016 ASC wage indexes (which would fully reflect the new OMB delineations). We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2015 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2016 ASC wage indexes and applied the resulting ratio of 1.0014 (the proposed CY 2016 ASC wage index budget neutrality adjustment) to the CY 2015 ASC conversion factor to calculate the proposed CY 2016 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. Therefore, the statute does not mandate the adoption of any particular update mechanism, but it requires the payment

amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI–U (referred to as the CPI–U update factor).

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v) which requires that any annual update under the ASC payment system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, effective with the calendar year beginning January 1, 2011. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). Clause (iv) of section 1833(i)(2)(D) of the Act authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) of section 1833(i)(2)(D) of the Act states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASCQR Program. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), we finalized a methodology to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for the CY 2014 payment determination and subsequent years. The application of the 2.0 percentage point reduction to the annual update factor, which currently is the CPI–U, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We amended §§ 416.160(a)(1) and 416.171 to reflect these policies.

In accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the ''percentage increase'' in the CPI–U, which we interpret cannot be a negative percentage. Thus, in the instance where the percentage change in the CPI–U for a year is negative, we would hold the CPI–U update factor for the ASC payment system to zero. For the CY 2014 payment determination and subsequent years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality information under the rules established by the Secretary in accordance with section 1833(i)(7) of the Act. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the annual update factor, after application of any quality reporting reduction, by the MFP adjustment, and states that application of the MFP adjustment to the annual update factor after application of any quality reporting reduction may result in the update being less than zero for a year. If the application of the MFP adjustment to the annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting update to the ASC payment rates would be negative and payments would decrease relative to the prior year. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064) for examples of how the MFP adjustment is applied to the ASC payment system.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39323 through 39324), based on IHS Global Insight's (IGI's) 2015 first quarter forecast with historical data through 2014 fourth quarter, for the 12-month period ending with the midpoint of CY 2016, the CPI–U update was projected to be 1.7 percent. Also, based on IGI's 2015 first quarter forecast, the MFP adjustment for the period ending with the midpoint of CY 2016 was projected to be 0.6 percent. We finalized the methodology for calculating the MFP adjustment in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396) as revised in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301).

As we discussed in the CY 2011 MPFS final rule with comment period, section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that any annual update to the ASC payment system after application of the quality adjustment be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). Historical published data on the measure of MFP is available on the Bureau of Labor Statistics' (BLS) Web site at *http://www.bls.gov/mfp*.

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projection of the components of MFP are currently produced by IHS Global Insight, Inc. (IGI), a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of MFP. To generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U.S. macroeconomic models. In the CY 2011 and CY 2012 MPFS final rules with comment period (75 FR 73394 through 73396, 76 FR 73300 through 73301), we set forth the current methodology to generate a forecast of MFP. We identified each of the major MFP component series employed by the BLS to measure MFP as well as provided the corresponding concepts determined to be the best available proxies for the BLS series.

Beginning with the CY 2016 rulemaking cycle, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model. This series provides a better fit to the BLS capital inputs, as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. Therefore, we are using IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with the CY 2016 rulemaking cycle. A complete description of the MFP projection methodology is available on CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*. Although we discuss the IGI changes to the MFP

proxy series in the CY 2016 OPPS/ASC proposed rule and in this final rule with comment period, in the future, when IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

For CY 2016, we proposed to reduce the CPI–U update of 1.7 percent by the MFP adjustment of 0.6 percentage point, resulting in an MFP-adjusted CPI–U update factor of 1.1 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a 1.1 percent MFP-adjusted CPI–U update factor to the CY 2015 ASC conversion factor for ASCs meeting the quality reporting requirements. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the CPI–U for ASCs that fail to meet the ASCQR Program requirements. We proposed to reduce the CPI–U update of 1.7 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then apply the 0.6 percentage point MFP reduction. Therefore, we proposed to apply a −0.9 percent quality reporting/MFP-adjusted CPI–U update factor to the CY 2015 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also proposed that if more recent data are subsequently available (for example, a more recent estimate of the CY 2016 CPI–U update and MFP adjustment), we would use such data, if appropriate, to determine the CY 2016 ASC update for the final rule with comment period.

For CY 2016, we also proposed to adjust the CY 2015 ASC conversion factor ($44.058) by the proposed wage index budget neutrality factor of 1.0014 in addition to the MFP-adjusted CPI–U update factor of 1.1 percent discussed above, which results in a proposed CY 2016 ASC conversion factor of $44.605 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2015 ASC conversion factor ($44.058) by the proposed wage index budget neutrality factor of 1.0014 in addition to the quality reporting/MFP-adjusted CPI–U update factor of −0.9 percent discussed above, which results in a proposed CY 2016 ASC conversion factor of $43.723.

We invited public comment on these proposals.

Comment: Some commenters suggested that CMS replace the CPI–U as the update mechanism for ASC payments with the hospital market basket. The commenters stated that the CPI–U measures inflation in a basket of consumer goods atypical of what ASCs purchase. In addition, the commenters stated that the Affordable Care Act requires CMS to reduce the update by a measure of productivity gains, which inappropriately subjects ASCs to two productivity adjustments: Improvements reflected in the price of consumer purchased goods; and the additional statutorily required reduction. While the commenters maintained that the hospital market basket would be the most appropriate update for ASCs, they suggested that there are various alternatives within the CPI–U that CMS could explore that more accurately reflect the economic climate in the ASC environment. MedPAC acknowledged that there may be a burden associated with requiring ASCs to submit cost reports, but recommended that CMS collect some sort of ASC cost data, to determine whether an existing Medicare index is a good proxy or if there should be an ASC specific market basket.

Response: As we have stated in response to similar comments in the past (for example, 77 FR 68465; 78 FR 75088 through 75089; 79 FR 66939), we continue to believe that, while commenters argued that the items included in the CPI–U index may not adequately measure inflation for the goods and services provided by ASCs, the hospital market basket does not align with the cost structures of ASCs. Hospitals provide a much wider range of services, such as room and board and emergency services, and the costs associated with providing these services are not part of the ASC cost structure. Therefore, at this time, we do not believe that it is appropriate to use the hospital market basket for the ASC annual update. We recognize that the CPI–U is an output price index that accounts for productivity. However, section 1833(i)(2)(D)(v) of the Act requires the agency to reduce the annual update factor by the MFP adjustment. For the reasons stated above, we do not believe that the hospital market basket appropriately reflects the cost structures of ASCs, and because we do not have cost data on ASCs, we are continuing to use the CPI–U which we believe provides a reasonable approximation of the price increases facing ASCs. We will continue to explore the feasibility of collecting ASC cost data. However, based on our past experience, we do not believe that collecting such data through surveys would be productive. We appreciate the commenter's suggestion to adjust the CPI–U, for productivity and will take this suggestion into consideration if we propose changes to the ASC update factor in the future.

After consideration of the public comments we received, we are applying our established methodology for determining the final CY 2016 ASC conversion factor. Using more complete CY 2014 data for this final rule with comment period than were available for the proposed rule, we calculated a wage index budget neutrality adjustment of 0.9997. Based on IGI's 2015 third quarter forecast, the CPI–U for the 12-month period ending with the midpoint of CY 2016 is now projected to be 0.8 percent, while the MFP adjustment (as finalized in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301) and revised as discussed above) is 0.5 percent, resulting in an MFP-adjusted CPI–U update factor of 0.3 percent for ASCs that meet the quality reporting requirements. The final ASC conversion factor of $44.177, for ASCs that meet the quality reporting requirements, is the product of the CY 2015 conversion factor of $44.058 multiplied by the wage index budget neutrality adjustment of 0.9997 and the MFP-adjusted CPI–U payment update of 0.3 percent. For ASCs that do not meet the quality reporting requirements, we are reducing the CPI–U update of 0.8 percent by 2.0 percentage points and then we are applying the 0.5 percentage point MFP reduction, resulting in a −1.7 percent quality reporting/MFP-adjusted CPI–U update factor. The final ASC conversion factor of $43.296 for ASCs that do not meet the quality reporting requirements is the product of the CY 2015 conversion factor of $44.058 multiplied by the wage index budget neutrality adjustment of 0.9997 and the quality reporting/MFP-adjusted CPI–U payment update of −1.7 percent.

3. Display of CY 2016 ASC Payment Rates

Addenda AA and BB to this CY 2016 OPPS/ASC final rule with comment period (which are available via the Internet on the CMS Web site) display the final updated ASC payment rates for CY 2016 for covered surgical procedures and covered ancillary services, respectively. For those covered surgical procedures and covered ancillary services where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the MPFS final rates, the payment indicators and rates set forth in this rule are based on a comparison using the MPFS rates that effective January 1, 2016. For a discussion of the MPFS rates, we refer readers to the CY 2016 MPFS final rule with comment period.

The payment rates included in these addenda reflect the full ASC payment update and not the reduced payment

update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the CY 2016 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''Subject to Multiple Procedure Discounting'' indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2016. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the interim APC assignment for the new code. Display of the comment indicator ''NP'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the proposed payment indicator assignments for the new code.

The values displayed in the column titled ''CY 2016 Payment Weight'' are the relative payment weights for each of the listed services for CY 2016. The relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the CY 2016 payment rate displayed in the ''CY 2016 Payment Rate'' column, each ASC payment weight in the ''CY 2016 Payment Weight'' column was multiplied by the CY 2016 conversion factor of $44.177. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment (as discussed in section XII.G.2.b. of this final rule with comment period).

In Addendum BB, there are no relative payment weights displayed in the ''CY 2016 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''CY 2016 Payment'' column displays the CY 2016 national unadjusted ASC payment rates for all items and services. The CY 2016 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in October 2015.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are excluded from payment in ASCs for CY 2016.

XIII. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. In pursuit of these goals, CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The Hospital OQR Program has generally been modeled after the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program).

In addition to the Hospital IQR and Hospital OQR Programs, CMS has implemented quality reporting programs for other care settings that provide financial incentives for the reporting of quality data to CMS. These additional programs include reporting for care furnished by:

- Physicians and other eligible professionals, under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI));
- Inpatient rehabilitation facilities, under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals, under the Long-Term Care Hospital Quality Reporting (LTCH QRP) Program;
- PPS-exempt cancer hospitals, under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers, under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities, under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program;
- Home health agencies, under the Home Health Quality Reporting Program (HH QRP); and
- Hospices, under the Hospice Quality Reporting Program.

In addition, CMS has implemented several value-based purchasing programs, including the Hospital Value-Based Purchasing (VBP) Program and the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP), that link payment to performance.

In implementing the Hospital OQR Program and other quality reporting programs, we have focused on measures that have high impact and support national priorities for improved quality and efficiency of care for Medicare beneficiaries as reflected in the National Quality Strategy (NQS) and the CMS Quality Strategy, as well as conditions for which wide cost and treatment variations have been reported, despite established clinical guidelines. To the extent possible under various authorizing statutes, our ultimate goal is to align the clinical quality measure requirements of the various quality reporting programs. As appropriate, we will consider the adoption of measures with electronic specifications to enable the collection of this information as part of care delivery.

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68467 through 68469) for a discussion on the principles underlying consideration for future measures that we intend to use in implementing this and other quality reporting programs.

While we did not propose any changes, we received a comment on the general principles we outlined above.

Comment: One commenter supported CMS' mission to promote higher quality and more efficient health care for Medicare beneficiaries through the alignment of various quality reporting programs for multiple care settings, including the quality reporting program for hospital outpatient care.

Response: We thank the commenter for its support. We will continue to seek opportunities, as appropriate, to align our quality reporting programs.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program.

B. Hospital OQR Program Quality Measures

1. Considerations in the Selection of Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. In the CY 2016 OPPS/ASC proposed rule (80 FR 39325), we did not propose any changes to our measure selection policy. However, we received several comments on the priorities we consider for the Hospital OQR Program quality measure selection.

Comment: Many commenters urged CMS to streamline and refocus the measure set for the Hospital OQR Program to ensure alignment with concrete national priority areas for improvement across the entire healthcare system. The commenters also expressed concern that program measures have proliferated in the Hospital OQR Program without a well-articulated link to national priorities or goals. The commenters recommended that CMS consider adopting the recommendations outlined in the Institute of Medicine's (IOM) Vital Signs Report [1] for streamlining and focusing national quality measurement efforts.

Response: We thank the commenters for their suggestions and will take them under consideration. We disagree that Hospital OQR Program measures are not streamlined or aligned with concrete national priority areas for improvement across the entire healthcare system. Guided by NQS priorities,[2] we focus on measures appropriate to HOPDs that reflect the level of care and the most important areas of service and measures for that provider category. In future rulemaking, we may consider strategies outlined in the IOM's Vital Signs Report [3] for streamlining and focusing national quality measurement efforts as well. We continuously work with stakeholders to improve and revise the Hospital OQR Program measure set to develop and implement measures that appropriately measure quality of care with the goal of improving health outcomes. Furthermore, to the extent feasible, we adopt measures that are appropriate for multiple care settings to promote alignment across programs.

Comment: One commenter generally expressed concern that the proposed rule lacked sufficient detail, analysis, and rationale for a complete understanding of the policies and its impact such that hospitals would not be ready to implement many of the changes.

Response: We disagree with the commenter; we believe that the proposals were fully articulated such that they can be implemented by HOPDs. However, we will continue to contact hospitals through our outreach and education programs to ensure hospitals are ready to comply with the Hospital OQR Program's requirements.

Comment: Another commenter urged CMS to reexamine its approach in selecting measures for adoption into the Hospital OQR Program.

Response: We strive to select measures that are appropriate for the Hospital OQR Program that further our goals under the NQS and CMS Quality Strategy, and we welcome specific feedback from stakeholders on ways we can improve this process. As stated above, we focus on measures appropriate to HOPDs that reflect the level of care and the most important areas of service and measures for that provider category. We continuously work with stakeholders to improve and revise the Hospital OQR Program measure set to develop and implement measures that appropriately measure quality of care with the goal of improving health outcomes.

Comment: A few commenters recommended that additional measures considered for adoption be endorsed by the National Quality Forum (NQF) or identified by national consensus building entities to assure that CMS achieves its goal of aligning national quality measures across reporting programs, improving patient safety, and supporting the NQS goals.

Response: To the extent practical and feasible, we propose and adopt measures endorsed by NQF or other consensus-based entities, but are not required to do so under section 1833(t)(17)(C)(i) of the Act. We believe that consensus among affected parties can be achieved by means other than endorsement by a national consensus building entity, including through the measure development process, through stakeholder input via Technical Expert Panel (TEP), through broad acceptance and use of the measure(s), and through public comment. It is our priority to ensure that all of our measures achieve CMS and NQS goals.

Comment: One commenter recommended that CMS use quality measures that can be used for both the Hospital OQR and ASCQR Programs.

Response: We thank the commenter for the recommendation to adopt measures that are applicable to both the Hospital OQR and ASCQR Programs. Because outpatient surgical services are provided in both settings and in order to foster alignment among quality reporting programs, to the extent feasible, we aim to adopt measures that are also appropriate for the ASC setting and can be proposed for the ASCQR Program. However, under section 1833(t)(17)(C)(i) of the Act, we have a statutory obligation to develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities. We have a responsibility to measure quality in the OPD setting according to this standard, and measures may not always overlap with the ASC setting.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously adopted a policy to retain measures from the previous year's Hospital OQR Program measure set for subsequent years' measure sets in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471). Quality measures adopted in a previous year's rulemaking are retained in the Hospital OQR Program for use in subsequent years unless otherwise specified. We refer readers to that rule for more information. In the CY 2016 OPPS/ASC proposed rule (80 FR 39325 through 39326), we did not propose any changes to our retention policy for previously adopted measures.

[1] Institute of Medicine. Vital Signs: Core Metrics for Health and Health Care Progress. April 2015. *https://iom.nationalacademies.org/~/media/Files/Report%20Files/2015/Vital_Signs/VitalSigns_RB.pdf.*

[2] National Strategy for Quality Improvement in Health Care. March 2011. *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.pdf.*

[3] Institute of Medicine. Vital Signs: Core Metrics for Health and Health Care Progress. April 2015. *https://iom.nationalacademies.org/~/media/Files/Report%20Files/2015/Vital_Signs/VitalSigns_RB.pdf.*

3. Removal of Quality Measures From the Hospital OQR Program Measure Set

a. Considerations in Removing Quality Measures from the Hospital OQR Program

In the FY 2010 IPPS/LTCH PPS final rule for the Hospital IQR Program, we finalized a process for immediate retirement, which we later termed ''removal'' (74 FR 43863), of Hospital IQR Program measures based on evidence that the continued use of the measure as specified raised patient safety concerns. We adopted the same immediate measure retirement policy for the Hospital OQR Program in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635). We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our reasons for changing the term ''retirement'' to ''removal'' in the Hospital OQR Program. In the CY 2016 OPPS/ASC proposed rule (80 FR 39326), we did not propose any changes to our policy to immediately remove measures as a result of patient safety concerns.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized a set of criteria for determining whether to remove measures from the Hospital OQR Program. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our policy on removal of quality measures from the Hospital OQR Program. The benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis (79 FR 66941 through 66942). We note that, under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific criterion.

The following criteria will be used to determine whether to remove a measure from the Hospital OQR Program: (i) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures); (ii) performance or improvement on a measure does not result in better patient outcomes; (iii) a measure does not align with current clinical guidelines or practice; (iv) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (v) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (vi) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (vii) collection or public reporting of a measure leads to negative unintended consequences such as patient harm.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39326), we did not propose any changes to our measure removal policy. However, we received two general comments about removing measures.

Comment: One commenter recommended that CMS holistically examine the quality measurement portfolio and remove measures that are overly burdensome for hospitals and focus on measures that provide the most value for both patients and hospitals.

Response: We focus on measures appropriate for HOPDs that reflect the level of care and the most important areas of service for that provider category. At this time, we continue to believe there is value in collecting and reporting on each of the measures in the Hospital OQR Program measure set. Moreover, as is currently done, we will continuously evaluate the utility of the measures as we engage in future rulemaking. As stated above, we evaluate measures based on many factors. We also consider the burden on hospitals and the value for both patients and hospitals associated with every measure adopted.

Comment: One commenter suggested that when NQF removes its endorsement of a measure, that measure should be considered for removal from the Hospital OQR Program, in order that the full set of Hospital OQR Program measures does not become unwieldy.

Response: Regarding removal of measures to the Hospital OQR Program based upon NQF endorsement, section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

Although NQF endorsement is a significant consideration in the selection of measures for the Hospital OQR Program, this provision does not require that the measures we adopt be endorsed by any particular entity. In some cases, we believe that consensus among affected parties can be achieved by other means, including through the measure development process, through stakeholder input via TEPs, through broad acceptance and use of the measure(s), and through public comment. Therefore, loss of NQF endorsement would not necessitate removal of a measure. However, we will consider loss of NQF endorsement in the ongoing evaluation of adopted measures for the Hospital OQR Program.

b. Criteria for Removal of ''Topped-Out'' Measures

As provided above, quality measures may be removed from the Hospital OQR Program when they are ''topped-out.'' We refer readers to CY 2015 OPPS/ASC final rule with comment period where we finalized our proposal to refine the criteria for determining when a measure is ''topped-out'' (79 FR 66942). In the CY 2016 OPPS/ASC proposed rule (80 FR 39326), we did not propose any changes to our ''topped-out'' criteria policy. However, we received one comment on our current ''topped-out'' measure policy.

Comment: One commenter suggested that hospitals should not be penalized for not reporting ''topped-out'' measures under the Hospital OQR Program, but these measures should continue to be separately reported until CMS deems it likely that quality care is not being sacrificed in the absence of incentive payments.

Response: We expect hospitals to always follow appropriate standards-of care and clinical guidelines, regardless of whether a quality measure exists. We believe that HOPDs are committed to providing quality care to patients, and we do not have any indication that HOPDs will stop doing so when measures are removed. However, we must balance the burdens and costs of continued monitoring of a successful measure with high levels of performance with the adoption of other measures where there are opportunities for improvement in clinical quality. We will consider the need for refinement of the criteria for removal of ''topped-out'' measures for the Hospital OQR Program and, if we determine changes are necessary, we will propose such changes in future rulemaking.

4. Hospital OQR Program Quality Measures Adopted in Previous Rulemaking

The previously finalized measure set for the Hospital OQR Program CY 2017 payment determination and subsequent years is listed below.

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure name
N/A	OP–1: Median Time to Fibrinolysis.
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP–4: Aspirin at Arrival.
0289	OP–5: Median Time to ECG.
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
N/A	OP–9: Mammography Follow-up Rates.
N/A	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
N/A	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery.
N/A	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
N/A	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.**
N/A	OP–17: Tracking Clinical Results between Visits.
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
N/A	OP–22: ED- Left Without Being Seen.
0661	OP–23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival.
N/A	OP–25: Safe Surgery Checklist Use.
N/A	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients.
0659	OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
1536	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.***

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244*.

** Measure we proposed for removal.

*** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

In the CY 2015 OPPS/ASC final rule with comment period, we finalized one new measure beginning with the CY 2018 payment determination: OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) (79 FR 66948 through 66955). The previously finalized measure set for the Hospital OQR Program CY 2018 payment determination and subsequent years is listed below.

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure name
N/A	OP–1: Median Time to Fibrinolysis.
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP–4: Aspirin at Arrival.
0289	OP–5: Median Time to ECG.
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
N/A	OP–9: Mammography Follow-up Rates.
N/A	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
N/A	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non- Cardiac Low-Risk Surgery.
N/A	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
N/A	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.**
N/A	OP–17: Tracking Clinical Results between Visits.
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
N/A	OP–22: ED—Left Without Being Seen.
0661	OP–23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival.
N/A	OP–25: Safe Surgery Checklist Use.
N/A	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

NQF #	Measure name
0658	OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients.
0659	OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
1536	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.***
2539	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244*

** Measure we proposed for removal.

*** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

We note that we proposed one new measure for the CY 2018 payment determination and subsequent years in section XIII.B.6.a. of the CY 2016 OPPS/ASC proposed rule (80 FR 39328).

A number of commenters expressed views on previously adopted Hospital OQR Program measures.

Comment: Some commenters supported previously adopted measures, and some commenters recommended changing measure specifications for some measures. Other commenters requested that CMS consider removing previously added measures from the Hospital OQR Program, specifically, OP–1 and OP–20, noting that these two chart-abstracted measures look at processes of care and not clinical outcomes of care, which the commenters believed should be CMS' main focus. A few commenters urged CMS to remove OP–4, OP–5, OP–9, OP–10, OP–14, OP–20, OP–22, OP–25 from the Hospital OQR Program because these measures are no longer NQF-endorsed, are not recommended by the MAP, or are, the commenters believed, unsuitable for public reporting. A few commenters did not support the continued inclusion of OP–32 in the Hospital OQR Program, stating concerns related to the validity, reliability, and necessity of the measure.

Response: We thank the commenters for their suggestions. At this time, we are not removing or modifying any of the measures suggested by the commenters. There is no scientific evidence that continued use of the measures as specified raises patient safety concerns that would require immediate removal of the measures based on our established policies. We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66941 through 66942) for more information about those policies. We continue to believe there is value in collecting and reporting these measures; however, we will consider these comments in developing policy for future rulemaking.

Comment: A few commenters recommended that the Influenza Vaccination Coverage among Healthcare Personnel measure (NQF #0431) should be maintained in the Hospital OQR Program for the CY 2018 payment determination and subsequent years.

Response: As previously discussed, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471), we finalized a policy that, beginning CY 2013, when we adopt measures for the Hospital OQR Program, these measures are automatically adopted for all subsequent years' payment determinations, unless we propose to remove, suspend, or replace the measures. The OP–27: Influenza Vaccination Coverage among Healthcare Personnel (HCP) measure (NQF #0431) was finalized for the Hospital OQR Program in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75099). Therefore, OP–27 continues to be adopted in the Hospital OQR Program measure set for all subsequent years' payment determinations, unless we propose to remove, suspend, or replace the measure.

Comment: One commenter suggested that, for OP–29 and OP–30, CMS provide specifications in a manner and format consistent with other chart-abstracted measures including defined initial patient population, acceptable sampling methods, measure algorithms complete with exclusions, and defined alpha data dictionary with abstraction guidelines.

Response: We thank the commenter for the suggestion. However, we believe our measure specifications are sufficiently detailed to facilitate reporting that is feasible for most HOPD settings. While other chart-abstracted measures (for example, OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496) and OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional (76 FR 74481 through 74482)) utilize the CMS Abstraction and Reporting Tool for Outpatient Department measures (CART–OPD) or third-party vendors for data submission, both OP–29 and OP–30 use a CMS Web-based Tool (QualityNet Web site). Thus, data must be abstracted from charts, aggregated, and submitted via the QualityNet Web site. Because the data for measures submitted via a Web-based tool are reported in aggregate, measure algorithms complete with exclusions and defined alpha data dictionary with abstraction guidelines are not currently provided. However, sampling approaches and specifications defining initial patient populations are included. We refer readers to our Specifications Manual and the ''Template for Collecting OP–29 and OP–30 Endoscopy and Polyp Surveillance Data'' located at: *http://www.qualityreportingcenter.com/wp-content/uploads/2015/02/OQR_Template-for-Collecting-OP29-and-OP30-Data_FINAL.pdf*. Because the data for OP–29 and OP–30 are reported in aggregate and submitted via a Web-based tool, specifications as listed by commenter are not provided by CMS as is consistent with other chart-abstracted measures submitted via a Web-based tool, such as OP–22 ED- Patient Left Without Being Seen (76 FR 74457 through 74458).

Comment: One commenter urged CMS to consider developing a cloud-based registry for measures OP–29 and OP–30 to grant providers faster access to data.

Response: The National Institute of Standards and Technology (NIST) defines cloud computing as, ''a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (*e.g.,* networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction.'' [4] Based upon this

[4] Special Publication 800–145: The NIST Definition of Cloud Computing. Recommendations of the National Institute of Standards and

definition, we interpret ''cloud-based registry'' to mean an on-demand network providing access to a shared pool of measure data. At this time, we are operationally unable to develop a cloud-based registry for measure data, but we may consider this in the future.

5. Hospital OQR Program Quality Measure Removed for the CY 2017 Payment Determination and Subsequent Years

In the CY 2016 OPPS/ASC proposed rule (80 FR 39327 through 39328), we proposed to remove one measure from the Hospital OQR Program quality measure set beginning with the CY 2017 payment determination and subsequent years: OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache. The inclusion of OP–15 in the Hospital OQR Program consistently has generated concerns from stakeholders since its adoption in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72077 through 72082). In the CY 2012 OPPS/ASC final rule with comment period, we deferred the public reporting of OP–15 (76 FR 74456). We extended the postponement of public reporting for this measure in the CY 2013 and CY 2014 OPPS/ASC final rules with comment period (77 FR 68478 and 78 FR 75096). In addition, as we noted in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66963), we did not propose any changes to this policy. Public reporting for OP–15 continues to be deferred, and this deferral has no effect on any payment determinations (79 FR 66963).

Since deferring the measure, we have continued to evaluate OP–15. In CY 2011, we conducted a dry run of the measure and received many suggestions for refinements to the measure. Our technical expert panel examined the suggestions we received regarding the measure during the dry run as well as the comments we received during the maintenance process for this measure. Based on these comments, CMS refined the measure specifications for OP–15 to address most stakeholder concerns. Nevertheless, as discussed below, given the continued inconsistency of current clinical practice guidelines on which the measure is based, we proposed to remove OP–15 for the CY 2017 payment determination and subsequent years.

Based on our analysis, OP–15 meets the following criterion (iii) for removal: The measure does not align with current clinical guidelines or practice. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472) and the discussion above for a list of criteria we consider when determining whether to remove quality measures from the Hospital OQR Program. In peer-reviewed literature, headache guidelines have either excluded older adults or recommended a lower threshold for the use of CT scans.[5] Furthermore, stakeholders have expressed concern that this measure is influenced significantly by case-mix, patient severity, and clinician behavior, and thus, fails to represent appropriateness or efficiency accurately.[6] Based upon guidelines for use of CT scans published in peer-reviewed literature, we believe that OP–15,[7] as currently adopted in the Hospital OQR Program, does not align with the most updated clinical guidelines or practice, satisfying removal criterion (iii).

For the reason stated above, we proposed to remove the OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache measure from the Hospital OQR Program beginning with the CY 2017 payment determination.

We invited public comment on this proposal.

Comment: Commenters supported removal of OP–15, stating that the measure does not align with the most updated clinical guidelines or practice and it is not NQF-endorsed. In addition, the commenters observed that removing this measure would simplify and reduce administrative burden.

Response: We thank the commenters for their support.

Comment: One commenter noted that there should be a focus on the incorporation of other measures for which the evidence regarding appropriate use of CTs is much more robust.

Response: We thank the commenter for the suggestion. We will consider incorporating other measures focused on CTs in future rulemaking.

After consideration of the public comments we received, we are finalizing the removal of the OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache measure for the CY 2017 payment determination and subsequent years as proposed. Set out in the table below is the measure we are removing for the CY 2017 payment determination and subsequent years.

HOSPITAL OQR PROGRAM MEASURE REMOVAL FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure
N/A	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.

6. New Hospital OQR Program Quality Measures for the CY 2018 and CY 2019 Payment Determinations and Subsequent Years

In the CY 2016 OPPS/ASC proposed rule (80 FR 39328 through 39334), we proposed to adopt a total of two new measures for the Hospital OQR Program: (1) A Web-based quality measure for the CY 2018 payment determination and subsequent years; and (2) a Web-based quality measure for the CY 2019 payment determination and subsequent years. These measures are discussed in detail below.

a. New Quality Measure for the CY 2018 Payment Determination and Subsequent Years: OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822)

Bone metastases are a common manifestation of malignancy. Some cancer types have a bone metastasis prevalence as high as 70 to 95 percent.[8] EBRT is a widely used modality[9] to

Technology. September, 2011. Available at: *http://csrc.nist.gov/publications/nistpubs/800-145/SP800-145.pdf.*

[5] Available at: *http://www.acepnow.com/article/proposed-measures-ct-scans-cause-concern/2/.*

[6] *Ibid.*

[7] Hartsell W, *et al.* Randomized Trial of Short-Versus Long-Course Radiotherapy for Palliation of Painful Bone Metastases. Journal of the National Cancer Institute, 2005: 97 (11): 798–804.

[8] Coleman RE. Metastatic bone disease: Clinical features, pathophysiology and treatment strategies. Cancer Treat Rev. 2001;27:165–176.

[9] Chow E, Zeng L, Salvo N, Dennis K, Tsao M, Lutz S. Update on the Systematic Review of Palliative Radiotherapy Trials for Bone Metastases. Clin Onc. 2012;24:112–124. doi:10.1016/j.clon.2011.11.004.

provide pain relief in 50 to 80 percent of patients with painful bone metastases.[10] In October 2009, the American Society for Radiation Oncology (ASTRO) organized a Task Force to perform an assessment of existing recommendations in order to address a lack of palliative radiotherapy guidelines. Based on a review of the literature, the Task Force recommended the following EBRT dosing schedules for patients with previously unirradiated painful bone metastases: 30 Gy over the course of 10 fractions; 24 Gy over the course of 6 fractions; 20 Gy over the course of 5 fractions; and a single 8 Gy fraction.[11] Despite the recommendations, the actual doses applied for EBRT continue to include dosing schedules as high as 25 fractions.[12] An international survey of radiation oncologists, of which ¾ of the respondents were members of ASTRO, found more than 100 different dose schedules in use.[13] Measure testing by ASTRO noted nearly a 20 percent performance gap. Many studies support the conclusion that shorter EBRT schedules produce similar pain relief outcomes when compared to longer EBRT schedules, and that patients prefer shorter EBRT schedules because of their convenience, increased tolerability, and reduced side effects.[14] In addition, the ASTRO Task Force found that the frequency and severity of side effects associated with a single fraction were the same or less than those associated with multiple fraction regimens, indicating that shorter treatment schedules may be preferable.[15]

To address concerns associated with unnecessary exposure to radiation and a desire for shorter and less painful treatment options, we proposed to adopt one new Web-based quality measure for the CY 2018 payment determination and subsequent years: OP–33: External Beam Radiotherapy for Bone Metastases (NQF #1822). This measure assesses the ''[p]ercentage of patients (all-payer) with painful bone metastases and no history of previous radiation who receive EBRT with an acceptable dosing schedule.'' [16] The measure numerator includes all patients with painful bone metastases and no previous radiation to the same site who receive EBRT with any of the following recommended fractionation schemes: 30Gy/10fxns; 24Gy/6fxns; 20Gy/5fxns; or 8Gy/1fxn. The measure denominator includes all patients with painful bone metastases and no previous radiation to the same site who receive EBRT. The following patients are excluded from the denominator: Patients who have had previous radiation to the same site; patients with femoral axis cortical involvement greater than 3 cm in length; patients who have undergone a surgical stabilization procedure; and patients with spinal cord compression, cauda equina compression, or radicular pain. Detailed specifications for this measure may be found at: *https://www.qualityforum.org/QPS/1822*. We note that this measure is currently undergoing an annual update. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278 through 50279), the PCHQR Program adopted the EBRT measure for the FY 2017 program and subsequent years.

We believe that this measure will reduce the rate of EBRT services overuse, support our commitment to promoting patient safety, and support the NQS priority of Making Care Safer. Specifically, the proposed External Beam Radiotherapy for Bone Metastases measure seeks to address the performance gap in treatment variation, ensure appropriate use of EBRT, and prevent the overuse of radiation therapy. We believe that this measure is necessary to support patient preferences for shorter EBRT schedules as well as to ensure patient safety, given that shorter treatment courses show similar or fewer side effects while producing similar clinical outcomes. The measure also takes into account the effective schedule for relieving pain from bone metastases, patient preferences and time and cost effectiveness.[17]

In compliance with section 1890A(a)(2) of the Act, this measure was included in the publicly available document: ''List of Measures under Consideration for December 1, 2014.'' [18] The Measure Applications Partnership, a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the Hospital OQR Program, among other Federal programs, and provides input on those measures to the Secretary. The MAP's 2015 recommendations for quality measures under consideration are captured in the ''Spreadsheet of MAP 2015 Final Recommendations.'' [19]

As required under section 1890A(a)(4) of the Act, we considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital OQR Program. The MAP supported this proposed measure, stating that ''External beam radiation can help provide patients with pain relief . . . this measure has a demonstrated performance gap and would begin to expand cancer care measurement to settings beyond the PPS-exempt cancer hospitals.'' [20]

Furthermore, we believe that this measure meets the requirement under section 1833(t)(17)(C)(i) of the Act, which states that the Secretary shall develop measures that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities. We believe that this proposed measure reflects consensus among the affected parties because it is NQF-endorsed and recommended by the MAP.

We invited public comment on the proposal to include this measure in the Hospital OQR Program for the CY 2018 payment determination and subsequent years.

Comment: Most commenters supported adoption of this measure because doing so supports alignment across hospital quality reporting programs (since the measure was previously adopted by the PCHQR Program), and because the measure targets the important topic of unnecessary radiation exposure.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern that the measure should be subject to additional testing prior to nationwide implementation and recommended that CMS delay implementation until additional data

[10] Lutz S, Berk L, Chang E, *et al.* Palliative radiotherapy for bone metastases: An ASTRO evidence-based guideline. Int J Radiat Oncol Biol Phys. 2011;79(4):965–976.

[11] *Ibid.*

[12] Available at: *http://www.qualityforum.org/Measure_Evaluation_Form/Cancer_Project/1822.aspx.*

[13] Fairchild A, Barnes E, Ghosh S, *et al.* International Patterns of Practice in Palliative Radiotherapy for Painful Bone Metastases: Evidence-Based Practice? Int J Radiat Oncol Biol Phys. 2009;75(5):1501–1510.

[14] Available at: *http://www.qualityforum.org/Measure_Evaluation_Form/Cancer_Project/1822.aspx.*

[15] Lutz S, Berk L, Chang E, *et al.* Palliative radiotherapy for bone metastases: An ASTRO evidence-based guideline. Int J Radiat Oncol Biol Phys. 2011;79(4):965–976.

[16] Available at: *http://www.qualityforum.org/Measure_Evaluation_Form/Cancer_Project/1822.aspx.*

[17] Measure Submission and Evaluation Worksheet. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70374.*

[18] ''List of Measures under Consideration for December 1, 2014.'' Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78318.*

[19] ''Spreadsheet of MAP 2015 Final Recommendations.'' Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711.*

[20] *Ibid.*

becomes available from the PCHQR Program to avoid issues through lessons learned from that program. One commenter urged CMS to ensure that data collection for this measure is feasible in the HOPD setting, stating that CMS should further test the measure in HOPDs to determine whether facilities are able to capture all of the exclusions called for in the measure.

Response: Because unnecessary radiation exposure is such an important topic, as outlined above, we believe that it is of sufficiently broad scope and priority to merit inclusion in the Hospital OQR Program beginning with the CY 2018 payment determination, and we do not that believe we should delay adopting this measure. However, we will work with the PCHQR Program to simultaneously identify any lessons learned as the measure is implemented. Furthermore, we do not believe the measure requires further testing to determine whether facilities are able to capture all of the exclusions called for in the measure; rather, we believe this measure is specified for immediate implementation. This measure has been rigorously tested, is NQF-endorsed, and is supported by the MAP for implementation in the HOPD setting. For more specifics on the testing of OP–33 (for example, specifically in reference to best practices, dosing outliers, and validation of medical records), we refer readers to the measure specifications for evidence and supporting documents for quality improvement purposes at: *http://www.qualityforum.org/QPS/1822.* This measure was last updated on October 2, 2014, and as stated above, we note that it is currently undergoing an annual update. The measure steward has maintained this specific measure to address best clinical practices.

Comment: Some commenters urged CMS to reassess whether this measure addresses an issue of sufficiently broad scope and priority to merit inclusion in the Hospital OQR Program. One commenter stated that this measure is insufficient to drive meaningful quality improvement for cancer care in the outpatient setting.

Response: We believe that the measure is sufficiently broad in scope, because it was tested in outpatient settings and not limited to only cancer hospitals. In addition, the measure was supported by the MAP for implementation in the outpatient setting and endorsed by the NQF. Furthermore, as stated in the measure description above, we believe that this is a priority area as the measure would reduce the rate of EBRT services overuse, support our commitment to promoting patient safety, and support the NQS priority of Making Care Safer. Specifically, OP–33 seeks to address the performance gap in treatment variation, ensure appropriate use of EBRT, and prevent the overuse of radiation therapy. We believe that this measure supports patient preferences for shorter EBRT schedules, as well as ensures patient safety, given that shorter treatment courses show similar or fewer side effects while producing similar clinical outcomes. The measure also takes into account the effective schedule for relieving pain from bone metastases, patient preferences and time and cost effectiveness.[21] We believe that adoption of a national quality measure will encourage hospitals and physicians to be more cognizant of and to reevaluate their current EBRT dosing schedules. For these reasons, we believe the measure would be sufficient to drive meaningful quality improvement for cancer care in the outpatient setting.

Comment: A few commenters expressed concern that the measure specifications are not sufficiently detailed to assess impact on resources to collect and report data on the measure and recommended delaying data collection until details of the specifications are published to allow hospitals adequate time to shift resources to collect and report data on the measure. Other commenters asserted that measures should apply to a unique patient population that is easily defined and believed that this measure includes vague terminology and exclusions.

Response: We believe that this measure, as currently specified, is sufficiently detailed and can assess impact on resources to collect and report data on the measure. We believe that the measure is ready for immediate implementation in the outpatient setting. We have been collaborating closely and frequently with the measure steward (American Society for Radiation Oncology) in implementing this measure for the PCHQR Program. For more details of the EBRT algorithm and acceptable dosing please refer to the measure steward's specifications manual as well as to the specifications that PCHQR program has adopted: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774479863.*

In addition, measure specification 2a1.34–35 [22] indicates that this measure was specified and tested for the following settings: Ambulatory Care: Clinician Office, Hospital/Acute Care Facility. The testing results indicated that the facilities had sufficient resources to collect and report the data. The average number of patients at the testing facilities ranged between 250 and 1,000 patients per month. Therefore, this measure has been and continues to be specified for and tested in both the Hospital outpatient setting and the cancer hospital setting. Furthermore, the measure was supported by the MAP for implementation in the outpatient setting and endorsed by the NQF. We believe that this measure applies to a unique patient population that is easily defined, and we disagree that this measure includes vague terminology and exclusions. For detailed specifications, we refer readers to the specifications posted on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774479863.*

Comment: One commenter cautioned against utilization of uniform fractionation schemes for all patients with bone metastases called for by this measure, because personalized treatment plans allow for more appropriate balancing of the risks and benefits associated with EBRT.

Response: Although we agree that all treatment plans should be decided within the context of the provider-patient relationship and tailored to each patient, testing of the measure and many studies as cited in the NQF Measure Evaluation Form,[23] support the

[21] Measure Submission and Evaluation Worksheet. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70374.*

[22] Measure Submission and Evaluation Worksheet. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70374.*

[23] Nine randomized studies were included in the body of evidence in the guideline. These studies compared single fraction (8Gy/1) with multiple fractionation schemes. References: 1. Jeremic B, Shibamoto Y, Acimovic L, *et al.* A randomized trial of three single-dose radiation therapy regimens in the treatment of metastatic bone pain. Int J Radiat Oncol Biol Phys 1998;42:161–167. NQF #1822 External Beam Radiotherapy for Bone Metastases See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable 6 2. Bone Pain Trial Working Party. 8 Gy single fraction radiotherapy for the treatment of metastatic skeletal pain: Randomized comparison with a multifraction schedule over 12 months of patient follow-up. Radiother Oncol 1999;52:111–121. 3. Roos D, Turner S, O'Brien P, *et al.* Randomized trial of 8 Gy in 1 versus 20 Gy in 5 fractions of radiotherapy for neuropathic pain due to bone metastases (Trans-Tasman Radiation Oncology Group, TROG 96.05). Radiother Oncol 2005;75: 54–63. 4. Hartsell W, Konski A, Scott C, *et al.* Randomized trial of short versus long-course radiotherapy for palliation of painful bone metastases. J Natl Cancer Inst 2005;97:798–804. 5. Kaasa S, Brenne E, Lund J–A, *et al.* Prospective randomized multicentre trial on single fraction radiotherapy (8Gy/1) versus multiple fractions (3Gy/10) in the treatment of painful bone

Continued

conclusion that, in general, shorter EBRT schedules produce similar pain relief outcomes with fewer side effects when compared to longer EBRT schedules.[24]

After consideration of the public comments we received, we are finalizing the adoption of the OP–33: External Beam Radiotherapy for Bone Metastases (NQF #1822) measure for the CY 2018 payment determination and subsequent years as proposed with a modification to the manner of data submission. We refer readers to section XIII.D.4.b. of this final rule with comment period for detailed data submission requirements, including the modification. The table below sets forth the measure we are finalizing in this final rule with comment period for the CY 2018 payment determination and subsequent years.

NQF #	New measure for the CY 2018 payment determination and subsequent years
1822	OP–33: External Beam Radiotherapy for Bone Metastases.

The complete list of finalized measures for the CY 2018 payment determination and subsequent years are listed below.

HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure name
N/A	OP–1: Median Time to Fibrinolysis.
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP–4: Aspirin at Arrival.
0289	OP–5: Median Time to ECG.
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
N/A	OP–9: Mammography Follow-up Rates.
N/A	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
N/A	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery.
N/A	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
N/A	OP–17: Tracking Clinical Results between Visits.
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
N/A	OP–22: ED—Left Without Being Seen.
0661	OP–23: ED—Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival.
N/A	OP–25: Safe Surgery Checklist Use.
N/A	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients.
0659	OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
1536	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**
2539	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
1822	OP–33: External Beam Radiotherapy for Bone Metastases.***

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244*.

** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

*** New measure for the CY 2018 payment determination and subsequent years.

metastases. Radiother Oncol 2006;79:278–284. 6. Foro A, Fontanals A, Galceran J, *et al.* Randomized clinical trial with two palliative radiotherapy regimens in painful bone metastases: 30 Gy in 10 fractions compared with 8 Gy in single fraction. Radiother Oncol 2008;89:150–155. 7. Sande T, Ruenes R, Lund J, *et al.* Long-term follow-up of cancer patients receiving radiotherapy for bone metastases: Results from a randomised multicentre trial. Radiother Oncol 2009;91:261–266. 8. Nielsen O, Bentzen S, Sandberg E, *et al.* Randomized trial of single dose versus fractionated palliative radiotherapy of bone metastases. Radiother Oncol 1998;47:233–240. 9. Steenland E, Leer J, van Houwelingen, *et al.* The effect of a single fraction compared to multiple fractions on painful bone metastases: A global analysis of the Dutch Bone Metastasis Study. Radiother Oncol 1999;52:101–109.

[24] Available at: *http://www.qualityforum.org/Measure_Evaluation_Form/Cancer_Project/1822.aspx*.

In the CY 2016 OPPS/ASC proposed rule, OP–4: Aspirin at Arrival (NQF #0286) was inadvertently omitted from tables for the CY 2018 and CY 2019 Payment Determination and Subsequent Years (80 FR 39329 and 80 FR 39334). We would like to clarify that OP–4 has not been removed from the Hospital OQR Program measure set and data for OP–4 should be submitted for the CY 2018 payment determination and subsequent years as previously finalized.

b. Proposed New Hospital OQR Program Quality Measure for the CY 2019 Payment Determination and Subsequent Years: OP–34: Emergency Department Transfer Communication (EDTC) (NQF #0291)

In the proposed rule, we proposed to adopt OP–34: Emergency Department Transfer Communication (EDTC) (NQF #0291) to address concerns associated with care transitions when patients are transferred from Emergency Departments to other facilities.

Communication problems significantly contribute to adverse events in hospitals, accounting for 65 percent of sentinel events (patient safety events not primarily related to the natural course of the patient's illness or underlying condition that result in death, permanent harm, or severe temporary harm where intervention is required to sustain life) tracked by The Joint Commission.[25] In addition, information deficits frequently result when patients transfer between hospitals and primary care physicians in the community [26] and between hospitals and long-term care facilities.[27] According to patient safety studies,[28] the highest percentage of preventable and negligent adverse events within a hospital occurs in the Emergency Department.[29] The prevention of medical errors in the Emergency Department setting is gaining attention throughout the nation,[30] but performance measures for Emergency Department care are lacking.[31]

Effective and timely communication of a patient's clinical status and other relevant information at the time of transfer from the hospital is essential for supporting appropriate continuity of care. Establishment of an effective transition from one treatment setting to another is enhanced by providing the receiving providers and facilities with sufficient information regarding treatment during hospitalization. Studies have shown that readmissions can be prevented by providing detailed, personalized information about patients at the time they are transferred to home or any other site.[32]

To address concerns associated with care when patients are transferred from Emergency Departments to other facilities, we proposed to adopt one new Web-based quality measure for the Hospital OQR Program effective with the CY 2019 payment determination and subsequent years: OP–34: Emergency Department Transfer Communication (EDTC) (NQF #0291).

We proposed to implement this measure beginning with the CY 2019 payment determination and subsequent years instead of the CY 2018 payment determination and subsequent years in order to give hospitals adequate time to implement the proposed measure. We believe hospitals will require approximately 3 to 6 months in order to familiarize themselves with the implementation protocol and tools related to the EDTC measure and to make associated improvements prior to the first reporting deadline. If we were to propose and finalize this measure beginning with the CY 2018 payment determination, we believe that hospitals may not have adequate time to put the processes and procedures in place necessary to collect this measure.

The EDTC measure captures the ''[p]ercentage of patients transferred to another healthcare facility whose medical record documentation indicated that administrative and clinical information was communicated to the receiving facility in an appropriate time frame.'' [33] This measure is designed to prevent gaps in care transitions caused by inadequate or insufficient information that lead to avoidable adverse events. Such events cost CMS approximately $15 billion due in part to avoidable patient readmissions.[34] The measure has been rigorously peer reviewed and extensively tested with field tests from 2004 to 2014 across 16 States in 249 hospitals.[35]

The measure consists of seven subcomponents: (a) Administrative data; (b) patient information; (c) vital signs; (d) medication; (e) physician information; (f) nursing information; and (g) procedure and test results. The subcomponents are further comprised of a total of 27 elements, illustrated in the table below. We note that the EDTC measure does not require hospitals to submit patient data on each of these elements. Rather, hospitals would be required to answer yes or no as to whether these clinical indicators were recorded and communicated to the receiving facility prior to departure (Subsection 1) or within 60 minutes of transfer (Subsections 2 through 7).

NUMERATOR ELEMENTS FOR OP–34—EMERGENCY DEPARTMENT TRANSFER COMMUNICATION (EDTC) MEASURE (NQF #0291)

Administrative communication (EDTC-Subsection 1):
Nurse to nurse communication
Physician to physician communication
Patient information (EDTC-Subsection 2):
Name

[25] Available at: *http://www.jointcommission.org/Improving_Americas_Hospitals_The_Joint_Commissions_Annual_Report_on_Quality_and_Safety_-_2007/.*

[26] Kripalani, S., LeFevre, F., Phillips, C. *et al.* Deficits in Communication and Information Transfer between Hospital-Based and Primary Care Physicians: Implications for Patient Safety and Continuity of Care. JAMA 297(8):831–841, 2007.

[27] Cortes T., Wexler S. and Fitzpatrick J. The transition of elderly patients between hospitals and nursing homes. Improving nurse-to-nurse communication. Journal of Gerontological Nursing. 30(6):10–5, 2004.

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[32] Jack BW, Chetty VK, Anthony D, *et al.* A reengineered hospital discharge program to decrease rehospitalization. *Ann Intern Med* 2009; 150:178–187.

[33] Available at: *http://www.qualityforum.org/QPS/0291.*

[34] Medicare Payment Advisory Commission. Promoting Greater Efficiency in Medicare. June 2007. Available at: *http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf.*

[35] Refining and Field Testing a Relevant Set of Quality Measures for Rural Hospitals Final Report June 30, 2005. Available at: *http://rhrc.umn.edu/wp-content/files_mf/rh_ruralmeasuresfinalreport_063005.pdf.*

NUMERATOR ELEMENTS FOR OP–34—EMERGENCY DEPARTMENT TRANSFER COMMUNICATION (EDTC) MEASURE (NQF #0291)—Continued

Address
Age
Gender
Significant others contact information
Insurance
Vital signs (EDTC—Subsection 3):
Pulse
Respiratory rate
Blood pressure
Oxygen saturation
Temperature
Glasgow score or other neuro assessment for trauma, cognitively altered or neuro patients only
Medication information (EDTC—Subsection 4):
Medications administered in ED
Allergies
Home medications
Physician or practitioner generated information (EDTC—Subsection 5):
History and physical
Reason for transfer and/or plan of care
Nurse generated information (EDTC—Subsection 6):
Assessments/interventions/response
Sensory Status (formerly Impairments)
Catheters
Immobilizations
Respiratory support
Oral limitations
Procedures and tests (EDTC—Subsection 7):
Tests and procedures done
Tests and procedure results sent

We proposed to use a scoring methodology by which the facility score is reported as the percentage (0–100 percent) of all cases with a perfect score of ''7.'' To calculate this score, hospitals assign a value of ''0'' or ''1'' to each of the seven subcomponents for each case. In order to achieve a value of ''1'' for each subcomponent, the hospital must have recorded and transferred patient data pertaining to all of the elements that comprise that particular subcomponent; if data for any element fails to be recorded or transferred, then the value assigned to that subcomponent would be ''0.'' Next, subcomponent scores are added together, for a total ranging from ''0'' to ''7'' per case. Finally, the facility score is calculated by adding all of the cases that achieved a perfect score of ''7'' and dividing that number by the total number of cases to reflect the percentage of all cases that received a perfect score.

Example 1 below illustrates a case in which all patient data elements were recorded and transferred to the receiving facility.

EXAMPLE 1 OF CALCULATION FOR OP–34—EMERGENCY DEPARTMENT TRANSFER COMMUNICATION (EDTC) MEASURE (NQF #0291) BY CASE

Administrative communication (EDTC—Subsection 1):
Y—Nurse to nurse communication
Y—Physician to physician communication
Sub-1 Score = 1.
Patient information (EDTC—Subsection 2):
Y—Name
Y—Address
Y—Age
Y—Gender
Y—Significant others contact information
Y—Insurance
Sub-2 Score = 1.
Vital signs (EDTC—Subsection 3):
Y—Pulse
Y—Respiratory rate
Y—Blood pressure
Y—Oxygen saturation
Y—Temperature
Y—Glasgow score or other neuro assessment for trauma, cognitively altered or neuro patients only
Sub-3 Score = 1.
Medication information (EDTC—Subsection 4):
Y—Medications administered in ED
Y—Allergies
Y—Home medications
Sub-4 Score = 1.

EXAMPLE 1 OF CALCULATION FOR OP–34—EMERGENCY DEPARTMENT TRANSFER COMMUNICATION (EDTC) MEASURE (NQF #0291) BY CASE—Continued

Physician or practitioner generated information (EDTC—Subsection 5):
Y—History and physical
Y—Reason for transfer and/or plan of care
Sub-5 Score = 1.

Nurse generated information (EDTC—Subsection 6):
Y—Assessments/interventions/response
Y—Sensory Status (formerly Impairments)
Y—Catheters
Y—Immobilizations
Y—Respiratory support
Y—Oral limitations
Sub-6 Score = 1.

Procedures and tests (EDTC—Subsection 7):
Y—Tests and procedures done
Y—Tests and procedure results sent
Sub-7 Score = 1.

(Sub-1 (1) + Sub-2 (1) + Sub-3 (1) + Sub-4 (1) + Sub-5 (1) + Sub-6 (1) + Sub-7 (1) = 7.
"7" equals a perfect score; therefore, TOTAL SCORE FOR THIS CASE = 7.

Example 2 below illustrates a case in which some patient data elements failed to be recorded and/or transferred to the receiving facility.

EXAMPLE 2 OF CALCULATION FOR OP–34—EMERGENCY DEPARTMENT TRANSFER COMMUNICATION (EDTC) MEASURE (NQF #0291) BY CASE

Administrative communication (EDTC—Subsection 1):
Y—Nurse to nurse communication
Y—Physician to physician communication
Sub-1 Score = 1.

Patient information (EDTC—Subsection 2):
Y—Name
Y—Address
Y—Age
Y—Gender
Y—Significant others contact information
Y—Insurance
Sub-2 Score = 1.

Vital signs (EDTC—Subsection 3):
Y—Pulse
Y—Respiratory rate
Y—Blood pressure
Y—Oxygen saturation
Y—Temperature
N—Glasgow score or other neuro assessment for trauma, cognitively altered or neuro patients only
Sub-3 Score = 0.

Medication information (EDTC—Subsection 4):
Y—Medications administered in ED
Y—Allergies
N—Home medications
Sub-4 Score = 0.

Physician or practitioner generated information (EDTC—Subsection 5):
Y—History and physical
Y—Reason for transfer and/or plan of care
Sub-5 Score = 1.

Nurse generated information (EDTC—Subsection 6):
Y—Assessments/interventions/response
Y—Sensory Status (formerly Impairments)
Y—Catheters
Y—Immobilizations
Y—Respiratory support
Y—Oral limitations
Sub-6 Score = 1.

Procedures and tests (EDTC—Subsection 7):
Y—Tests and procedures done
Y—Tests and procedure results sent
Sub-7 Score = 1.

(Sub-1 (1) + Sub-2 (1) + Sub-3 (0) + Sub-4 (0) + Sub-5 (1) + Sub-6 (1) + Sub-7 (1) = 5.
"5" does not equal a perfect score of "7"; therefore, TOTAL SCORE FOR THIS CASE = 0.

For more information on this measure, including its specifications, we refer readers to the Current Emergency Department Transfer Communication Measurement Specifications, Data Definitions, and Data Collection Tool at: *http://rhrc.umn.edu/2012/02/ed-transfer-submission-manual*.

Additional information on this measure is also available at: *http://www.qualityforum.org/QPS/0291*.

As discussed above, the proposed EDTC measure seeks to address gaps in care coordination, by ensuring that vital patient information is both recorded and shared with the subsequent provider. We believe that the EDTC measure would increase the quality of care provided to patients, reduce avoidable readmissions, and increase patient safety. More timely communication of vital information results in better care, reduction of systemic medical errors, and improved patient outcomes. In addition, we believe that this measure will promote the NQS priority of Effective Communication and Coordination of Care. As articulated by HHS, ''Care coordination is a conscious effort to ensure that all key information needed to make clinical decisions is available to patients and providers. It is defined as the deliberate organization of patient care activities between two or more participants involved in a patient's care to facilitate appropriate delivery of health care services.'' [36] Critically, the availability of the transfer record to the next level provider within 60 minutes after departure supports more effective care coordination and patient safety, since a delay in communication can result in medication or treatment errors.

In compliance with section 1890A(a)(2) of the Act, this measure was included in the publicly available document: ''List of Measures under Consideration for December 1, 2014.'' [37] As stated above, the MAP reviews the measures under consideration for the Hospital OQR Program, among other federal programs, and provides input on those measures to the Secretary. The MAP's 2015 recommendations for quality measures under consideration are captured in the ''Spreadsheet of MAP 2015 Final Recommendations.'' [38]

As required under section 1890A(a)(4) of the Act, we considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital OQR Program. The MAP supported this measure, stating that ''This measure would help to address a previously identified gap around improving care coordination and would help ensure vital information is transferred between sites of care. The EDTC measure set consists of seven components that focus on communication between facilities around the transfer of patients. The measure set assists in filling the workgroup identified priority gap of enhancing care coordination efforts.'' [39] In addition, as stated above, the proposed measure addresses the NQS priority of Communication and Care Coordination.

We believe this measure meets the requirement under section 1833(t)(17)(C)(i) of the Act, which states that the Secretary shall develop measures that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities. We believe this proposed measure reflects consensus among the affected parties, because it is NQF-endorsed and supported by the MAP.

We invited public comment on the proposal to include the following measure in the Hospital OQR Program for the CY 2019 payment determination and subsequent years.

NQF #	Proposed measure for the CY 2019 payment determination and subsequent years
0291	OP–34: Emergency Department Transfer Communication Measure.

The public comments we received on the EDTC measure and our responses are set forth below.

Comment: Commenters supported the concept of improving care transitions, but the majority of commenters did not support the adoption of this measure for three primary reasons. First, commenters asserted that this measure overlaps significantly with the EHR Incentive Program Meaningful Use Stage 2 Core Objective—Transition of Care Requirements since 20 of the 27 elements in OP–34 are also collected as part of the Stage 2 Eligible Hospital and Critical Access Hospital (CAH) Meaningful Use Core Objectives. Second, many commenters expressed concern that chart-abstraction for this measure would be overly burdensome on hospitals, and particularly burdensome on hospitals that do not have fully operational Electronic Health Records (EHRs). Lastly, other commenters also had concerns that the scoring methodology relied upon overly complex calculations and set an unrealistically stringent standard. As a result, a few commenters expressed concern that implementation of this measure should be delayed beyond the CY 2019 payment determination because additional time and training would be necessary to develop new systems and processes to ensure the measure was correctly documented.

Response: The EHR Incentive Program Health Information Exchange Objective for 2015 through 2017 (80 FR 62806) requires that the Eligible Professional (EP), eligible hospital, or Critical Access Hospital (CAH) who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral in order to successfully demonstrate meaningful use. For this objective, CMS is also maintaining the requirements for the data elements included in the summary of care documents at 80 FR 62805. We recognize the proposed OP–34 would require hospitals to evaluate elements that would indeed overlap with information already collected as part of the EHR Incentive Program [40] The overlapping elements, as defined by the measure steward, during measure development can be found in the OP–34 measure specifications at Appendix C: Emergency Department Transfer Communication Measures: Crosswalk with Meaningful Use Stage Two Requirements (*http://www.stratishealth.org/documents/ED_Transfer_Data_Collection_Guide_Specifications.pdf*).

[36] U.S. DHHS. ''National Healthcare Disparities Report 2013.'' Available at: *http://www.ahrq.gov/research/findings/nhqrdr/nhdr13/chap7.html*.

[37] ''List of Measures under Consideration for December 1, 2014.'' Available at: *www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78318*.

[38] MAP. February 2015. ''Spreadsheet of MAP 2015 Final Recommendations''. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711*.

[39] *Ibid.*

[40] Stage 2 Eligible Hospital and Critical Access Hospital (CAH) Meaningful Use Core and Menu Objectives Table of Contents. October 2015. *http://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-25595.pdf*.

We note that this document, Appendix C: Emergency Department Transfer Communication Measures: Crosswalk with Meaningful Use Stage Two Requirements, was developed prior to publication of The EHR Incentive Program Health Information Exchange Objective for 2015 through 2017 summary of care documents (80 FR 62805). The overlapping data elements found in the OP–34 measure specifications were based upon standards set forth in The EHR Incentive Program Meaningful Use Stage 2 Core Objective—Transition of Care (77 FR 53970). However, the data elements submitted under the transition of care standards as part of the Meaningful Use Stage Two Requirements remain unchanged in The EHR Incentive Program Health Information Exchange Objective for 2015 through 2017 summary of care documents (80 FR 62805). Therefore, the overlapping data elements found in the OP–34 measure specifications remain the same.

Currently, 95 percent of hospitals attest to successful electronic clinical quality measure reporting under the EHR Incentive Program (80 FR 49694). As a result, we agree that adopting OP–34 would significantly overlap with the Meaningful Use Stage 2 requirements diverting attention and resources away from another CMS priority and potentially adding additional costs to hospitals in order to re-specify EHR systems to comply with both programs' requirements.

Also, we recognize that the burden associated with chart-abstracting for 27 elements associated with this measure presents a significant burden for hospitals and that the scoring methodology is complex and sets a very high standard. Initially, we intended that delaying implementation of this measure until the CY 2019 payment determination would allow facilities additional time to implement the proposed measure (that is, to put the necessary processes and procedures in place), to familiarize themselves with the implementation protocol, tools, and scoring methodology related to the EDTC measure, and to make associated improvements prior to the first reporting deadline. However, in light of these comments, delayed implementation may not sufficiently address these concerns. In general though, we do not agree that hospitals without fully operational EHRs would be disadvantaged in chart-abstracting data for measures compared to hospitals with operational EHRs. Other measures in the Hospital OQR Program also require chart abstraction and do not distinguish between hospitals with fully operational EHRs versus those without.

Therefore, after considering the comments and for the reasons discussed above, we are not finalizing our proposal to adopt OP–34 for the CY 2019 payment determination and subsequent years as proposed.

Comment: Some commenters questioned whether the measure is necessary and asked if there is evidence that hospitals are failing to sufficiently report and transfer patient data. One commenter stated that the references cited in the proposed rule that indicate that the highest percentage of preventable and negligent adverse events occurring within hospital emergency departments are inaccurate and based on limited and outdated data.

Response: As stated in the measure background above, the proposed EDTC measure seeks to address gaps in care coordination, by ensuring that vital patient information is both recorded and shared with the subsequent provider. More timely communication of vital information results in better care, reduction of systemic medical errors, and improved patient outcomes. We believe that an EDTC measure would increase the quality of care provided to patients, reduce avoidable readmissions, and increase patient safety. In addition, we believe that a transfer communication measure would promote the NQS priority of Effective Communication and Coordination of Care. As articulated by HHS, ''Care coordination is a conscious effort to ensure that all key information needed to make clinical decisions is available to patients and providers. It is defined as the deliberate organization of patient care activities between two or more participants involved in a patient's care to facilitate appropriate delivery of health care services.'' Critically, the availability of the transfer record to the next level provider supports more effective care coordination and patient safety, since a delay in communication can result in medication or treatment errors. Furthermore, the MAP supported this measure, stating that, ''[t]his measure would help to address a previously identified gap around improving care coordination and would help ensure vital information is transferred between sites of care.'' In addition, we believe that references cited are accurate as of the time of measure development and the proposed rule. However, as discussed above, we are not finalizing this measure, but will take these comments into consideration in developing future policy.

Comment: Several commenters suggested that CMS consider adopting this measure as an eCQM.

Response: We did not propose this measure as an eCQM because it is not currently electronically specified. However, because we believe care coordination in the emergency department setting is an important aspect for quality measurement, if the measure is electronically specified in the future, we may consider proposing it or a similar electronic measure addressing this topic in future rulemaking.

Comment: A few commenters supported adopting the measure as proposed. One commenter suggested that CMS include at least one companion, NQF-endorsed measure that captures communication of medication information. This commenter also recommended that CMS include OP–17: Tracking Clinical Results between Visits (former NQF measure #0491; NQF endorsement removed April 8, 2014) in patient care plans, noting that this measure is significant and very important to patient safety and clinical outcomes.

Response: We thank the commenters for their support. However, for the reasons stated above, we have decided not to finalize this measure. We will consider these suggestions if we decide to propose a similar measure in future rulemaking.

Comment: Many commenters requested clarification on various technical aspects of the measure, such as the definition of ''communication'' and how to report data for John/Jane Doe patients, patients that are unresponsive, or information that is otherwise unknown.

Response: In the CY 2016 OPPS/ASC proposed rule (80 FR 39334), we directed readers to the following Web site for a complete listing of the measure specifications: *http://www.qualityforum.org/QPS/0291*. Documents available on this Web site provide detailed definition of ''communication'' and answers to the commenter's concerns regarding how to report data for John/Jane Doe patients, patients that are unresponsive, or information that is otherwise unknown. According to the measure specifications, a hospital would not be penalized for missing information as long as information, even if the information for a particular element is documented as ''unknown,'' is transferred to the receiving facility. However, as discussed above, we are not finalizing this measure but will take these comments into consideration in developing future policy.

After considering the public comments we received, we are not finalizing the OP–34: Emergency Department Transfer Communication (EDTC) measure (NQF #0291) for the CY 2019 payment determination and subsequent years as proposed.

The finalized measures for the CY 2019 payment determination and subsequent years are listed below.

HOSPITAL OQR PROGRAM MEASURE SET FOR THE CY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF #	Measure name
N/A	OP–1: Median Time to Fibrinolysis.
0288	OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival.
0290	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
0286	OP–4: Aspirin at Arrival.
0289	OP–5: Median Time to ECG.
0514	OP–8: MRI Lumbar Spine for Low Back Pain.
N/A	OP–9: Mammography Follow-up Rates.
N/A	OP–10: Abdomen CT—Use of Contrast Material.
0513	OP–11: Thorax CT—Use of Contrast Material.
N/A	OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data.
0669	OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery.
N/A	OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT).
N/A	OP–17: Tracking Clinical Results between Visits.
0496	OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients.
N/A	OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional.
0662	OP–21: Median Time to Pain Management for Long Bone Fracture.
N/A	OP–22: ED-Left Without Being Seen.
0661	OP–23: ED—Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival.
N/A	OP–25: Safe Surgery Checklist Use.
N/A	OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures.*
0431	OP–27: Influenza Vaccination Coverage among Healthcare Personnel.
0658	OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients.
0659	OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
1536	OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**
2539	OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
1822	OP–33: External Beam Radiotherapy for Bone Metastases.***

* OP–26: Procedure categories and corresponding HCPCS codes are located at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244.*

** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

*** New measure for the CY 2018 payment determination and subsequent years.

As stated above, we reiterate that in the CY 2016 OPPS/ASC proposed rule, OP–4: Aspirin at Arrival (NQF #0286) was inadvertently omitted from tables for the CY 2018 and CY 2019 Payment Determination and Subsequent Years (80 FR 39329 and 80 FR 39334). We would like to clarify that OP–4 has not been removed from the Hospital OQR Program measure set and data for OP–4 should be submitted for the CY 2018 payment determination and subsequent years as previously finalized.

7. Hospital OQR Program Measures and Topics for Future Consideration

The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED throughput efficiency, the use of health information technology (health IT), care coordination, patient safety, and volume. In the CY 2016 OPPS/ASC proposed rule (80 FR 39335), we stated that for future payment determinations, we are considering expanding these measure areas and creating measures in new areas. Specifically, we are exploring electronic clinical quality measures (eCQMs) and whether, in future rulemaking, we would propose that hospitals have the option to voluntarily submit data for OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496) electronically beginning with the CY 2019 payment determination. Hospitals would otherwise still be required to submit data for this measure through chart abstraction.

We believe all patients, their families, and their healthcare providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care.[41] To that end, we are committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health IT across the broader care continuum through a number of initiatives including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of health IT and HIE services through Medicare and Medicaid payment policies; (2) adoption of common standards and certification requirements for interoperable health IT; (3) support for privacy and security of patient information across all HIE-focused initiatives; and (4) governance of health information networks. More information on the governance of health information networks and its role in facilitating interoperability of health information systems can be found at: *http://www.healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf.*

[41] HHS August 2013 Statement, ''Principles and Strategies for Accelerating Health Information Exchange.'' Available at: *http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf.*

We believe that HIE and the use of certified EHR technology can effectively and efficiently help providers improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of electronically specified clinical quality measures. On March 30, 2015, ONC published in the **Federal Register** a proposed rule (80 FR 16804) that proposes a new 2015 Edition Base EHR definition, as well as modifications to the ONC Health IT Certification Program to make it open and accessible to more types of health IT and health IT that supports various care and practice settings. It also proposes to establish the capabilities and specifications that certified EHR technology (CEHRT) would need to include, at a minimum, to support the achievement of meaningful use by eligible professionals and hospitals under the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) when such edition is required for use under these programs. More information on the 2015 Edition EHR Certification Criteria proposed rule can be found at: *http://healthit.gov/policy-researchers-implementers/standards-and-certification-regulations*.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810), the Hospital IQR Program finalized a policy to allow hospitals to voluntarily electronically report at least one quarter of CY 2014 quality measure data for each measure in one or more of four measure sets (STK, VTE, ED, and PC). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50246 and 50249 through 50253), the Hospital IQR Program finalized a policy that hospitals may voluntarily report any 16 of 28 Hospital IQR Program electronic clinical quality measures that align with the Medicare EHR Incentive Program as long as those measures span three different NQS priority areas. Most recently in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698), the Hospital IQR Program finalized a policy to make reporting of electronic clinical quality measures required rather than voluntary. Under that finalized policy, hospitals will be required to submit only one quarter of data for either Q3 (July 1–September 30) or Q4 (October 1–December 31) of 2016 for at least 4 electronic clinical quality measures.

We anticipate that as EHR technology evolves and more health IT infrastructure is operational, we will begin to accept electronic reporting of many measures from EHR technology certified under the ONC Health IT Certification Program. We are working diligently toward this goal. We believe that this progress would significantly reduce the administrative burden on hospitals under the Hospital OQR Program to report chart-abstracted measures.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72074), we finalized OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496), the only measure in our current measure set which is specified as an eCQM, or e-specified. The e-specification for this measure is available at: *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2014_eCQM_Specs_for_EH.zip* in the folder entitled: EH_CMS32v2_NQF0496_ED3_MedianTime.

The same measure, Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496), was adopted by the Medicare and Medicaid EHR Incentive Program for Eligible Hospitals and Critical Access Hospitals (CAHs) as one of 29 clinical quality measures available for reporting under the program beginning with Federal fiscal year 2014 (77 FR 54086 through 54087).

For the reasons stated above, we believe it is important to encourage providers to submit this measure electronically. In addition, allowing submission of OP–18 as an eCQM will begin to align the Hospital OQR Program with the Medicare EHR Incentive Program for Eligible Hospitals and CAHs in a manner similar to our policies for the Hospital IQR Program (80 FR 50319 through 50321). Therefore, we stated in the CY 2016 OPPS/ASC proposed rule (80 FR 39335) that we are considering proposing a policy in future rulemaking that would give hospitals an option to voluntarily submit data for this measure electronically for the Hospital OQR Program beginning with the CY 2019 payment determination. Hospitals that chose not to submit electronically would still be required to submit data though chart abstraction.

We invited public comment on our intention to make this proposal in the future.

Comment: Most commenters supported voluntary electronic submission of data for OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients beginning with the CY 2019 payment determination. In addition to voluntary electronic submission of OP–18, one commenter suggested that CMS transition OP–20 to electronic reporting in order to align ED through-put measures. A few commenters urged that proposed reporting requirements for eCQMs be aligned with the requirements and timelines as much as possible with other eCQM initiatives across care settings, specifically, the Medicare EHR Incentive Program clinical quality data reporting criteria for demonstrating Meaningful Use of EHRs. With respect to voluntary submission of data for OP–18 as an eCQM, one commenter requested clarification on three points: (1) Whether the latest version of the measure specification would be required as is the case for other electronically reported measures; (2) whether measure reporting would count toward the hospital's reporting requirements for the EHR Incentive Program; and (3) whether CMS could provide a more detailed description of the timeframe for voluntary reporting (for example, calendar year, quarters, etc.). This commenter also suggested that submission timeframes be consistent between EHR Incentive Program Meaningful Use requirements and the Hospital IQR Program.

Response: We thank the commenters for their support and will take these comments into consideration for future rulemaking. Ideally, we would aim to align the Hospital OQR Program timeframes with those for the EHR Incentive Program and the Hospital IQR Program in order to reduce burden for hospitals. We are evaluating eCQM implementation in the Hospital IQR Program and will take any lessons learned, including those related to aligned requirements across CMS programs, submission timeframes, and general overlap with the EHR Incentive Program, into consideration in crafting policy for the Hospital OQR Program. We aim to ease the transition to reporting of electronic clinical quality measures, but any policies regarding the specific timelines and requirements related to the voluntary submission of data for OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients as an eCQM would be proposed in future rulemaking.

Comment: Some commenters did not support the option to report eCQMs in quality reporting programs, because they believed that such requirement might create a duplicative penalty for hospitals unable to meet Meaningful Use Requirements. Several commenters urged CMS to not require eCQM reporting for OP–18, noting that hospitals should have the option to continue to submit data via chart abstraction if they determine this method to be more feasible.

Response: As we stated in the CY 2016 OPPS/ASC proposed rule (80 FR 39335), we are considering proposing a

policy in future rulemaking that would give hospitals an option to voluntarily submit data for OP–18 electronically beginning with the CY 2019 payment determination. Hospitals that chose not to submit electronically would still have the option of submitting data though chart abstraction. As a voluntary option, no penalty would be incurred by hospitals choosing not to submit data for OP–18 electronically. However, we have observed the successes of hospitals meeting the Meaningful Use requirements and our data show that 95 percent of hospitals already attest to successful eCQM reporting under the EHR Incentive Program.

We anticipate that, as EHR technology evolves and more health IT infrastructure is operational, we will begin to accept electronic reporting of many measures from EHR technology certified under the ONC Health IT Certification Program. We believe it is important to encourage providers to submit measures electronically, and we expect that, if proposed and finalized, the option to voluntarily submit data for OP–18 electronically beginning with the CY 2019 payment determination will begin the gradual transition toward electronic reporting on measures. As noted above, if we choose to allow voluntary electronic submission of OP–18, we will propose this policy in future rulemaking.

Comment: One commenter supported CMS' commitment to eCQMs, but cautioned that disparate information systems and conflicting data elements may result in potentially inconsistent data that fail to accurately reflect care. Another commenter suggested that no electronically reported measures be used for public reporting of data or for determinations in financial incentive/disincentive programs until the issues of comparability, completeness, and accuracy are fully addressed. A few commenters stated that there is currently no validation process in place to confirm the accuracy of eCQM data and urged CMS to develop a validation process for eCQMs that will allow for future public reporting of these measures. One commenter recommended continued reporting of manually abstracted measures in parallel with eCQMs and simultaneous expansion of the eCQM pilot process, using manually abstracted measures as a control, to allow for evidence-based comparison data, in order to address concerns that removal of manual measures in favor of immature eCQM technology might yield poor quality performance.

Response: We thank the commenters for their suggestions. Similar concerns about disparate information systems and conflicting data elements resulting in issues of comparability, completeness, and accuracy of eCQM data were also expressed by commenters in the FY 2016 IPPS/LTCH PPS final rule under the Hospital IQR Program (80 FR 49695 through 49698). We anticipate that as EHR technology evolves and more health IT infrastructure is operational, in cooperation with the efforts of the ONC Health IT Certification Program, data elements and information systems requirements will become more standardized. Reliable, accurate data and electronic reporting are all important priorities to us. We believe that, with the advancement of technology and the use of electronic measures, even more precise, accurate, and reliable data will be captured for analysis. We are working diligently toward this goal.

The development of a validation process for eCQMs is also a suggestion we will consider if we decide to move forward with the proposal to allow OP–18 to be electronically reported in future rulemaking. We note that a validation pilot is currently under way in the Hospital IQR Program and the results of that pilot are pending, as described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50269 through 50273). We will take into consideration lessons learned in the Hospital IQR Program before developing Hospital OQR Program policies. In regard to the suggestion of a simultaneous expansion of the eCQM pilot process, using manually abstracted measures as a control, to allow for evidence-based comparison data, we will consider these recommendations if we decide to move forward with the proposal in future rulemaking.

Comment: While supporting the concept of using data collected from electronic health records, one commenter expressed concern that CMS might have direct access to a facility's EHR for data abstraction, adding that requirements for electronic submission of data may be premature and there is little confidence that health care providers are prepared to do so with great accuracy.

Response: We thank the commenter for its support. Matters of patient privacy and medical record integrity are of utmost importance, and we will give those issues serious consideration prior to proposing any electronic reporting in future rulemaking. However, we note that it is extremely unlikely that we would propose to access a facility's EHR system directly for data abstraction purposes.

We also received several general comments regarding future measures for the Hospital OQR Program.

Comment: Several commenters suggested the inclusion of more outcome-based measures into the Hospital OQR Program measure set. Another commenter expressed concern that outcome-based measures unfairly penalize HOPDs because most follow-up care is not provided by HOPDs.

Response: We will consider adopting more outcome-based measures in the future, and in doing so, we will be mindful of the concerns the commenters have about these measures.

Comment: A few commenters suggested that CMS include additional immunization performance measures in the Hospital OQR Program to help ensure vaccines are routinely offered and administered to patients in the outpatient setting.

Response: We thank the commenters for their suggestion. We will take this suggestion into consideration for future rulemaking.

8. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we continue to develop the Hospital OQR Program. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244*.

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68469 through 68470), for a discussion of our policy for updating Hospital OQR Program measures, the same policy we adopted for updating Hospital IQR Program measures, which includes the subregulatory process for making updates to the adopted measures (77 FR 53504 through 53505). This policy expanded upon the subregulatory process for updating measures that we finalized in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767). In the CY 2016 OPPS/ASC proposed rule (80 FR 39335 through 39336), we did not propose any changes to these policies.

9. Public Display of Quality Measures

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75092) for our finalized public display policy. A more robust discussion of our policy for the

publication of Hospital OQR Program data on the Hospital Compare Web site and noninteractive CMS Web sites can be found in the CY 2014 OPPS/ASC proposed rule (78 FR 43645). In the CY 2016 OPPS/ASC proposed rule (80 FR 39336), we did not propose any changes to our public display policy. However, we received one comment on these policies.

Comment: While stating support for the public display of outpatient quality data on Hospital Compare, one commenter expressed concerns about the outpatient categories on the Web site, noting that while these particular categories may be meaningful to health care providers and others with a professional interest in health care services, health care policy, or health care economics, the categories are less meaningful to the average consumer/patient.

Response: We thank the commenter for its observation. To the extent feasible and practical, we work with as many stakeholders as possible to ensure data are accurately reported and displayed on Hospital Compare and other CMS Web sites. In the future, we will continue working with stakeholders to improve the display of data in such a way that is more accessible and meaningful to the public.

C. Administrative Requirements

1. QualityNet Account and Security Administrator

The QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are unchanged from those adopted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109). In that final rule with comment period, we codified these procedural requirements at 42 CFR 419.46(a). In the CY 2016 OPPS/ASC proposed rule (80 FR 39336), we did not propose any changes to these requirements.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) for requirements for participation and withdrawal from the Hospital OQR Program. In that final rule with comment period, we codified procedural requirements at 42 CFR 419.46(b).

In the CY 2016 OPPS/ASC proposed rule (80 FR 39336), we proposed to make one change to the requirements regarding participation in the Hospital OQR Program beginning with the CY 2017 payment determination. Currently, a participating hospital may withdraw from the Hospital OQR Program any time from January 1 to November 1 (42 CFR 419.46(b)) of the year prior to the affected annual payment update by submitting a withdrawal form to CMS via the secure portion of the QualityNet Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1192804525137*.

We proposed that beginning with the CY 2017 payment determination, hospitals must submit a withdrawal form to CMS via the QualityNet Web site up to and including August 31 of the year prior to the affected annual payment update. For example, for the CY 2017 payment determination, the withdrawal deadline would change from November 1, 2016 to any time up to and including August 31, 2016 under this proposal.

The change to the withdrawal deadline is consistent with the ASCQR Program withdrawal deadline described in section XIV.C.2. of this final rule with comment period and in 42 CFR 416.305(b). We believe aligning deadlines across programs will reduce provider burden by streamlining processes and procedures.

In addition, as we discussed in section XIII.D.1. of the CY 2016 OPPS/ASC proposed rule (80 FR 39336 through 39337) and finalized in section XIII.D.1. of this final rule with comment period, we proposed to move the timeline for when we make annual percentage update (APU) determinations to allow both CMS and stakeholders more time to review the APU determinations before the beginning of the calendar year. To ensure the correct hospitals are included in the APU determinations, we also need to know at an earlier date which hospitals have withdrawn from the Hospital OQR Program.

We also proposed to make a conforming revision to 42 CFR 419.46(b) which currently states that the hospital may withdraw any time from January 1 to November 1 of the year prior to the affected annual payment updates to state that the hospital may withdraw any time up to and including August 31 of the year prior to the affected annual payment updates.

We invited public comment on our proposals to change the withdrawal deadline and to revise 42 CFR 419.46(b) to reflect this change.

Comment: One commenter supported the proposed change of the withdrawal deadline from the Hospital OQR Program from November 1 to August 31, noting that this change fosters alignment and consistency with the ASCQR Program.

Response: We thank the commenter for its support.

After consideration of the public comment we received, we are finalizing our proposals to change the withdrawal deadline for the Hospital OQR Program from November 1 to August 31 and to revise 42 CFR 419.46(b) to reflect this change as proposed.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Change Regarding Hospital OQR Program Annual Percentage Update (APU) Determinations

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 through 75111), we specify that our data submission deadlines will be posted on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1205442058760*.

The data submission requirements document, Hospital OQR Quality Measures and Timelines for CY 2016 and Subsequent Payment Determinations,[42] explains that the chart-abstracted data on which we base APU determinations is quarter 3 of the 2 years prior to the payment determination through quarter 2 of the year prior to the payment determination. For example, we base our APU determinations for the CY 2016 Hospital OQR Program on chart-abstracted data from quarter 3, 2014, through quarter 2, 2015. Chart-abstracted data from quarter 2, 2015 must be submitted by November 1, 2015. APU determinations are applied to payments beginning in January of the following year, providing less than 2 months between the time the data on which we base APU determinations is submitted for validation and the beginning of the payments that are affected by this data. This timeline creates compressed processing issues for CMS, and compressed timelines for hospitals to review their APU determination decisions.

To ease this burden for both CMS and hospitals, in the CY 2016 OPPS/ASC

[42] The Hospital OQR Quality Measures and Timelines for CY 2016 and Subsequent Payment Determinations. Available at: *https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890446207&blobheader=multipart%2Foctet-stream&blobheadernameI=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DHOQR_CY2016_MsrTmlns_0315.pdf&blobcol=urldata&blobtable=MungoBlobs*.

proposed rule (80 FR 39336 through 39337), we proposed to change the timeframe on which we base APU determinations for the Hospital OQR Program. As stated above, we currently base APU determinations on chart-abstracted data from patient encounter quarter 3 of 2 years prior to the payment determination through patient encounter quarter 2 of the year prior to the payment determination. We proposed to change that timeframe to patient encounter quarter 2 of the 2 years prior to the payment determination through patient encounter quarter 1 of the year prior to the payment determination beginning with the CY 2018 payment determination and for subsequent years. Because the deadline for hospitals to submit chart-abstracted data for quarter 1 is August 1, this will afford both CMS and hospitals additional time to review the APU determinations before they are implemented in January. Current and detailed information about data validation requirements and deadlines is posted on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228758729356*.

To facilitate this process, we proposed to transition to the newly proposed timeframe for the CY 2018 payment determination and subsequent years and use only three quarters of data for determining the CY 2017 payment determination as illustrated in the tables below. However, we noted that data submission deadlines will not be changing.

APU Determination Transition

CY 2016 Payment Determination

[Current State]

Patient encounter quarter	Clinical data submission deadline
Q3 2014 (July 1–Sept. 30) ...	2/1/2015
Q4 2014 (Oct. 1–Dec. 31)	5/1/2015
Q1 2015 (Jan. 1–March 31)	8/1/2015
Q2 2015 (April 1–June 30) ...	11/1/2015

Proposed CY 2017 Payment Determination

[Future state—transition period]

Patient encounter quarter	Clinical data submission deadline
Q3 2015 (July 1–Sept. 30) ...	2/1/2016
Q4 2015 (Oct. 1–Dec. 31)	5/1/2016
Q1 2016 (Jan. 1–March 31)	8/1/2016

Proposed CY 2018 Payment Determination and Subsequent Years

[Future state]

Patient encounter quarter	Clinical data submission deadline
Q2 2016 (April 1–June 30) ...	11/1/2016
Q3 2016 (July 1–Sept. 30) ...	2/1/2017
Q4 2016 (Oct. 1–Dec. 31)	5/1/2017
Q1 2017 (Jan. 1–March 31)	8/1/2017

We refer readers to section XIII.D.6. of the CY 2016 OPPS/ASC proposed rule (80 FR 39339) (inadvertently referenced in the proposed rule as section XIII.D.8.), where we proposed to update our validation processes to also reflect these changes. In addition, we refer readers to section XIII.D.6. of this final rule with comment period where those proposals are finalized.

We invited public comment on our proposals.

Comment: Most commenters supported the proposed change to the timeframe for APU determinations for the Hospital OQR Program, noting that the change will ease the burden on hospitals and allow them additional time to review APU determinations prior to their impact on payments.

Response: We thank the commenters for their support.

Comment: One commenter expressed concern about the inherent 2-year gap between the reporting and payment adjustment periods for claims-based measures because the delay limits the effectiveness of measures as a tool for quality improvement. Alternatively, the commenter encouraged CMS to incorporate more measures based on clinical and registry data.

Response: We thank the commenter for its suggestion. We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112) for a discussion of the general claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years. The timeframe required to finalize claims is about 4 months. Processing and matching of claims takes several months as well. A majority of claims are processed within the full year allowed for timely filing under the OPPS (78 FR 75111). For the current claims-based measures for example, the reporting period is July 1, 2013 through June 30, 2014. Using this timeframe, these data affect the CY 2016 payment determination and are publicly reported in July 2015. Payment adjustments for the Hospital OQR Program are based on the calendar year. Thus, if there is any overlap into another year, the payment has to be applied to the following year. Furthermore, testing and preview time for public reporting require additional time. Therefore, because of the time required for: (1) Claims data to be finalized; (2) data analysis; and (3) the preview period prior to public reporting, operationally, we are not able to close the gap between reporting and payment adjustment. However, we will take these comments into consideration in developing future policy. We may also consider incorporating more measures based on clinical and registry data in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to shift the quarters upon which the Hospital OQR Program APU determinations are based as proposed.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS

The following previously finalized Hospital OQR Program chart-abstracted measures require patient-level data to be submitted for the CY 2018 payment determination and subsequent years:

- OP–1: Median Time to Fibrinolysis;
- OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (NQF #0288);
- OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention (NQF #0290);
- OP–4: Aspirin at Arrival (NQF #0286);
- OP–5: Median Time to ECG (NQF #0289);
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496);
- OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional;
- OP–21: ED—Median Time to Pain Management for Long Bone Fracture (NQF #0662); and
- OP–23: ED—Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 Minutes of Arrival (NQF #0661).

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of these measures for the CY 2014 payment determination and subsequent years.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39337), we did not propose any changes to these policies.

3. Claims-Based Measure Data Requirements

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112) for a discussion of the general claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years. We note that, in section XIII.B.5. of this final rule with comment period, we are removing OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache, beginning with the CY 2017 payment determination and subsequent years. Therefore, for the CY 2017 payment determination and subsequent years, there will be a total of seven claims-based measures:

- OP–8: MRI Lumbar Spine for Low Back Pain (NQF #0514);
- OP–9: Mammography Follow-Up Rates;
- OP–10: Abdomen CT—Use of Contrast Material;
- OP–11: Thorax CT—Use of Contrast Material (NQF #0513);
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (NQF #0669);
- OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT); and
- OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539).

In the CY 2016 OPPS/ASC proposed rule (80 FR 39337), we did not propose any changes to our claims-based measure data submission requirements.

4. Data Submission Requirements for Measure Data Submitted via a Web-Based Tool

a. Previously Finalized Measures

The following Web-based quality measures previously finalized and retained in the Hospital OQR Program require data to be submitted via a Web-based tool (CMS' QualityNet Web site or CDC's NHSN Web site) for the CY 2018 payment determination and subsequent years:

- OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data (via CMS' QualityNet Web site);
- OP–17: Tracking Clinical Results between Visits (via CMS' QualityNet Web site);
- OP–22: ED—Left Without Being Seen (via CMS' QualityNet Web site);
- OP–25: Safe Surgery Checklist Use (via CMS' QualityNet Web site);
- OP–26: Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (via CMS' QualityNet Web site); and
- OP–27: Influenza Vaccination Coverage among Healthcare Personnel (via the CDC NHSN Web site) (NQF #0431).

In addition to these measures, the following chart-abstracted measures previously finalized and retained in the Hospital OQR Program require data to be submitted via the Web-based tool for the CY 2017 payment determination and subsequent years:

- OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); and
- OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #1536).

We note that, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66962 through 66963), we categorized OP–29 and OP–30 as chart-abstracted measures. However, unlike other chart-abstracted measures, OP–29 and OP–30 are submitted through a Web-based tool (CMS' QualityNet Web site).

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115) for a discussion of the requirements for measure data submitted via the CMS QualityNet Web site (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1205442125082*) for the CY 2016 payment determination and subsequent years. In addition, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the requirements for measure data submitted via the CDC NHSN Web site.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39337 through 39338), we proposed to make one change to the data submission requirements for measures submitted via the CMS Web-based tool (QualityNet Web site) beginning with the CY 2017 payment determination. This proposal does not affect OP–27, which is submitted via the CDC NHSN Web site. Previously, we finalized that for measures reported via the CMS Web-based tool, hospitals must report data between July 1 and November 1 of the year prior to the payment determination with respect to the encounter period of January 1 to December 31 of 2 years prior to the payment determination year (78 FR 75112).

Beginning with the CY 2017 payment determination, however, we proposed that hospitals must report data between January 1 and May 15 of the year prior to the payment determination with respect to the encounter period of January 1 to December 31 of 2 years prior to the payment determination year. For example, for the CY 2017 payment determination, the data submission window would be January 1, 2016 through May 15, 2016 for the January 1, 2015 to December 31, 2015 encounter period.

We proposed this new data submission period to be consistent with the data submission deadlines proposed by the ASCQR Program in section XIV.D.3. of the CY 2016 OPPS/ASC proposed rule (80 FR 39345) and to align with the submission deadline for OP–27: Influenza Vaccination Coverage among Healthcare Personnel, reported via the CDC NHSN Web site. We have determined that aligning all Web-based tool data submission deadlines with this May 15 deadline would allow for streamlined hospital submissions, earlier public reporting of that measure data—possibly as soon as October of the data submission year—and reduced administrative burden associated with tracking multiple submission deadlines for these measures.

We invited public comment on our proposal to change the data submission period for measures submitted via the CMS Web-based tool.

Comment: One commenter supported the change in the deadline for the measures that are reported via the CMS Web-based tool (QualityNet Web site) to conform to the deadline for the National Healthcare Safety Network (NHSN) measure reporting, noting that the change will help avoid confusion resulting from multiple reporting dates.

Response: We thank the commenter for its support.

Comment: One commenter expressed concern over competing data submission requirements in the first part of the year with other quality reporting programs as well as the current timing for the release of measurement specifications and updates for OP–26.

Response: While we acknowledge that hospitals will no longer have deadlines spread over a wider period of time for measures submitted via a Web-based tool, we believe that aligning these data submission deadlines will ultimately streamline and reduce administrative burden on hospitals. The release of measure specifications and updated CPT (Current Procedural Terminology) codes for OP–26 was delayed for the CY 2017 payment determination. Ideally, we planned to release CPT codes for the CY 2017 payment determination prior to

the beginning of CY 2015. CPT codes were published in the Specifications Manual 8.0a supplemental document posted on QualityNet on April 1, 2015 and are available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228774592819*. However, we do not anticipate future delays. Future releases of measure specifications and updated codes for OP–26 are anticipated to be made available in November for the subsequent program year. Therefore, we do not believe that hospitals will have difficulty submitting these data by May 15.

Comment: One commenter expressed concerns about ongoing issues with access and functionality of the NHSN Web site for reporting CMS-required measures, adding that CMS should work to ensure that the NHSN has the resources it needs to maintain the proper infrastructure to support the growing role it plays in quality reporting.

Response: We appreciate the commenter's concerns. The NHSN Web site is not maintained by CMS. However, we will share these concerns with the CDC NHSN program.

Comment: One commenter recommended that measures submitted via a Web-based tool be subject to a validation process.

Response: We thank the commenter for the suggestion. Due to limited resources and the time needed to update our systems, at this time, operationally we are not able to validate measures submitted through the Web-based tool. We will take this recommendation into consideration in developing future policy.

After consideration of the public comments we received, we are finalizing our proposal to change the deadline for the measures that are reported via the CMS Web-based tool (QualityNet Web site) to conform to the deadline for the NHSN measure reporting as proposed. The deadline for these measures beginning with the CY 2017 payment determination will be May 15 of the year prior to the payment determination. We note that the ASCQR Program is not finalizing the May 15 deadline in section XIV.D.3. of this final rule with comment period due to commenters' concerns specific to the ASC setting. However, we believe that aligning with the NHSN measure submission deadline serves our goals of streamlining hospital submissions, earlier public reporting of measure data, and reduced administrative burden associated with tracking multiple submission deadlines for these measures.

b. Data Submission Requirements for Web-Based Measure OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) for the CY 2018 Payment Determination and Subsequent Years

As discussed in section XIII.B.6.a. of the CY 2016 OPPS/ASC proposed rule (80 FR 39328 through 39330), we proposed one new Web-based measure for the CY 2018 payment determination and subsequent years, OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822). As discussed in section XIII.B.6.a. of this final rule with comment period, we are finalizing this measure.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39338), for data submission for the CY 2018 payment determination and subsequent years, we proposed that hospitals can either: (1) Report OP–33 beginning with services furnished on January 1, 2016 in accordance with the data submission requirements for measure data submitted via the CMS Web-based tool (QualityNet Web site) as proposed in section XIII.D.4.a. of the CY 2016 OPPS/ASC proposed rule (80 FR 39337 through 39338); or (2) submit an aggregate data file (for example, a file in comma separated value (csv) format or other format as will be specified in the data submission requirements on QualityNet [43]) for this measure through a vendor (via QualityNet infrastructure) containing aggregated data at the hospital level. The aggregate data file would combine all patient information, rather than reporting individual patient level data. The data submission deadline for either method would be May 15. We stated our belief that giving hospitals the option to submit data via vendors would help to streamline processes and procedures. Detailed information about format and submission requirements will be posted on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1191255879384*.

We invited public comment on our proposal.

Comment: Some commenters expressed concern that chart-abstracted quality measures submitted via a CMS Web-based tool impose a heavy administrative burden on providers. One commenter suggested that CMS consider limiting data collection to radiation oncology sites. In addition, this commenter noted that an abundance of data is readily available through Tumor Registry services and suggested that CMS should consider using this source for needed data, rather than implementing another manually abstracted measure.

Response: While we understand the commenters' concerns about the additional administrative burden of reporting data for the new measure, we have weighed any associated burden of reporting this data against the benefit of having data. We believe that OP–33 provides valuable data that will enable us to address concerns associated with unnecessary exposure to radiation and a desire for shorter and less painful treatment options sufficient to justify its adoption into the Hospital OQR Program measure set. In addition, as noted in section XIII.B.6.a. of this final rule with comment period, because unnecessary radiation exposure is such an important topic, we believe that this measure is of sufficiently broad scope and priority to merit inclusion in the Hospital OQR Program and not be limited to only radiation oncology sites. Furthermore, we note that the MAP supported this measure, stating that ''External beam radiation can help provide patients with pain relief . . . this measure has a demonstrated performance gap and would begin to expand cancer care measurement to settings beyond the PPS-exempt cancer hospitals.'' [44]

However, we will take into consideration commenters' suggestions for future rulemaking and may consider using data available through registry services as a source of data for the Hospital OQR Program provided there are no associated costs for data submission or membership.

Comment: One commenter requested clarification regarding whether this is a chart-abstracted measure or if data will be collected by other means. The commenter suggested that, if this measure is a chart-abstracted measure, CMS provide specifications in a manner and format consistent with other chart-abstracted measures including defined initial patient population, acceptable sampling methods, measure algorithms complete with exclusions, and defined alpha data dictionary with abstraction guidelines.

Response: In previous rulemaking (77 FR 68483 and 77 FR 68530), we have referred to measures in which data are submitted via a Web-based tool on a CMS Web site under our quality data

[43] Data Submission Requirements will be available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228775181731*.

[44] *Ibid.*

reporting programs as structural measures (measures concerned with attributes of where care occurs, such as material resources, human resources, and organizational structures).[45] For example, OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data, is a structural measure. However, because measures for which data are submitted via a Web-based tool on a CMS Web site may or may not, in fact, be structural (for example, the Hospital IQR Program chart abstracted, process of care measure PC–01: Elective Delivery Prior to 39 Completed Weeks Gestation (NQF #0469) is submitted via a Web-based tool, but measures quality-of-care rather than structural elements (79 FR 50059)), we clarified our terminology to refer to the mode of data submission as Web-based (78 FR 75112).

In particular, the source of the data for OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases is via charts gathered by chart-abstraction. However, unlike some other chart-abstracted measures in the Hospital OQR Program (OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496) and OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional (76 FR 74481 through 74482)) which utilize either the CART–OPD or third-party vendors for data submission, for OP–33, the data submission method will be via a CMS Web-based Tool (QualityNet Web site). Thus, data must be abstracted from charts, aggregated, and submitted via the QualityNet Web site. Because the data for measures submitted via a Web-based tool are reported in aggregate, measure algorithms complete with exclusions, and defined alpha data dictionary with abstraction guidelines are not currently provided. However, sampling approaches and specifications defining initial patient population are included. We refer readers to our Specifications Manual at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244*.

Comment: One commenter suggested that patient-level data be collected for this measure as opposed to aggregate-level data.

Response: We thank the commenter for its suggestion. At this time, we believe it is less burdensome for hospitals to report aggregate-level data as opposed to patient-level data. In addition, for this particular measure, we are not aware of any quality improvement benefits that collecting patient-level data would provide. If we determine that it would be beneficial to collect patient-level data for this measure, weighed against the associated burden, we may consider proposing to do so in future rulemaking.

Furthermore, as discussed above, we proposed to allow hospitals to submit these data through a vendor because we believed this submission method would further decrease burden. After analyzing this option further, we do not believe that we will be able to accept data operationally using this method for CY 2018 as our IT systems cannot feasibly collect and provide hospitals timely and relevant submission and measure rate feedback. If operationally we are able to accept data through vendors in the future, we may propose to do so through rulemaking.

After consideration of the public comments we received, we are finalizing a modified version of our proposals. We are finalizing that hospitals report OP–33 beginning with services furnished on January 1, 2016 in accordance with the data submission requirements for measure data submitted via the CMS Web based tool (QualityNet Web site) as proposed. However, we are not finalizing our second proposal that hospitals can submit an aggregate data file for this measure through a vendor (via the QualityNet infrastructure) containing aggregated data at the hospital level for reasons discussed above.

c. Proposed Data Submission Requirements for Web-Based Measure OP–34: Emergency Department Transfer Communication (EDTC) Measure for the CY 2019 Payment Determination and Subsequent Years

As discussed in section XIII.B.6.b. of the CY 2016 OPPS/ASC proposed rule (80 FR 39330 through 39334), we proposed one new Web-based measure for the CY 2019 payment determination and subsequent years, OP–34: Emergency Department Transfer Communication (EDTC) Measure (NQF #0291). In the CY 2016 OPPS/ASC proposed rule (80 FR 39338), for data submission for the CY 2019 payment determination and subsequent years, we proposed that hospitals can either: (1) Report OP–34 beginning with January 1, 2017 outpatient encounter dates in accordance with the data submission requirements for measure data submitted via the CMS Web-Based Tool (QualityNet Web site) as proposed in section XIII.D.4.a. of the proposed rule (80 FR 39337 through 39338); or (2) submit an aggregate data file (for example, a file in comma separated value (csv) format or other format as will be specified in the data submission requirements on QualityNet[46]) for this measure through a vendor (via QualityNet infrastructure) containing aggregated data at the hospital level. The aggregate data file shall combine all patient information, rather than reporting individual patient level data. The data submission deadline for either method would be May 15. We stated our belief that also giving hospitals the option to submit data via vendors will help to streamline processes and procedures. Detailed information about format and submission requirements will be posted on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1191255879384*.

We invited public comment on our proposals.

Comment: Many commenters expressed concern that the proposed manner of data submission for this measure would be overly burdensome for hospital abstractors. Several commenters suggested that patient-level data be collected for this measure as opposed to aggregate-level data, specifically through using a CART–OPD module. One commenter recommended that the required data elements be tailored based on the patient's clinical presentation, noting that not all elements are relevant to all individual patients.

Response: As proposed, the EDTC measure does not require hospitals to submit patient data on each of the 27 elements listed. Rather, hospitals would be required to answer yes or no as to whether these clinical indicators were recorded and communicated. Initially, we intended that delaying implementation of this measure until the CY 2019 payment determination would allow facilities additional time to implement the proposed measure (that is, to put the necessary processes and procedures in place), to familiarize themselves with the implementation protocol, tools, and scoring methodology related to the EDTC measure, and to make associated improvements prior to the first reporting deadline. However, in light of commenters' concerns, we acknowledge that delayed implementation may not

[45] Maintz, J. Defining and Classifying Clinical Indicators for Quality Improvement, Inter J Quality Health Care (2003) 15(6), 523–530).

[46] Data Submission Requirements will be available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228775181731*.

sufficiently address these concerns. We refer readers to section XIII.B.6.b. of this final rule with comment period, for our discussion regarding not finalizing the EDTC measure for the CY 2019 payment determination and subsequent years. Regardless, we will take these comments into consideration in developing future policy.

After consideration of the public comments we received, we are not finalizing the data submission methods for the EDTC measure as proposed, because we are not finalizing the EDTC measure, as discussed in section XIII.B.6.b. of this final rule with comment period.

5. Population and Sampling Data Requirements for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our policy that hospitals may voluntarily submit aggregate population and sample size counts for Medicare and non-Medicare encounters for the measure populations for which chart-abstracted data must be submitted.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39338), we did not propose any changes to our population and sampling requirements.

6. Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965) for a discussion of finalized policies regarding our validation requirements. We codified these policies at 42 CFR 419.46(e). Currently, validation is based on four quarters of data (validation quarter 2, validation quarter 3, validation quarter 4, and validation quarter 1) (75 FR 72104 and 79 FR 66965).

As discussed in section XIII.D.1. of the CY 2016 OPPS/ASC proposed rule (80 FR 39336 through 39337), we proposed to make conforming changes to our validation scoring process to reflect proposed changes in the APU determination timeframes. For the CY 2017 payment determination, we proposed that validation be based on three quarters of data (validation quarter 2, validation quarter 3, and validation quarter 4 of 2015). In addition, for the CY 2018 payment determination and subsequent years, we proposed that validation again be based on four quarters of data. However, those quarters are validation quarter 1, validation quarter 2, validation quarter 3, and validation quarter 4. We note that the data submission deadlines will remain unchanged. Detailed information about data validation requirements and deadlines will be posted on QualityNet at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228758729356*.

Finally, we also proposed to make one editorial correction to 42 CFR 419.46(e)(2) to replace the term ''fiscal year'' with the term ''calendar year.''

We invited public comment on our proposals.

We did not receive any public comments on these proposals. Therefore, we are finalizing changes to our validation scoring process to reflect changes in the APU determination timeframes and correcting 42 CFR 419.46(e)(2) to replace the term ''fiscal year'' with the term ''calendar year'' as proposed.

7. Extension or Exemption Process for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances extension or exception process under the Hospital OQR Program.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39339), we proposed to fix a typographical error to correct the name of this process from extension and exception to extension and exemption (inadvertently presented as a process name change). We also proposed to make corresponding typographical error corrections (inadvertently presented as a name change) to the regulation text at 42 CFR 419.46(d). These proposed corrections align the Hospital OQR Program policies with those of the Hospital IQR Program (79 FR 50101) and ASCQR Program (79 FR 66987). We would like to clarify that we are not renaming this process, but rather we are proposing to fix a typographical error to correct the name of this process from extension and exception to extension and exemption. We invited public comment on our proposals.

We did not receive any public comments on these proposals. Therefore, we are finalizing the correction of this typographical error at 42 CFR 419.46(d) to extension and exemption as proposed.

8. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119) for a discussion of our reconsideration and appeals procedures. We codified this process by which participating hospitals may submit requests for reconsideration at 42 CFR 419.46(f). We also codified language at § 419.46(f)(3) stating that a hospital that is dissatisfied with a decision made by CMS on its reconsideration request may file an appeal with the Provider Reimbursement Review Board.

Currently, a hospital must submit a reconsideration request to CMS via the QualityNet Web site no later than the first business day of the month of February of the affected payment year (78 FR 75118 through 75119). In the CY 2016 OPPS/ASC proposed rule (80 FR 39339), we proposed that beginning with the CY 2018 payment determination, hospitals must submit a reconsideration request to CMS via the QualityNet Web site by no later than the first business day on or after March 17 of the affected payment year.

We proposed this new reconsideration submission deadline to be consistent with the proposed ASCQR Program reconsideration submission deadline in section XIV.D.8. of the CY 2016 OPPS/ASC proposed rule (80 FR 39347) and finalized in section XIV.D.8. of this final rule with comment period. As stated above, we believe that aligning deadlines across programs leads to decreased provider burden by streamlining processes and procedures.

We also proposed to make a conforming change to 42 CFR 419.46(f)(1) to reflect the above change in submission deadline from the first business day of the month of February of the affected payment year to the first business day on or after March 17 of the affected payment year.

In addition, we proposed to make an editorial correction to 42 CFR 419.46(f)(1) to replace the term ''fiscal year'' with the term ''calendar year.''

We invited public comment on these proposals.

We did not receive any public comments on these proposals. Therefore, we are finalizing these policies as proposed.

E. Payment Reduction for Hospitals That Fail To Meet the Hospital Outpatient Quality Reporting (OQR) Program Requirements for the CY 2016 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on the measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent payment year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the Internet on the CMS Web site): ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' or ''U.'' We note that we proposed to adopt status indicator ''J2'' for certain comprehensive services furnished to beneficiaries who receive at least 8 hours of observation services in the hospital outpatient department; more information about this status indicator may be found in section XI.A. of this final rule with comment period. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T.'' We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: The wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this final rule with comment period.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2016

In the CY 2016 OPPS/ASC proposed rule (80 FR 39340), we proposed to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2016 annual payment update factor. For the CY 2016 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of $72.478 by the proposed full conversion factor of $73.929. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2016 OPPS, we proposed to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,''

and ''U'' (other than new technology APCs to which we have proposed status indicator assignment of ''S'' and ''T''). We note that, discussed in sections II.A.2.e. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66962), we finalized our proposal to develop status indicator ''J1'' as part of our CY 2015 comprehensive APC policy, and to apply the reporting ratio to the comprehensive APCs. We proposed to continue to exclude services paid under New Technology APCs. We proposed to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also proposed to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we proposed to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.

We invited public comments on these proposals.

We did not receive any public comments on these proposals. Therefore, we are finalizing our proposal to apply the Hospital OQR Program reduction in the manner described above. We also are finalizing our proposal to reflect the CY 2016 OPPS status indicators to which the adjustment would apply. For the CY 2016 OPPS, the final reporting ratio is 0.980, calculated by dividing the final reduced conversion factor of $72.251 by the final full conversion factor of $73.725.

XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIII.A.1. of this final rule with comment period for a general overview of our quality reporting programs.

2. Statutory History of the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

We refer readers to section XIV.K.1. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to section XV.A.3. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75122) for an overview of the regulatory history of the ASCQR Program, and to section XIV.4. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966 through 66987) for subsequently enacted policies.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39340), we proposed to establish a new Subpart H under 42 CFR part 416 to codify many of the administrative policies regarding the ASCQR Program. We proposed to codify our statutory authority for the ASCQR Program in new proposed 42 CFR 416.300(a). In that proposed section, we state that section 1833(i)(2)(D)(iv) and (i)(7) of the Act authorizes the Secretary to implement a revised ASC payment system in a manner so as to provide for a 2.0 percentage point reduction in any annual update for an ASC's failure to report on quality measures in accordance with the Secretary's requirements. In new proposed 42 CFR 416.300(b), we state that this subpart contains the specific requirements and standards for the ASCQR Program. We note that we have previously referenced the statutory basis for the ASCQR Program in 42 CFR part 416, subpart F (42 CFR 416.160(a)) and the 2 percentage point reduction for ASCs that do not meet ASCQR Program requirements at 42 CFR 416.171(a)(2)(iii).

We invited public comment on our proposals to codify the scope and basis for the ASCQR Program.

Comment: Several commenters supported CMS' proposals to codify the scope and basis for the ASCQR Program. Some commenters expressed concerns that codification was not warranted for a program that was still under development and that codification could make program changes in the future more difficult.

Response: We thank the commenters that supported our proposals to codify the scope and basis for the ASCQR Program. While some commenters believe codification could make program changes in the future more difficult, we assure these commenters that future program changes to codified ASCQR Program regulatory text is not more difficult than updating non-codified regulatory policies. Codified regulatory text can be and is modified through the rulemaking process, which for the ASCQR Program, occurs on an annual basis.

After consideration of the public comments we received, we are finalizing our proposals to establish a new Subpart H under 42 CFR part 416 to codify many of the administrative policies regarding the ASCQR Program, and to codify the scope and basis of the ASCQR Program in 42 CFR 416.300.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for ASCQR Program quality measure selection. In the CY 2016 OPPS/ASC proposed rule (80 FR 39341), we did not propose any changes to this policy. However, we received several comments on our priorities for measure selection.

Comment: One commenter stated that outcome reporting is the most direct way to measure clinical improvements in the quality of care provided to patients and expressed support for the ASCQR Program's use of outcome measures.

Response: We thank the commenter for its support. We also believe that outcome measures are important and are a direct way to measure clinical improvement.

2. Policies for Retention and Removal of Quality Measures From the ASCQR Program

We previously adopted a policy that quality measures adopted for an ASCQR Program measure set for a previous payment determination year be retained in the ASCQR Program for measure sets for subsequent payment determination years, except when they are removed, suspended, or replaced as indicated (76 FR 74494 and 74504; 77 FR 68494 through 68495; 78 FR 75122; 79 FR 66967 through 66969). In the CY 2016 OPPS/ASC proposed rule (80 FR 39341), we did not propose any changes to this policy. However, we proposed to codify this policy at proposed new 42 CFR 416.320(a).

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66969), we finalized a process for removing adopted measures. Specifically, in cases where we believe that the continued use of a measure as specified raises patient safety concerns, we will immediately remove a quality measure from the ASCQR Program. In these situations, we will promptly notify ASCs and the public of the removal of the measure and the reasons for its removal through the ASCQR

Program ListServ and the ASCQR Program QualityNet Web site. We will confirm the removal of the measure due to patient safety concerns in the next ASCQR Program rulemaking. In the CY 2016 OPPS/ASC proposed rule (80 FR 39341), we did not propose any changes to this process. However, we proposed to codify this process at proposed new 42 CFR 416.320(b).

As stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66968), unless a measure as specified raises patient safety concerns, we will use the regular rulemaking process to remove, suspend, or replace quality measures in the ASCQR Program to allow for public comment. In these situations, we will use the following criteria to determine whether to remove a measure from the ASCQR Program: (1) Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures); (2) availability of alternative measures with a stronger relationship to patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. The benefits of removing a measure from the ASCQR Program will be assessed on a case-by case basis. We intend for all the criteria to apply to all measures to the extent possible. A measure will not be removed solely on the basis of meeting any specific criterion.

As provided above, one of the criteria to determine whether to remove a measure from the ASCQR Program is when it is ''topped-out'' (that is, when measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made). For purposes of the ASCQR Program, a measure is considered to be topped-out when it meets both of the following criteria: (1) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an ASC's measure is within two times the standard error of the full data set); and (2) a truncated coefficient of variation less than or equal to 0.10 (79 FR 66968 through 66969). In the CY 2016 OPPS/ASC proposed rule (80 FR 39341), we did not propose any changes to this process for measure removal, suspension, or replacement. However, we proposed to codify this measure removal criterion at proposed new 42 CFR 416.320(c).

We invited public comment on our proposals to codify these existing policies.

We did not receive any public comments on the proposals to codify our policies for the retention and removal of quality measures from the ASCQR Program and, therefore, are finalizing them as proposed in 42 CFR 416.320.

3. ASCQR Program Quality Measures Adopted in Previous Rulemaking

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we implemented the ASCQR Program effective with the CY 2014 payment determination. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74496 through 74511), we adopted five claims-based measures for the CY 2014 payment determination and subsequent years, two measures with data submission directly to CMS via an online Web-based tool for the CY 2015 payment determination and subsequent years, and one process of care, preventive service measure submitted via an online, Web-based tool to CDC's National Health Safety Network (NHSN) for the CY 2016 payment determination and subsequent years. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75130), we adopted three chart-abstracted measures with data submission to CMS via an online Web-based tool for the CY 2016 payment determination and subsequent years. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985), we excluded one of these measures, ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536), from the CY 2016 payment determination measure set and allowed for voluntary data collection and reporting for the CY 2017 payment determination and subsequent years. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66970 through 66979), we adopted one additional claims-based measure for the CY 2018 payment determination and subsequent years.

Most of the quality measures adopted for use by the ASCQR Program are NQF-endorsed, although such endorsement is not an ASCQR Program requirement for adopting a measure. Two measures previously adopted for the ASCQR Program are not currently NQF-endorsed and were not endorsed when adopted for the program (ASC–6: Safe Surgery Checklist Use and ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures). Further, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) was not NQF-endorsed at the time it was adopted for the ASCQR Program, but now is NQF-endorsed. Recently, NQF removed endorsement from ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing (formerly NQF #0264).[47] We continue to believe that ASC–5 is appropriate for measurement of the quality of care furnished by ASCs and should be retained by the ASCQR Program; the measure is supported by clinical evidence[48] and the measure steward will be continuing to support the measure.[49] We will continue to evaluate the appropriateness of this measure for the ASCQR Program as we do other measures.

The previously finalized measure set for the ASCQR Program CY 2017 payment determination and subsequent years is listed below.

ASCQR Program Measure Set Previously Finalized for the CY 2017 Payment Determination and Subsequent Years

ASC #	NQF #	Measure name
ASC–1	0263	Patient Burn.

[47] Available at: *http://www.qualityforum.org/Publications/2015/02/NQF-Endorsed_Measures_for_Surgical_Procedures.aspx.*

[48] Burke J. Maximizing appropriate antibiotic prophylaxis for surgical patients: an update from LDS Hospital, Salt Lake City. Clin Infect Dis. 2001;33(Suppl 2):S78–83.

[49] Available at: *http://ascquality.org/documents/ASC_QC_ImplementationGuide_3.0_January_2015.pdf.*

ASCQR PROGRAM MEASURE SET PREVIOUSLY FINALIZED FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

ASC #	NQF #	Measure name
ASC–2	0266	Patient Fall.
ASC–3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4	0265	All-Cause Hospital Transfer/Admission.*
ASC–5	N/A	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC–6	N/A	Safe Surgery Checklist Use.
ASC–7	N/A	ASC Facility Volume Data on Selected ASC Surgical Procedures Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754.*
ASC–8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
ASC–9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
ASC–11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**

* This measure was previously titled ''Hospital Transfer/Admission.'' According to the NQF Web site, the title was changed to better reflect what is being measured. We have updated the title of this measure to align it with the NQF update to the title.
** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

The previously finalized measure set for the ASCQR Program CY 2018 payment determination and subsequent years is listed below.

ASCQR PROGRAM MEASURE SET PREVIOUSLY FINALIZED FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

ASC #	NQF #	Measure name
ASC–1	0263	Patient Burn.
ASC–2	0266	Patient Fall.
ASC–3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant.
ASC–4	0265	All-Cause Hospital Transfer/Admission.*
ASC–5	N/A	Prophylactic Intravenous (IV) Antibiotic Timing.
ASC–6	N/A	Safe Surgery Checklist Use.
ASC–7	N/A	ASC Facility Volume Data on Selected ASC Surgical Procedures. Procedure categories and corresponding HCPCS codes are located at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754.*
ASC–8	0431	Influenza Vaccination Coverage among Healthcare Personnel.
ASC–9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
ASC–10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.
ASC–11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.**
ASC–12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.***

* This measure was previously titled ''Hospital Transfer/Admission.'' According to the NQF Web site, the title was changed to better reflect what is being measured. We have updated the title of this measure to align it with the NQF update to the title.
** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).
*** New measure finalized for the CY 2018 payment determination and subsequent years in the CY 2015 OPPS/ASC final rule with comment period (79 FY 66970 through 66979).

Several commenters expressed views on previously adopted ASCQR Program measures.

Comment: Some commenters supported previously adopted measures, and some commenters recommended changing measure specifications for some measures. Other commenters requested that CMS consider removing previously added measures from the ASCQR Program, specifically ASC–5, ASC–9, ASC–10, and ASC–12, because these measures are no longer NQF-endorsed, and the commenters believed that they are inappropriate for ASCs due to concerns about measure reliability or validity, or are too burdensome for ASCs. Some of these commenters expressed ongoing concerns about the ASC–12 measure. They requested that CMS conduct additional analyses of the reliability and validity of the measure as specified for the ASCQR Program and implemented during the dry run, and provide those results to the ASC community.

Response: We thank the commenters for their suggestions. At this time, we have not made any proposals to remove or modify any of the measures suggested by commenters. Further, there is no evidence that continued use of the measures as specified raises patient

safety concerns that would require immediate removal of the measures based on the process we finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66969). However, we will take these suggestions into consideration in future years using our measure removal criteria. We continue to believe there is value in collecting and reporting these measures. We thank commenters for these suggestions regarding the current ASCQR Program measures and will share them with the measure stewards.

4. ASCQR Program Quality Measures for the CY 2018 Payment Determination and Subsequent Years

In the CY 2016 OPPS/ASC proposed rule (80 FR 39343), we did not propose to adopt any additional measures for the ASCQR Program for the CY 2018 payment determination and subsequent years.

5. ASCQR Program Measures for Future Consideration

In the CY 2013 OPPS/ASC final rule with comment period, we set forth our approach to future measure selection and development (77 FR 68493 through 68494). We seek to develop a comprehensive set of quality measures to be available for widespread use for making informed decisions and quality improvement in the ASC setting (77 FR 68496). We also seek to align these quality measures with the National Quality Strategy (NQS), the CMS Strategic Plan (which includes the CMS Quality Strategy), and our other quality reporting and VBP programs, as appropriate. Accordingly, as we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66979), in considering future ASCQR Program measures, we are focusing on the following NQS and CMS Quality Strategy measure domains: Make care safer; strengthen person and family engagement; promote effective communication and coordination of care; promote effective prevention and treatment; work with communities to promote best practices of healthy living; and make care affordable. We did not propose any changes to this policy. However, we received one comment on our priorities for measure selection.

Comment: One commenter supported alignment of the ASCQR Program with the NQS, the CMS Strategic Plan, and other quality reporting and value-based purchasing programs. The commenter also recommended that CMS focus on the NQS and CMS Quality Strategy measure domains of: (1) Make care safer, (2) strengthen person and family engagement, and (3) promote effective communication and coordination of care, because these domains fall within the scope of an ASC's accountability. This commenter asserted that the remaining three domains (promote effective prevention and treatment; work with communities to promote best practices of healthy living; and make care affordable) are more the responsibility of the primary care provider, not ASCs.

Response: We thank the commenter for these suggestions. We seek to align our programs as much as possible, and we believe that it is important to have measures that encompass each of the NQS priority areas. We have and will continue to consider whether our current and future measures are actionable by ASCs.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39343), we also invited public comment on two measures developed by the ASC Quality Collaboration for inclusion in the ASCQR Program in the future.

a. Normothermia Outcome

The first measure under consideration is the Normothermia Outcome measure which assesses the percentage of patients having surgical procedures under general or neuraxial anesthesia of 60 minutes or more in duration who are normothermic within 15 minutes of arrival in the post-anesthesia care unit. This issue is of interest to the ASCQR Program because impairment of thermoregulatory control due to anesthesia may result in perioperative hypothermia. Perioperative hypothermia is associated with numerous adverse outcomes, including: Cardiac complications;[50] surgical site infections;[51] impaired coagulation;[52] and colligation of drug effects.[53] When intraoperative normothermia is maintained, patients experience fewer adverse outcomes and their overall care costs are lower.[54] This measure is also of interest to the ASCQR Program because many surgical procedures performed at ASCs involve anesthesia; therefore, it is an outcome measure of significance for ASCs.[55] It also addresses the MAP-identified priority measure area for the ASCQR Program of anesthesia-related complications.[56]

The specifications for this measure for the ASC setting can be found at: *http://ascquality.org/documents/ASC_QC_ImplementationGuide_3.0_January_2015.pdf.*

b. Unplanned Anterior Vitrectomy

The second measure under consideration for future payment determination years is the Unplanned Anterior Vitrectomy measure. This measure assesses the percentage of cataract surgery patients who have an unplanned anterior vitrectomy (removal of the vitreous present in the anterior chamber of the eye). Cataracts are a leading cause of blindness in the United States, with 24.4 million cases in 2010.[57] Each year, approximately 1.5 million patients undergo cataract surgery to improve their vision.[58] An unplanned anterior vitrectomy is performed when vitreous inadvertently prolapses into the anterior segment of the eye during cataract surgery. While unplanned anterior vitrectomy rates are relatively low, this procedure complication may result in poor visual outcomes and other complications, including retinal detachment.[59] This measure is of interest to the ASCQR Program because cataract surgery is a procedure commonly performed at ASCs; therefore, it is an outcome measure of significance for ASCs.[60] It also addresses the MAP-identified priority measure area of procedure

[50] Frank SM, Fleisher LA, Breslow MJ, *et al.* Perioperative maintenance of normothermia reduces the incidence of morbid cardiac events: A randomized clinical trial. *JAMA.* 1997;277(14): 1127–1134.

[51] Kurz A, Sessler DI, Lenhardt R. Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization: Study of wound infection and temperature group. *N Engl J Med.* 1996;334(19): 1209–1215.

[52] Rajagopalan S, Mascha E, Na J, Sessler DI. The effects of mild hypothermia on blood loss and transfusion requirements during total hip arthroplasty. *Lancet.* 1996;347(8997):289–292.

[53] Kurz A. Physiology of thermoregulation. *Best Pract Res Clin Anaesthesiol.*2008;22(4):627–644.

[54] Mahoney CB, Odom J. Maintaining intraoperative normothermia: A meta-analysis of outcomes with costs. AANA Journal. 1999;67(2): 155–164.

[55] MAP Hospital Workgroup Transcript.

[56] National Quality Forum. MAP 2015 *Considerations for Selection of Measures for Federal Programs: Hospitals.* Rep. National Quality Forum, Feb. 2015. Available at: *http://www.qualityforum.org/Publications/2015/02/MAP_Hospital_Programmatic_Deliverable_-_Final_Report.aspx.*

[57] National Eye Institute. ''Cataracts.'' *Cataracts.* National Institutes of Health, n.d. Available at: *https://www.nei.nih.gov/eyedata/cataract#1.*

[58] ''Measure Application Partnership Hospital Workgroup'', National Quality Forum. Dec. 2014, Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

[59] Chen M, Lamattina KC, Patrianakos T, Dwarakanathan S. Complication rate of posterior capsule rupture with vitreous loss during phacoemulsification at a Hawaiian cataract surgical center: A clinical audit. *Clin Ophthamlol.* 2014 Feb 5;8:375–378.

[60] ''Measure Application Partnership Hospital Workgroup'', National Quality Forum. Dec. 2014, Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369.*

complications for the ASCQR Program.[61]

The specifications for this measure for the ASC setting can be found at: *http://ascquality.org/documents/ASC_QC_ImplementationGuide_3.0_January_2015.pdf*.

Both measures have received conditional support from the MAP, pending the completion of reliability testing and NQF endorsement. A summary of the MAP recommendations can be found at: *http://www.qualityforum.org/setting_priorities/partnership/measure_applications_partnership.aspx* under the title ''Spreadsheet of MAP 2015 Final Recommendations.''

We invited public comment on the possible inclusion of these measures in the ASCQR Program measure set in the future. As stated previously, we did not propose to adopt any new measures for the CY 2018 payment determination or subsequent years in the CY 2016 OPPS/ASC proposed rule.

Comment: Many commenters supported future adoption of the Normothermia Outcome measure in the ASCQR Program, because it would help promote quality care in ASCs and because public reporting of these data would serve as a key measure to assist patients, policymakers, and researchers in comparing quality among ASCs. One commenter noted that the measure's reliability testing in the ASC setting was very strong, and that the measure is already in use in the ASC Quality Collaboration's quarterly public reporting program, which is a voluntary reporting program that collects data from ASCs and provides quarterly aggregated performance data for ASC facility-level quality measures developed by the ASC Quality Collaboration. One commenter recommended that CMS adopt the Normothermia Outcome measure in the future and retire the measure once there is validation of sustained normothermia among ASCs. Another commenter noted that the NQF's 2015 Surgical Standing Committee recently approved a change in the definition of normothermia from 96.8 degrees Fahrenheit (36 degrees Celsius) to 95.9 degrees Fahrenheit (35.5 degrees Celsius) and urged CMS to ensure that any future measure on normothermia adopt this updated definition in order to maintain uniformity in anesthesia quality improvement efforts across programs.

A number of commenters did not support future adoption of the Normothermia Outcome measure for the ASCQR Program. The commenters asserted that the measure implementation guide states there is no evidence of a performance gap in hypothermia for ASC providers. Other commenters requested that CMS provide additional information regarding the gap or variation in care that justifies future adoption of the Normothermia Outcome measure, the risk adjustment methodology used under the measure, and the measure's reliability testing data. The commenters recommended CMS perform reliability and field testing of the Normothermia Outcome measure, submit the measure to NQF for endorsement, and resubmit the measure to the MAP for review before proposing to add this measure to the ASCQR Program measure set.

Some commenters requested additional information regarding the Normothermia Outcome measure. One commenter requested additional information regarding the volume of postoperative hypothermia events captured under the Normothermia Outcome measure, how CMS intends to collect data for the measure, and how CMS will calculate this measure.

Response: We thank the commenters for sharing their comments and recommendations regarding future inclusion of the Normothermia Outcome measure in the ASCQR Program. We will take these suggestions and concerns into consideration if we propose to adopt the Normothermia Outcome measure in the future.

Comment: The majority of commenters supported future adoption of the Unplanned Anterior Vitrectomy measure for the ASCQR Program. One commenter noted that the measure's reliability testing in the ASC setting was very strong, and that the measure is already in use in the ASC Quality Collaboration's public reporting program. The commenter further stated the measure does not require NQF endorsement because the requirement of the ASCQR Program to reflect consensus among affected parties has been met through the measure developer's collaboration with the ASC industry. Some commenters recommended CMS perform reliability and field testing of the Unplanned Anterior Vitrectomy measure, submit the measure to NQF for endorsement, and resubmit the measure to the MAP for review before proposing to add this measure to the ASCQR Program measure set. One commenter requested additional information regarding the volume of unplanned anterior vitrectomies captured under the Unplanned Anterior Vitrectomy measure, how CMS intends to collect data on the measures, and how CMS will calculate this measure.

Response: We thank the commenters for their comments and recommendations regarding future inclusion of the Unplanned Anterior Vitrectomy measure in the ASCQR Program. We will take these comments and recommendations into consideration if we propose to adopt the Unplanned Anterior Vitrectomy measure for the ASCQR Program in the future.

Comment: One commenter recommended that CMS consider the measure topic of Equipment Reprocessing (for patient safety, high-level disinfection and sterilization, with a particular emphasis on endoscope reprocessing) for the ASCQR Program.

Response: We thank the commenter for this recommendation and will consider this measure topic for the ASCQR Program in future years.

Comment: One commenter recommended CMS consider including additional quality measures covering vaccine preventable disease for the ASCQR Program.

Response: We thank the commenter for this recommendation. We agree that quality measures covering vaccine preventable disease are important; the ASCQR Program currently contains one measure on influenza immunizations, ASC–8: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431). We will consider adopting additional measures in this measure topic for the ASCQR Program in future years.

Comment: One commenter expressed concern about the MAP, specifically the public comment process and the practice of submitting measure concepts for consideration.

Response: We thank the commenter for expressing this concern. As we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66980) in response to similar concerns, we invite the commenter to submit its MAP-specific concerns directly to the NQF, which convenes the MAP.

Comment: One commenter recommended that, to the extent feasible, CMS adopt measures that can be used for both the Hospital OQR and ASCQR Programs.

Response: We thank the commenter for the recommendation to adopt measures that are applicable to both the Hospital OQR and ASCQR Programs. We agree that because outpatient surgical services are provided in both

[61] National Quality Forum. *MAP 2015 Considerations for Selection of Measures for Federal Programs: Hospitals*. Rep. National Quality Forum, Feb. 2015. Available at: *http://www.qualityforum.org/Publications/2015/02/MAP_Hospital_Programmatic_Deliverable_-_Final_Report.aspx*.

settings, measures that apply to both settings should be adopted to the extent feasible. We note that we have adopted the following for both settings: ASC–6/OP–25 Safe Surgery Checklist Use; ASC–7/OP–26 ASC/Hospital Outpatient Volume on Selected ASC/Outpatient Surgical Procedures; ASC–8/OP–27 Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431); ASC–9/OP–29 Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); ASC–10/OP–30 Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF #0659); ASC–11/OP–31 Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536); and ASC–12/OP–32 Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539).

Comment: One commenter stated that it would welcome opportunities to work with CMS to explore alternative reporting options for measures that cut across CMS quality reporting programs, particularly measures that are included in both the ASCQR Program and PQRS.

Response: We thank the commenter for the offer to collaborate with us on alternative reporting options. We will continue to look for opportunities to work with ASC community stakeholders to continuously improve the ASCQR Program, including alternate reporting options for cross-cutting measures.

Comment: One commenter expressed support for the establishment of a VBP program for ASCs, and recommended that the Secretary seek legislative authority from Congress to implement an ASC VBP program. The commenter noted that the ASCQR Program could lay the foundation for a future ASC VBP program if modifications were made to the existing measure set.

Response: We thank the commenter for these recommendations.

6. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74513 through 74514), where we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures, including the subregulatory process for making updates to the adopted measures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68496 through 68497), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66981), we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy, including the processes for addressing nonsubstantive and substantive changes to adopted measures.

We maintain technical specifications for previously adopted ASCQR Program measures in the ASCQR Program Measures Specifications Manual. These specifications are updated as we continue to develop the ASCQR Program. We maintain the technical specifications for the measures adopted for the ASCQR Program by updating this Specifications Manual. The versions of the Specifications Manual that contain specifications for the previously adopted measures can be found on the QualityNet Web site at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754*.

As stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131), we will determine what constitutes a substantive versus a nonsubstantive change to a measure's specifications on a case-by-case basis. If we determine that a change to a measure previously adopted in the ASCQR Program is nonsubstantive, we will use a subregulatory process to revise the ASCQR Program Specifications Manual so that it clearly identifies the updates to that measure and provide links to where additional information on the changes can be found. We will provide notification of the measure specification update on the QualityNet Web site and in the ASCQR Program Specifications Manual, and will provide sufficient lead time for ASCs to implement the revisions where changes to the data collection systems are necessary. We will continue to use rulemaking to adopt substantive updates to measures in the ASCQR Program. In the CY 2016 OPPS/ASC proposed rule (80 FR 39343 through 39344), we did not propose any changes to these policies. However, we proposed to codify these policies at proposed new 42 CFR 416.325.

We previously finalized a policy to post technical specifications on a CMS Web site in addition to posting this information on QualityNet because we believed doing so would increase ASC awareness of our technical specifications in our outreach and education (76 FR 74514). However, we now believe that posting technical specifications on QualityNet alone is preferable to prevent possible inconsistencies associated with accessing multiple sites for information and to reduce burden. We believe that posting this information on a single site is a more efficient process that still provides ASCs with complete access to the technical specifications for ASCQR Program purposes. Therefore, we are not posting the technical specifications on a CMS Web site but will continue to post this information on QualityNet for the ASCQR Program.

We invited public comment on our proposal to codify our existing policies.

Comment: One commenter expressed concern that, moving forward, CMS will only post technical specifications on the QualityNet Web site, asserted that many ASCs are more comfortable accessing the CMS Web site, and, therefore, recommended that CMS continue to post information about the ASCQR Program technical specifications on both the CMS and QualityNet Web sites.

Response: We thank the commenter for this recommendation. However, we believe that ASCs should be comfortable accessing the QualityNet Web site because they currently use the QualityNet Web site's secure portal to submit data under the ASCQR Program. Furthermore, we believe the commenter's concerns regarding the use of a single Web site to post technical specifications are outweighed by the benefits—providing this information on a single site is a more efficient process; it could prevent potential inconsistencies associated with accessing multiple sites for information; and it reduces burden.

After consideration of the public comments we received, we are not displaying the technical specifications for the ASCQR Program on the CMS Web site but will continue to display the technical specifications for the ASCQR Program on the QualityNet Web site. In addition, we are finalizing our proposal to codify our policies regarding the maintenance of technical specifications for the ASCQR Program at 42 CFR 416.325.

7. Public Reporting of ASCQR Program Data

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS Web site after providing an ASC an opportunity to review the data to be made public. In the CY 2016 OPPS/ASC proposed rule (80 FR 39344), we proposed to codify this existing policy at proposed new 42 CFR 416.315.

We also finalized a policy to display these data at the CMS Certification Number (CCN) level in the CY 2012

OPPS/ASC final rule with comment period (76 FR 74514 through 74515). However, in the CY 2016 OPPS/ASC proposed rule (80 FR 39344), we proposed to change this policy. ASCs typically report quality measure data to CMS using their National Provider Identifier (NPI), which is their billing identifier on the CMS–1500 form as non-institutional billers. Further, payment determinations are made by NPI. Because an ASC CCN can have multiple NPIs, publication of data by CCN can aggregate data for multiple facilities, thereby reducing identification of individual facility information. To allow for identification of individual facility information, beginning with any public reporting that occurs on or after January 1, 2016, we proposed to display the data by the NPI when data are submitted by the NPI. We believe identifying data by the NPI would enable consumers to make more informed decisions about their care because the public would be able to distinguish between ASCs. Further, it would help ASCs to better understand their performance on measures collected under the ASCQR Program. We also proposed, beginning with any public reporting that occurs on or after January 1, 2016, to display data by the CCN when data are submitted by the CCN. When data are submitted by the CCN, all NPIs associated with the CCN would be assigned the CCN's value because we would not be able to parse the data by the NPI. For example, in the case of ASC–8: Influenza Vaccination Coverage among Healthcare Personnel measure (NQF #0431), the one ASCQR Program measure where data are submitted by the CCN as this is the identifier used by the CDC's NHSN Healthcare Personnel Vaccination Module, we would not be able to parse the data by the NPI. Thus, the data displayed for ASC–8 would be the same for all of the NPIs under the same CCN. We proposed to codify this proposal at proposed new 42 CFR 416.315.

We invited public comment on our proposal to display data by the NPI if the data are submitted by the NPI and to display data by the CCN if the data are submitted by the CCN beginning with any public reporting that occurs on or after January 1, 2016, and to codify this policy and our existing policies.

Comment: Some commenters did not support CMS' proposal to assign all NPIs associated with a CCN the CCN's value when the data are submitted by CCN for that reporting. These commenters asserted that doing so is not statistically valid and may misrepresent an individual ASC's performance. The commenters recommended that CMS instead publicly report data using the identifier it is reported under; that is, by NPI when the data are submitted by NPI, and by CCN when data are submitted by CCN.

Response: We thank the commenters for their recommendation. We recognize that attributing data reported under a CCN to all NPIs associated with that CCN has the potential to misrepresent ASC's performance on a quality measure. For this reason, we are not finalizing the proposal to assign all NPIs associated with a CCN the CCN's value for reporting when data are submitted by CCN. Instead, as proposed, beginning with any public reporting that occurs on or after January 1, 2016, we will publicly report data under the identifier used to submit that data; that is, reporting by NPI when the data are submitted by NPI, and reporting by CCN when the data are submitted by CCN. However, we are not finalizing our proposal to assign the CCN's value to all NPIs associated with that CCN when data are submitted by CCN.

Comment: Some commenters supported allowing ASCs to report data for the ASCQR Program by either their NPI or CCN, depending upon the collection requirements of the measure.

Response: We thank the commenters for their support. However, we note that our proposal was to attribute data submitted at the CCN level to all NPIs associated with that CCN, not just to report data by CCN when the data are submitted by CCN. As discussed above, we are not finalizing this proposed policy because of the potential unintended negative effects of attributing the CCN's data to all NPIs associated with that CCN.

Comment: One commenter recommended that CMS work toward collecting all facility data under the facility NPI because reporting at this level would ensure that consumers can distinguish performance at the individual facility level and thereby better inform consumer decision-making. Specifically, the commenter recommended that CMS work with the CDC to modify the reporting tools for ASC–8, the only current ASCQR Program measure collected by CCN, to allow facilities to report data using their NPI for future payment determinations. The commenter further stated that, because the public reporting policy should be revised to allow ASCs to report all data by NPI, the current public reporting policy should not be codified at this time.

Response: We thank the commenter for the recommendation to modify ASC–8 to allow facilities to report data for this measure using their NPI in the future. We will take this recommendation into consideration as we continue to refine the public reporting policies for the ASCQR Program so that data accuracy and transparency are maximized to the extent possible.

We also thank the commenter for sharing its concerns regarding the codification of our current public reporting policy when changes may be made to this policy in future rulemaking. Again, we assure the commenter that making future program changes to codified ASCQR Program regulatory text is not more difficult. Codified regulatory text can be and is modified through the rulemaking process, which, for the ASCQR Program, occurs on an annual basis. In addition, for some users, codified regulatory text is both easier to access and easier to understand than programmatic policies found only in preamble text. Thus, we believe it is appropriate to codify our currently public reporting policy at this time and incorporate any future changes to this policy after they are finalized through notice-and-comment rulemaking.

Comment: Commenters encouraged CMS to make ASC data publicly available as soon as possible to help patients, policymakers, and researchers compare quality among facilities. The commenters also urged CMS to ensure that the public reporting Web site for ASCQR Program data is developed for use by the average consumer or patients.

Response: We thank the commenters for these comments. We agree that it is important to make data collected under the ASCQR Program publicly available and are working to do so. In addition, we are working to ensure that the data publicly reported for the ASCQR Program will be presented in a format that is easily understood by consumers and patients and is user-friendly.

Comment: One commenter urged CMS to further specify its policies regarding the public reporting of ASCQR Program data through future rulemaking. Specifically, the commenter recommended that CMS provide ASCs with more notice of the preview period; provide ASCs with more time in which to review their data; and establish a means either for ASCs to correct erroneous data or for CMS to suppress clearly incorrect data. In the absence of a correction or suppression process, this commenter further recommended that CMS make preview reports available to ASCs well in advance of the withdrawal deadline for the ASCQR Program so that an ASC with erroneous data has sufficient opportunity to determine if it would like to withdraw from the

ASCQR Program, because, it stated, this would be its only recourse to avoid publication of incorrect quality data.

Response: We thank the commenters for their comments and recommendations, and will take these recommendations into consideration during future policy development efforts. We note that ASCs can edit any measure data submitted via an online data submission tool until the data submission deadline for that measure. In addition, although we understand that ASCs cannot currently change claims-based data submitted for the ASCQR Program once submitted, or edit measure quality data submitted via an online data submission tool after the submission deadline for the measure has passed, we believe it is the responsibility of each ASC to ensure that its data, as reported to CMS, are accurate. We will continue looking for ways to address any data inaccuracies in the future. Regarding the length of time available to preview data prior to public release, we agree that sufficient time to do so is important and will consider proposals for this in future rulemaking.

Comment: One commenter urged CMS to maintain its established practice of reporting data as ''Not Available'' for ASCs with denominators greater than 0 and less than 11 for a given measure when publicly reporting data for the ASCQR Program.

Response: We thank the commenter for its comment. We note that, consistent with the CMS Policy for Privacy Act Implementation & Breach Notification, 2007, CMS, statistical, aggregate, or summarized information created as a result of analysis conducted using identifiable CMS data obtained under CMS-approved projects/studies may only be disclosed if the data are not individual-specific and the data are aggregated to a level where no data cells contain 10 or fewer individuals (*https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/SystemLifecycleFramework/downloads/privacypolicy.pdf*). Thus, when case numbers are at issue, we will publicly report data only for those measures for which an ASC had a numerator greater than or equal to 11. However, this data reporting requirement does not apply to data expressed as a rate or percentage.

After consideration of the public comments we received, we are finalizing our proposal to publicly display data by the NPI when the data are submitted by the NPI and to publicly display data by the CCN when the data are submitted by the CCN, but are not finalizing our proposal to attribute data submitted by the CCN to all NPIs associated with the CCN. We are finalizing our proposal to codify the CCN and NPI display policy at 42 CFR 416.315, with the modification discussed above. We also are finalizing without modification our proposal to codify our existing policies at 42 CFR 416.315.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133), we finalized our requirements regarding QualityNet accounts and QualityNet security administrators under the ASCQR Program for the CY 2016 payment determination and subsequent years. Under these requirements, ASCs must maintain a QualityNet account in order to submit quality measure data to the QualityNet Web site for all Web-based measures submitted via a CMS online data submission tool. Further, a QualityNet security administrator is necessary to set up a QualityNet user account to be able to enter data via an online tool located on the QualityNet Web site. The registration process for the QualityNet security administrator is described on the QualityNet Web site. We recommend that ASCs submit documentation required for the creation of a QualityNet Account at least 4 to 6 weeks prior to any quality measure data submission deadline for the ASCQR Program. The QualityNet security administrator typically fulfills a variety of tasks related to quality reporting for ASCs, such as creating, approving, editing, and terminating QualityNet user accounts, and monitoring QualityNet usage to maintain proper security and confidentiality. In the CY 2016 OPPS/ASC proposed rule (80 FR 39344), we did not propose any changes to these policies. We proposed to codify these existing requirements at proposed new 42 CFR 416.310(c)(1)(i).

We invited public comment on our proposal to codify our existing requirements.

We did not receive any public comments on the proposal to codify the administrative requirements regarding maintenance of a QualityNet account and security administrator for the ASCQR Program and, therefore, are finalizing it as proposed at 42 CFR 416.310(c)(1)(i).

2. Requirements Regarding Participation Status

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53639 through 53640), we finalized our participation policy. Under this policy, an ASC is considered as participating in the ASCQR Program once the ASC submits any quality measure data to the ASCQR Program. Further, once an ASC submits any quality measure data and is considered participating in the ASCQR Program, an ASC would still be considered participating in the ASCQR Program, regardless of whether the ASC continues to submit quality measure data, unless the ASC withdraws from the ASCQR Program.

An ASC may withdraw from the ASCQR Program by submitting to CMS a withdrawal of participation form that can be found in the secure portion of the QualityNet Web site, indicating that it is withdrawing and the initial payment determination year to which the withdrawal applies. Once the ASC has withdrawn, an ASC will incur a 2.0 percentage point reduction in its ASC annual payment update for that payment determination year and any subsequent payment determinations in which it is withdrawn.

An ASC will be considered as rejoining the ASCQR Program if it begins to submit any quality measure data again to the ASCQR Program. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135), for the CY 2016 payment determination and subsequent years, we finalized our policies that all program requirements would apply to all ASCs designated as open in the Certification and Survey Provider Enhanced Reporting (CASPER) system for at least 4 months prior to the beginning of data collection for a payment determination and that an ASC may withdraw from the ASCQR Program any time up to and including August 31 of the year preceding a payment determination. For example, an ASC can withdraw from the ASCQR Program at any time up to and including August 31, 2016 for the CY 2017 payment determination. In the CY 2016 OPPS/ASC proposed rule (80 FR 39344 through 39345), we did not propose any changes to these policies. However, we proposed to codify these existing requirements at proposed new 42 CFR 416.305(a) and (b).

As finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135 through 75137), for the CY 2016 payment determination and subsequent years, ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) per year during an annual reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent annual reporting period for that subsequent payment determination year. For example, an

ASC with fewer than 240 Medicare claims in CY 2016 (payment determination year 2018) would not be required to participate in the ASCQR Program in CY 2017 (payment determination year 2019). We did not propose any changes to these existing requirements. However, we proposed to codify these existing requirements at proposed new 42 CFR 416.305(c).

We invited public comment on our proposal to codify our existing policies.

We did not receive any public comments on the proposals to codify the requirements regarding participation status for the ASCQR Program and, therefore, are finalizing them as proposed at 42 CFR 416.305(a), (b), and (c).

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

We received public comments on alternate methods for submitting data for the ASCQR Program.

Comment: One commenter recommended that CMS allow ASCs to meet the requirements of the ASCQR Program using registry-based reporting, noting that using a registry is an option under the PQRS and that other registries are already in existence. The commenter also recommended that ASCs should have the option of submitting quality data to CMS through an EHR-based reporting mechanism, as there are ASCs that have implemented this technology and could benefit from this option.

Response: We thank the commenter for these suggestions, and agree that it could reduce burden to have a registry-based mechanism for data submission because a registry would enable ASCs to contract with a vendor that would collect and report quality data on the ASC's behalf. We have not proposed a registry-based reporting option because, currently, there is not a registry in place that is collecting information on the quality measures that we have adopted for this program. If registry-based reporting of the ASC quality measures adopted for the ASCQR Program becomes available in the future, we will explore further the viability of incorporating a registry-based reporting mechanism in the ASCQR Program.

Regarding the use of EHR systems for reporting quality data, we agree that reporting by this method could reduce reporting burden. However, we are not aware of quality measures for ASCs that have been specified for electronic reporting. If such measures do exist, we would need to understand the level of EHR adoption and capabilities of ASCs to utilize this method at that time before proposing their adoption in the ASCQR Program. As we discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75126), in a recent environmental scan, which included an assessment of the readiness of ASCs to electronically report quality data, we found evidence of low levels of EHR use by ASCs. We believe that ASCs continue to be slow to adopt EHRs because many of these facilities are small and the cost of EHRs may pose a barrier to adoption.

Comment: One commenter requested a batch-processing data submission option for entities that own multiple ASCs.

Response: We thank the commenter for this request. We agree that a batch submission approach, which would allow ASCs to report data for multiple facilities at once using their preexisting or a new information technology infrastructure, has merit, especially for entities that own multiple ASCs, and are considering how to implement this capability into our data submission process. In the event this method can be available for data submission, we would issue proposals through future rulemaking for ASCQR Program implementation.

1. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68497 through 68498), we finalized our data processing and collection policies for the claims-based measures using QDCs for the CY 2015 payment determination and subsequent years. Specifically, ASCs must submit complete data on individual claims-based quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims. The data collection period for claims-based quality measures reported using QDCs is the calendar year 2 years prior to the payment determination year. Only claims for services furnished in each calendar year paid by the MAC by April 30 of the following year of the ending data collection time period will be included in the data used for the payment determination. In the CY 2016 OPPS/ASC proposed rule (80 FR 39345), we did not propose any changes to these existing requirements. However, we proposed to codify these existing requirements at proposed new 42 CFR 416.310(a)(1) and (2).

We invited public comment on our proposal to codify our existing policies.

We did not receive any public comments on the proposal to codify the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program and, therefore, are finalizing it as proposed at 42 CFR 416.310(a)(1) and (2).

2. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

The requirements for minimum threshold, minimum case volume, and data completeness for participation in the ASCQR program for the CY 2015 payment determination and subsequent years are set forth in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68498 through 68499) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135 through 75137). As stated in the CY 2013 rule, for ASCQR Program purposes, data completeness for claims-based measures using QDCs is determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims that meet measure specifications, but do not have the appropriate QDCs on the submitted Medicare claims. For the CY 2016 payment determination and subsequent years, the minimum threshold for successful reporting is that at least 50 percent of Medicare claims meeting measures specifications contain the appropriate QDCs. ASCs that meet this minimum threshold are regarded as having provided complete data for the claims-based measures using QDCs for the ASCQR Program. In the CY 2016 OPPS/ASC proposed rule (80 FR 39345), we did not propose any changes to these existing requirements. However, we proposed to codify these existing requirements at proposed new 42 CFR 416.310(a)(3).

We invited public comment on our proposal to codify our existing policies.

Comment: One commenter recommended that CMS raise the 50-percent threshold for claims meeting measure specifications containing QDCs, noting that many of the issues in the early years of the program that led to this standard have been resolved. In addition, the commenter did not support codifying the current 50-percent threshold for claims meeting measure specifications containing QDCs because, the commenter stated, CMS has previously expressed its intent to modify this threshold and, the commenter stated, regulatory text should be reserved for permanent policies.

Response: We thank the commenter for the recommendation. While we did not propose any changes to our QDC use

threshold in this rulemaking, we will consider this comment as we move forward with program planning as ASCs now have experience in submitting data in this manner. We note that the threshold is a minimum and holding at this level can enable an ASC that encounters reporting issues during the year to recover and still meet requirements.

We also thank the commenter for sharing its concerns about the ASCQR Program's proposal to codify this policy in regulatory text. However, we note that codified regulatory text is regularly revised to reflect changes in policy or position on a given issue. In addition, for some users, codified text is both easier to access and easier to understand than programmatic policies found only in preamble text. Therefore, we believe it is appropriate to codify programmatic policies, such as the minimum data threshold, and incorporate any future changes to those policies when they are finalized through notice-and-comment rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to codify our policies regarding the minimum threshold and data completeness for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(3). We codified our policy regarding the minimum case volume at 42 CFR 416.305(c), as discussed it in section XIV.C.2. of this final rule with comment period.

3. Requirements for Data Submitted Via an Online Data Submission Tool

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75137 through 75139), we finalized the data collection time period for quality measures for which data are submitted via a CMS online data submission tool as services furnished during the calendar year 2 years prior to the payment determination year. We also finalized our policy that these data will be submitted during the time period of January 1 to August 15 in the year prior to the affected payment determination year.

We established a different time period for data collection and submission for ASC–8: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), which is submitted via the CDC's NHSN rather than a CMS online data submission tool. For ASC–8, the data collection for the CY 2016 payment determination is from October 1, 2014 through March 31, 2015 (the 2014–2015 influenza season data) (76 FR 74510), and for the CY 2017 payment determination and subsequent years is from October 1 of the year 2 years prior to the payment determination year to March 31 of the year prior to the payment determination year (79 FR 66986), and the submission deadline is May 15 of the year when the influenza season ends (79 FR 66985 through 66986).

In the CY 2016 OPPS/ASC proposed rule (80 FR 39345 through 39346), we proposed to implement a May 15 submission deadline for all data submitted via a CMS Web-based tool in the ASCQR Program for the CY 2017 payment determination and subsequent years. This proposal currently would include the following measures: ASC–6: Safe Surgery Checklist Use; ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures; ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); and ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).[62] Therefore, we proposed that data collected for a quality measure for which data are submitted via a CMS online data submission tool must be submitted during the time period of January 1 to May 15 in the year prior to the payment determination year for the CY 2017 payment determination and subsequent years. We proposed this change because we believe that aligning all Web-based tool data submission deadlines with the end date of May 15 would allow for earlier public reporting of measure data and reduce the administrative burden for ASCs associated with tracking multiple submission deadlines for these measures.

We also proposed to codify these proposed and existing requirements at proposed new 42 CFR 416.310(c)(1)(ii) and (2).

We invited public comment on our proposal to change the data submission time period beginning with the CY 2017 payment determination for measures for which data are submitted via a CMS online data submission tool, and our proposal to codify this proposed policy and our existing policy.

Comment: Commenters did not support CMS' proposal to implement a May 15 submission deadline for all data submitted via a CMS online data submission tool. The commenters asserted that a May 15 deadline would increase ASC administrative burden by giving ASCs less time to collect and report data. The commenters also noted that the current August 15 deadline was extended for the CY 2016 payment determination due to technical issues, and expressed concern that similar issues may arise each time new measures are added in the future. For these same reasons, the commenters did not support CMS' proposal to codify the May 15 submission deadline for all data submitted via a CMS online data submission tool. The commenters recommended that, if CMS wishes to align the deadlines for submission of the Web-based measures, it use an August 15 deadline instead.

Response: We thank the commenters for their comments regarding the increased administrative burden associated with changing the submission deadline for all data submitted via an online data submission tool from August 15 to May 15. We seek to reduce the administrative burden of participation in the ASCQR Program on ASCs where feasible and practicable. For this reason, we have decided not to finalize the proposal to change the deadline at this time. We will instead maintain the August 15 submission deadline for all measures submitted via a CMS online data submission tool.

However, we note that we are not changing the May 15 submission deadline for ASC–8, which is submitted via a non-CMS online data submission tool. As stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66986), we finalized a submission deadline of May 15 for ASC–8 in order to enable ASCs to use data summarizing the results of their previous influenza vaccination campaign to set targets and make plans for the next influenza season; to enable us to post and for the public to review the summary data before the start of the next influenza season; and to align this measure's submission deadline with the Hospital IQR and OQR Programs. We continue to believe that the May 15 submission deadline is appropriate for ASC–8, and therefore are not changing the submission deadline for this measure to August 15 at this time. We will consider whether there is another way to reduce ASC burden and expedite public reporting of these data in the future.

After consideration of the public comments we received, we are not finalizing the proposal to implement a

[62] We note that ASC–11 is a voluntary measure for the CY 2017 payment determination and subsequent years. This proposal would mean that ASCs that choose to submit data for this measure also would need to submit such data between January 1 and May 15 for the CY 2018 payment determination and subsequent years.

May 15 submission deadline for data submitted using a CMS online data submission tool. Instead, the ASCQR Program will continue to use the currently adopted submission deadlines for these measures; that is, the August 15 submission deadline for ASC–6, ASC–7, ASC–9, ASC–10, and ASC–11. The ASCQR Program also will continue to use the currently adopted May 15 submission deadline for ASC–8, which is submitted via a non-CMS online data submission tool (the CDC's NHSN Web site). Furthermore, consistent with the policy we are finalizing above regarding the August 15 submission deadline, we are codifying our policies for quality measures for which data are submitted via a CMS online data submission tool with the August 15 submission deadline at 42 CFR 416.310(c)(1)(ii) instead of May 15 as originally proposed. In addition, we are finalizing our proposal to codify our existing policies regarding the data collection time periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool at 42 CFR 416.310(c)(2). However, we proposed to include the word ''calendar'' in the proposed codification of this policy at 42 CFR 416.310(c)(2). This word was not part of the finalized policy and we believe this word is unnecessary. We have made a technical change to not include this word in the final regulation.

4. Claims-Based Measure Data Requirements for the ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy Measure for the CY 2018 Payment Determination and Subsequent Years

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66970 through 66979), we adopted ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) in the ASCQR Program for the CY 2018 payment determination and subsequent years. At the time we adopted this measure, it was not NQF-endorsed; it has subsequently been endorsed by the NQF. Unlike the other claims-based measures adopted for the ASCQR Program, this claims-based measure does not require any additional data submission, such as QDCs. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985), we finalized the policy to use paid Medicare fee-for-service (FFS) claims from the calendar year 2 years before the payment determination year. In the CY 2016 OPPS/ASC proposed rule (80 FR 39346), we proposed to align our policy regarding the paid claims to be included in the calculation for claims-based measures not using QDCs with our policy regarding the paid claims to be included for the claims-based measures using QDCs.

Therefore, beginning with the CY 2018 payment determination, we proposed to use claims for services furnished in each calendar year that have been paid by the MAC by April 30 of the following year of the ending data collection time period to be included in the data used for the payment determination. We believe that this claim paid date would allow ASCs sufficient time to submit claims and at the same time allow CMS sufficient time to complete required data analysis and processing to make payment determinations and to supply this information to the MACs. For example, for the CY 2018 payment determination, for calculating ASC–12, we would use claims for services furnished in CY 2016 (January 1, 2016 through December 21, 2016) that were paid by the MAC by April 30, 2017.

We proposed to codify this policy at proposed new 42 CFR 416.310(b).

We invited public comment on our proposal regarding the paid claims to be included in the data used for ASC–12 beginning with the CY 2018 payment determination, and our proposal to codify this proposal and our existing policies.

We did not receive any public comments on these proposals. Therefore, we are finalizing our policy regarding paid claims to be included in the calculation for claims-based measures not using QDCs, and codifying this proposal and our existing policies at 42 CFR 416.310(b). We inadvertently did not include the word ''paid'' in the proposed codification of this policy at 42 CFR 416.310(b) and have made this technical change to the final regulation.

5. Indian Health Service (IHS) Hospital Outpatient Departments Not Considered ASCs for the Purpose of the ASCQR Program

Indian Health Service (IHS) hospital outpatient departments are able to bill Medicare for ASC services and be paid based on the ASC rates for services under the ASC payment system as described in Section 40.2.1, Chapter 19 of the Medicare Claims Processing Manual and Section 260.1, Chapter 15 of the Medicare Benefit Policy Manual (*http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c19.pdf, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf*). We have considered these entities to be ASCs for purposes of the ASCQR Program due to their payment under the ASC payment system. These entities are included under Section 260.1 (Definition of Ambulatory Surgical Centers), Chapter 15 of the Medicare Benefit Policy Manual.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39346), we proposed that these facilities not be considered ASCs for purposes of the ASCQR Program, beginning with the CY 2017 payment determination. As stated in the manuals, in order to bill for ASC services, these IHS hospital outpatient departments must meet the conditions of participation for hospitals defined in 42 CFR part 482 and are not certified as separate ASC entities. Because these IHS hospital outpatient departments are required to meet the conditions of participation for hospitals, which state that the hospital's governing body must ensure that its quality assessment and performance improvement program involves all hospital departments and services, they should be included in the hospitals' ongoing, hospital-wide, data-driven quality assessment and performance improvement programs (42 CFR 482.21), which we believe ensures that these IHS hospital outpatient departments engage in continuous quality improvement efforts outside of participation in CMS' quality reporting programs. For these reasons, we proposed that IHS hospital outpatient departments that bill Medicare for ASC services under the ASC payment system are not to be considered as ASCs for the purposes of the ASCQR Program. These facilities would not be required to meet ASCQR Program requirements and would not receive any payment reduction under the ASCQR Program. We proposed to codify this proposal at proposed new 42 CFR 416.305(d).

We invited public comment on this proposal and our proposal to codify it.

We did not receive any public comments on the proposal not to consider IHS hospital outpatient departments ASCs for the purposes of the ASCQR Program or the proposal to codify this policy and, therefore, are finalizing and codifying this policy as proposed at 42 CFR 416.305(d).

6. ASCQR Program Validation of Claims-Based and CMS Web-Based Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641 through 53642) for a complete discussion of our policy not to require validation of claims-based measures (beyond the usual claims validation activities conducted by our MACs) or Web-based measures for the ASCQR

Program. In the CY 2016 OPPS/ASC proposed rule (80 FR 39346 through 39347), we did not propose any changes to this policy.

7. Extraordinary Circumstances Extensions or Exemptions for the CY 2018 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75140 through 75141), we adopted procedures for extraordinary circumstance extensions or exemption requests for the submission of information required under the ASCQR Program.[63] Specifically, CMS may grant an extension or exemption for the submission of information in the event of extraordinary circumstances beyond the control of an ASC, such as when an act of nature affects an entire region or locale, or a systematic problem with one of our data collection systems directly or indirectly affects data submission. We may grant an extension or exemption as follows:

(1) Upon request by the ASC. Specific requirements for submission of a request for an extension or exemption are available on the QualityNet Web site; or

(2) At the discretion of CMS. CMS may grant extensions or exemptions to ASCs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39347), we did not propose any changes to these requirements. However, we proposed to codify these existing procedures at proposed new 42 CFR 416.310(d). We invited public comment on our proposal to codify our existing policies.

We did not receive any public comments on the proposal to codify our policies regarding extraordinary circumstances extensions or exceptions in the ASCQR Program and, therefore, are finalizing it as proposed at 42 CFR 416.310(d).

8. ASCQR Program Reconsideration Procedures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53643 through 53644) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75141), we set forth our requirements for an informal reconsideration process. Specifically, an ASC may request reconsideration of a decision by CMS that it has not met the requirements of the ASCQR Program for a particular payment determination year by submitting a reconsideration request (signed by a person who has authority to sign on behalf of the ASC) to CMS by March 17 of the affected payment determination year. A reconsideration request must contain the following information:

- ASC CCN and related NPI(s);
- The name of the ASC;
- The CMS-identified reason for not meeting the requirements of the ASCQR Program for the affected payment determination year as provided in any CMS notification to the ASC;
- The ASC's basis for requesting reconsideration. The ASC must identify its specific reason(s) for believing it met the ASCQR Program requirements for the affected payment determination year and should not be subject to the reduced ASC annual payment update;
- The ASC-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical mailing address, not just a post office box); and
- A copy of all materials that the ASC submitted to comply with the requirements of the affected ASCQR Program payment determination year. With regard to information on claims, ASCs are not required to submit copies of all submitted claims, but instead may focus on the specific claims at issue. For these claims, ASCs should submit relevant information, which could include copies of the actual claims at issue.

Upon receipt of a request for reconsideration, CMS will do the following:

- Provide an email acknowledgement, using the contact information provided in the reconsideration request, notifying the ASC that the request has been received; and
- Provide a formal response to the ASC contact, using the information provided in the reconsideration request notifying the ASC of the outcome of the reconsideration process.

For those ASCs that submit a timely reconsideration request, the reconsideration determination is the final ASCQR Program payment determination. For ASCs that do not submit a timely reconsideration request, the CMS determination is the final payment determination. There is no appeal of any final ASCQR Program payment determination.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39347), we proposed one change to these requirements. Under our current reconsideration procedures, ASCs are required to submit reconsideration requests by March 17 of the affected payment determination year (77 FR 53643 through 53644). However, we recognize that, in some payment years, March 17 may fall outside of the business week. Therefore, we proposed that, beginning with the CY 2017 payment determination, ASCs must submit a reconsideration request to CMS by no later than the first business day on or after March 17 of the affected payment year . We proposed to codify these existing procedures and the proposed change to the deadline at proposed new 42 CFR 416.330.

We invited public comment on our proposal to change the reconsideration request submission deadline and our proposal to codify our existing policies.

We did not receive any public comments on the proposal to change the reconsideration request submission deadline for the ASCQR Program or the proposal to codify this policy and our existing reconsideration policies and, therefore, are finalizing them at 42 CFR 416.330. We are making a technical change to add the word ''timely'' at 42 CFR 416.330(d) to clarify that the reconsideration determination is the final ASCQR Program payment determination for an ASC that submits a timely reconsideration request.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to section XV.C.1. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75131 through 75132) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system equal the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. Currently, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the MFP-adjusted CPI–U update factor, which is the adjustment set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted CPI–U update factor is the Consumer Price Index for all urban consumers (CPI–U), which currently is the annual update for the ASC payment

[63] In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66987), we stated that we will refer to the process as the ''Extraordinary Circumstances Extensions or Exemptions'' process rather than the ''Extraordinary Circumstances Extensions or Waivers'' process.

system, minus the MFP adjustment. As discussed in the CY 2011 MPFS final rule with comment period (75 FR 73397), if the CPI–U is a negative number, the CPI–U would be held to zero. Under the ASCQR Program, any annual update will be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates. For a complete discussion of the calculation of the ASC conversion factor, we refer readers to section XII.G. of this final rule with comment period.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: a full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to this final rule with comment period, which are available via the Internet on the CMS Web site): ''A2,'' ''G2,'' ''P2,'' ''R2,'' and ''Z2,'' as well as the service portion of device-intensive procedures identified by ''J8.'' We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor.

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2,'' ''G2,'' ''J8,'' ''P2,'' ''R2,'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, certain radiology services and diagnostic tests where payment is based on the MPFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment. As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update.

Office-based surgical procedures (performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the MPFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in section XII.D.2.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for the new category of covered ancillary services (that is, certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS and when they are integral to an ASC covered surgical procedure) will be at the lesser of the MPFS nonfacility PE RVU-based amounts or the rate calculated according to the standard ASC ratesetting methodology. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries. Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: The wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, and the adjustment for devices furnished with full or partial credit or without cost. We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements.

In the CY 2014 and CY 2015 OPPS/ASC final rules with comment periods (78 FR 75132 and 79 FR 66981 through 66982), we did not make any changes to these policies. In the CY 2016 OPPS/ASC proposed rule (80 FR 39347 through 39348), we did not propose any changes to these policies.

XV. Short Inpatient Hospital Stays

A. Background on the 2-Midnight Rule

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), we discussed CMS' longstanding policy on how Medicare contractors review inpatient hospital and CAH admissions for payment purposes. In that final rule, we discussed previously existing Medicare policy contained in the Section 10, Chapter 1 of the Medicare Benefit Policy Manual (MBPM) that stated that when a beneficiary receives a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours (less than 24 hours), the services generally should be billed as outpatient hospital services, regardless of the hour the beneficiary comes to the hospital, whether he or she uses a bed, and whether he or she remains in the hospital past midnight. We noted that we have been clear that this billing instruction does not override the clinical judgment of the physician to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital. Rather, this instruction provided a benchmark to ensure that all beneficiaries received consistent application of their Medicare Part A benefit to whatever clinical services were medically necessary.

However, due to persistently large improper payment rates in short-stay hospital inpatient claims, requests to provide additional guidance regarding the proper billing of those services, and concerns about increasingly long stays of Medicare beneficiaries as outpatients due to hospital uncertainties about payment, we modified and clarified our general rule in the regulations with respect to Medicare payment for inpatient hospital admissions. Specifically, in the FY 2014 IPPS/LTCH PPS final rule, we provided guidance for payment purposes that specified that, generally, a hospital inpatient admission is considered reasonable and necessary if a physician or other qualified practitioner (collectively, ''physician'') orders such admission based on the expectation that the beneficiary's length of stay will exceed 2 midnights or if the beneficiary requires a procedure specified as inpatient-only under § 419.22 of the regulations. We finalized at § 412.3(d)(1) of the regulations that services designated under the OPPS as inpatient only procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A. In addition, we finalized a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. Conversely, when a beneficiary enters a hospital for a surgical procedure not specified as inpatient-only under § 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A, regardless of the hour that the beneficiary came to the hospital or whether the beneficiary used a bed.

We finalized a policy at § 412.3(d)(2) (originally designated as § 412.3(e)(2) and later redesignated as § 412.3(d)(2)) of the regulations that if an unforeseen circumstance, such as beneficiary death or transfer, results in a shorter beneficiary stay than the physician's reasonable expectation of at least 2 midnights, the patient may still be considered to be appropriately treated on an inpatient basis for payment purposes, and the hospital inpatient payment may be made under Medicare Part A.

In addition to the new hospital admission guidance, we also finalized two distinct, although related, medical review policies, a 2-midnight ''benchmark'' and a 2-midnight ''presumption,'' effective for admissions on or after October 1, 2013. The 2-midnight benchmark, which is described in more detail below, represents guidance to reviewers to identify when an inpatient admission is generally appropriate for Medicare coverage and payment, while the 2-midnight presumption relates to instructions to medical reviewers regarding the selection of claims for medical review. Specifically, under the 2-midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are presumed to be appropriate for Medicare Part A payment and are not the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption.

With respect to the 2-midnight benchmark, the starting point is when the beneficiary begins receiving hospital care either as a registered outpatient or after inpatient admission. That is, for purposes of determining whether the 2-midnight benchmark is met and, therefore, whether an inpatient admission is appropriate for Medicare Part A payment, we consider the physician's expectation including the total time spent receiving hospital care—not only the expected duration of care after inpatient admission, but also any time the beneficiary has spent (before inpatient admission) receiving outpatient services, such as observation services, treatments in the emergency department, and procedures provided in the operating room or other treatment area. From the medical review perspective, while the time the beneficiary spent as an outpatient before the admission order is written is not considered inpatient time, it is considered during the medical review process for purposes of determining whether the 2-midnight benchmark was met and, therefore, whether payment is appropriate under Medicare Part A. For beneficiaries who do not arrive through the emergency department or are directly receiving inpatient services (for example, inpatient admission order written prior to admission for an elective admission), the starting point for medical review purposes is when the beneficiary starts receiving medically responsive services following arrival at the hospital. For Medicare payment purposes, both the decision to keep the patient at the hospital and the expectation of needed duration of the stay must be supported by documentation in the medical record based on factors such as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event during hospitalization.

With respect to inpatient stays spanning less than 2 midnights after admission, we instructed contractors that, although such claims would not be subject to the presumption, the admission may still be appropriate for Medicare Part A payment because time spent as an outpatient should be considered in determining whether there was a reasonable expectation that the hospital care would span 2 or more midnights. In other words, even if an inpatient admission was for only 1 Medicare utilization day, medical reviewers are instructed to consider the total duration of hospital care, both pre- and post-inpatient admission, when making the determination of whether the inpatient stay was reasonable and necessary for purposes of Medicare Part A payment.

We continue to believe that use of the 2-midnight benchmark gives appropriate consideration to the medical judgment of physicians and also furthers the goal of clearly identifying when an inpatient admission is appropriate for payment under Medicare Part A. More specifically, as we described in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), factors such as the procedures being performed and the beneficiary's condition and comorbidities apply when the physician formulates his or her expectation regarding the need for hospital care, while the determination of whether an admission is appropriately billed and paid under Medicare Part A or Part B is based upon the physician's medical judgment regarding the beneficiary's expected length of stay. We have not identified any circumstances where the 2-midnight benchmark restricts the physician to a specific pattern of care because the 2-midnight benchmark, like the previous 24-hour benchmark, does not prevent the physician from ordering or providing any service at any hospital, regardless of the expected duration of the service. Rather, this policy provides guidance on when the hospitalized beneficiary's care is appropriate for coverage and payment under Medicare Part A benefits as an inpatient, and when the beneficiary's care is appropriate for coverage and payment

under Medicare Part B benefits as an outpatient.

On the other hand, we also acknowledge that certain procedures may have intrinsic risks, recovery impacts, or complexities that would cause them to be appropriate for inpatient coverage under Medicare Part A regardless of the length of hospital time the admitting physician expects a particular patient to require. We believe that the OPPS inpatient-only list of procedures identifies those procedures and, therefore, procedures on that list are not subject to the 2-midnight benchmark for purposes of inpatient hospital payment. We explained in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954) that we might specify additional exceptions to the generally applicable benchmark through subregulatory guidance, including manual instructions. Accordingly, since publication of the final rule, we have accepted and considered suggestions from stakeholders regarding potential ''rare and unusual'' circumstances under which an inpatient admission that is expected to span less than 2 midnights would nonetheless be appropriate for Medicare Part A payment.

In January 2014, we identified newly initiated mechanical ventilation (when medically necessary and excluding anticipated intubations related to minor surgical procedures or other treatment) as the first such rare and unusual exception to the 2-midnight benchmark. We announced this exception by posting it on the CMS Web site. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50147), we invited further feedback on suggested exceptions to the 2-midnight benchmark, in recognition that there could be additional rare and unusual circumstances that we have not identified that justify payment as an inpatient admission under Medicare Part A, absent an expectation of care spanning at least 2 midnights.

With respect to the 2-midnight benchmark, we have been clear that this instruction does not override the clinical judgment of the physician regarding the need to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital. Rather, as with the previous 24-hour benchmark in the MBPM, this instruction provides a benchmark to ensure that all beneficiaries receive consistent application of their Medicare Part A benefit to medically necessary clinical services.

As part of our efforts to provide education to stakeholders on the 2-midnight rule, CMS has hosted numerous ''Open Door Forums,'' conducted national provider calls, and shared information and answers to frequently asked questions on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/InpatientHospitalReviews.html.*

In addition, we instructed MACs to conduct a ''Probe and Educate'' process for inpatient claims with dates of admission on or after October 1, 2013 through September 30, 2014, to assess provider understanding and compliance with the new policy. We also prohibited Recovery Auditor post-payment medical reviews of inpatient hospital patient status for claims with dates of admission between October 1, 2013 and September 30, 2014. On April 1, 2014, the Protecting Access to Medicare Act of 2014 Pub. L. 113–93) was enacted. Section 111 of Pub. L. 113–93 permitted CMS to continue medical review activities under the MAC Inpatient Probe and Educate process through March 31, 2015. The same law also extended the prohibition on Recovery Auditor reviews of inpatient hospital patient status for claims with dates of admission through March 31, 2015, absent evidence of systematic gaming, fraud, abuse, or delays in the provision of care by a provider of services. On April 16, 2015, the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) was enacted. Section 521 of Pub. L. 114–10 permitted CMS to further extend the medical review activities under the MAC hospital Probe and Educate process for inpatient claims through September 30, 2015, and extended the prohibition of Recovery Auditor reviews of inpatient hospital patient status for claims with dates of admission through September 30, 2015. CMS announced in August 2015 that it will not approve Recovery Auditors to conduct patient status reviews for dates of admission of October 1, 2015 through December 31, 2015. (We refer readers to the CMS Web site at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/InpatientHospitalReviews.html* for more information on this announcement.) MACs have completed the first and second rounds of probe reviews and provider education and were instructed to complete a third round of probe reviews on or before September 30, 2015. Throughout the Probe and Educate process to date, we have seen positive effects and improved provider understanding of the 2-midnight rule. For example, the second round of probe and educate denial rates were lower than those in the first round, which may reflect improved provider understanding of the 2-midnight rule after the implementation of the first round of provider education. In addition, anecdotal reports indicate that providers found that the education provided as a result of probe reviews was effective in promoting a better understanding of the policy.

In response to industry feedback, including suggestions to alter the Recovery Audit Program, on December 30, 2014, we announced a number of changes to the Recovery Audit Program. To address hospitals' concerns that they do not have the opportunity to rebill for medically necessary Medicare Part B inpatient services by the time a medical review contractor has denied a Medicare Part A inpatient claim, we changed the Recovery Auditor ''look-back period'' for patient status reviews to 6 months from the date of service in cases where a hospital submits the claim within 3 months of the date that it provides the service. We established incrementally applied Additional Documentation Request (ADR) limits for providers that are new to Recovery Auditor reviews and will establish limits on ADRs that are based on a hospital's compliance with Medicare rules and that are diversified across all claim types of a facility. We also indicated that we plan to establish a requirement that Recovery Auditors must complete complex reviews within 30 days, and failure to do so will result in the loss of the Recovery Auditor's contingency fee, even if an error is found. Finally, we plan to require Recovery Auditors to wait 30 days before sending a claim to the MAC for adjustment to allow the provider to submit a discussion period request to the Recovery Auditor before the MAC makes any payment adjustments. We plan to complete implementation of these changes through modifications to the current Recovery Auditor contracts.

B. Policy Change for Medical Review of Inpatient Hospital Admissions Under Medicare Part A

While we have been clear that the 2-midnight benchmark does not override the clinical judgment of the physician regarding the need to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital, some stakeholders have argued that the 2-midnight benchmark removes physician judgment from the decision to

admit a patient for inpatient hospital services. We disagree. We continue to believe that the 2-midnight benchmark provides, for payment purposes, clear guidance on when a hospital inpatient admission is appropriate for Medicare Part A payment, while respecting the role of physician judgment. However, we believe the concerns raised by stakeholders merit continued consideration.

In light of the aforementioned stakeholder concern and in our continued effort to develop the most appropriate and applicable framework for determining when payment under Medicare Part A is appropriate for inpatient admissions, in the CY 2016 OPPS/ASC proposed rule (80 FR 39350 through 39351), we proposed to modify our existing ''rare and unusual'' exceptions policy to allow for Medicare Part A payment on a case-by-case basis for inpatient admissions that do not satisfy the 2-midnight benchmark, if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than 2 midnights. For payment purposes, the following factors, among others, would be relevant to determining whether an inpatient admission where the patient stay is expected to be less than 2 midnights is nonetheless appropriate for Part A payment:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of something adverse happening to the patient; and
- The need for diagnostic studies that appropriately are outpatient services (that is, their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more).

We noted that, under the existing rare and unusual policy, only one exception—prolonged mechanical ventilation—has been identified to date. Upon further consideration and based on feedback from stakeholders, we stated our belief that there may be other patient-specific circumstances where certain cases may nonetheless be appropriate for Part A payment, absent an expected stay of at least 2 midnights, and that such circumstances should be determined on a case-by-case basis. We proposed a revised policy under which, for purposes of Medicare payment, an inpatient admission would be payable under Part A if the documentation in the medical record supports either the admitting physician's reasonable expectation that the patient will require hospital care spanning at least 2 midnights, or the physician's determination based on factors such as those identified above that the patient requires formal admission to the hospital on an inpatient basis.

Accordingly, we proposed to revise § 412.3(d)(1) of the regulations to reflect this modification. Existing § 412.3(d)(1) specifies, in relevant part, that if the physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services are generally inappropriate for inpatient admission and inpatient payment under Medicare Part A, regardless of the hour that the patient came to the hospital or whether the patient used a bed. We proposed to revise § 412.3(d) to state that when the admitting physician expects a hospital patient to require hospital care for only a limited period of time that does not cross 2 midnights, the services may be appropriate for payment under Medicare Part A if the physician determines and documents in the patient's medical record that the patient requires a reasonable and necessary admission to the hospital as an inpatient. We noted that, in general, we would expect that with most inpatient admissions where the stay is expected to last less than the 2-midnight benchmark, the patient will remain in the hospital at least overnight. However, we acknowledged that the patient can be unexpectedly discharged or transferred to another hospital and not actually use a hospital bed overnight. We proposed that cases for which the physician determines that an inpatient admission is necessary, but that do not span at least 1 midnight, would be prioritized for medical review. In addition to the proposed substantive changes discussed earlier in this section, we also proposed to revise existing paragraphs (d)(1) and (d)(2) for clarity.

Under the proposed policy change, for stays for which the physician expects the patient to need less than 2 midnights of hospital care and the procedure is not on the inpatient only list or on the national exception list, an inpatient admission would be payable on a case-by-case basis under Medicare Part A in those circumstances under which the physician determines that an inpatient stay is warranted and the documentation in the medical record supports that an inpatient admission is necessary.

We did not propose any changes for hospital stays that are expected to be greater than 2 midnights; that is, if the physician expects the patient to require hospital care that spans at least 2 midnights and admits the patient based on that expectation, the services are generally appropriate for Medicare Part A payment. (We note that this policy applies to hospital admissions where the patient is reasonably expected to stay at least 2 midnights, and payment will still be appropriate where the medical record supports the admitting physician's reasonable expectation that the patient would stay at least 2 midnights, but the actual stay was less due to unforeseen circumstances, such as unexpected patient death, transfer, clinical improvement, or departure against medical advice.) We also did not propose to change the 2-midnight presumption.

Our existing policy provides for payment under Part A based upon the admitting physician's clinical judgment that a patient will require hospital care that is expected to span at least 2 midnights. The proposed change would also allow for payment under Part A on a case-by-case basis for stays expected to last less than the 2-midnight benchmark, based upon the admitting physician's clinical judgment that inpatient hospital admission is appropriate. Consistent with longstanding Medicare policy, the decision to formally admit a patient to the hospital is subject to medical review.

Under our proposed revision to the policy for cases not meeting the 2-midnight benchmark, where the medical record does not support a reasonable expectation of the need for care crossing at least 2 midnights, and for inpatient admissions not related to a surgical procedure specified by Medicare as inpatient-only under § 419.22(n) or for which there was not a national exception (currently, there is an exception for new onset mechanical ventilation), payment of the claim under Medicare Part A will be subject to the clinical judgment of the medical reviewer. Consistent with our current practices, under our proposed revised policy, the medical reviewer's clinical judgment would involve the synthesis of all submitted medical record information (for example, progress notes, diagnostic findings, medications, nursing notes, and other supporting documentation) to make a medical review determination on whether the clinical requirements in the relevant policy have been met. In addition, Medicare review contractors must abide by CMS policies in conducting payment determinations, but are permitted to take into account evidence-based guidelines or commercial utilization tools that may aid such a decision. While Medicare review contractors may continue to use commercial screening tools to help evaluate the inpatient

admission decision for purposes of payment under Medicare Part A, such tools are not binding on the hospital, CMS, or its review contractors. This type of information also may be appropriately considered by the physician as part of the complex medical judgment that guides his or her decision to keep a beneficiary in the hospital and formulation of the expected length of stay. Some members of the hospital industry have argued that Medicare should adopt specific criteria for medical review entities to use when reviewing short-stay hospital claims. We invited public comments on whether specific medical review criteria should be adopted for inpatient hospital admissions that are not expected to span at least 2 midnights and, if so, what those criteria should be.

Although CMS reviewers will take into consideration the physician's decision to admit a beneficiary, the admission must be reasonable and necessary and supported by clear documentation in the patient's medical record in order to be covered under Medicare Part A. Likewise, in order to be covered under Medicare Part A, the care furnished must also be reasonable and necessary. Section 1862(a)(1) of the Act prohibits payment under the Medicare program for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury. In cases where CMS reviewers find that an inpatient admission is not medically reasonable and necessary and thus not appropriate for payment under Medicare Part A, we note that the beneficiary's patient status remains ''inpatient'' as of the time of the inpatient admission, and is not changed to outpatient, because the beneficiary was formally admitted as an inpatient and there is no provision to change a beneficiary's status after he or she is discharged from the hospital, as stated in CMS Ruling 1455–R (78 FR 16617). In these cases, the hospital will not receive payments for the beneficiary under Medicare Part A but may be able to submit a Medicare Part B inpatient claim for the Part B services that would have been payable to the hospital had the beneficiary originally been treated as an outpatient.

We note that our proposed change in policy for payment of hospital care expected to last less than 2 midnights does not negate another longstanding policy, recognizing that there are certain situations in which a hospital inpatient admission is rarely appropriate for Medicare Part A payment. We continue to believe, as stated above and as stated in the MBPM, that when a beneficiary receives a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours (less than 24 hours), the services should generally be billed as outpatient hospital services, regardless of the hour the beneficiary comes to the hospital, whether he or she uses a bed, and whether he or she remains in the hospital past midnight (Section 10, Chapter 1 of the MBPM). Accordingly, we would expect it to be rare and unusual for a beneficiary to require inpatient hospital admission after having a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours and not at least overnight. We stated in the proposed rule that we will monitor the number of these types of admissions and plan to prioritize these types of cases for medical review.

Comment: Several commenters expressed appreciation for CMS' proposal and stated their belief that the proposal is more reflective of the agency's longstanding policy that recognizes the important role of physician judgment and individual patient needs in the hospital admission decision-making process. Commenters in support of the proposed policy also expressed appreciation that CMS did not propose a change to the 2-midnight presumption, which maintains the certainty that patient stays of 2 midnights or longer after admission are presumptively appropriate as inpatient cases.

Response: We appreciate the commenters' support and agree that our proposed policy continues to recognize the important role of physician judgment and individual patient needs in the hospital admission decision-making process while also maintaining the certainty that patient stays of 2 midnights or longer after admission are generally appropriate for payment under Medicare Part A and will generally only be selected for review in circumstances of fraud or gaming.

Comment: A number of commenters who supported the proposal requested that CMS provide hospitals with the important details, tools, and time necessary to effectively implement changes to the 2-midnight policy the agency may finalize. Some commenters making this request specifically asked that CMS consider a March 31, 2016 enforcement date, for potential changes to the 2-midnight policy. A few commenters who supported the proposal asked CMS to clarify in the final rule if this proposal means CMS intends to return to its policy position prior to the implementation of the 2-midnight rule, with the exception of cases where the patient stays 2 midnights after admission and is presumed to be a medically necessary inpatient.

Response: Consistent with our annual rulemaking process, we believe that there is sufficient time between the date the final rule becomes available (on or before November 1, 2015) to the public and the effective date of the policy (January 1, 2016) for hospitals to become familiar with and adopt any changes necessitated by the final policies outlined in this final rule with comment period, including adoption of our proposed changes to the 2-midnight rule, and therefore do not see a reason to delay the effective date of this policy beyond January 1, 2016. We also believe that the details pertinent to the final policy on 2-midnights are sufficiently set forth in this final rule with comment period and its supporting documents and guidance and that all tools necessary for the effective implementation of the final policy have been made available to hospitals, physicians and other stakeholders.

In response to comments requesting that we clarify whether the proposed policy is a return to the policy that was in effect prior to the implementation of the 2-midnight rule (with the exception of cases where the patient stays 2 midnights and is presumed to be a medically necessary inpatient), we explicitly note that our proposal is not a return to the policy prior to the adoption of the 2-midnight rule. The proposed policy continued to employ the 2-midnight rule (both the 2-midnight benchmark and the 2-midnight presumption) and proposed to allow for greater flexibility in determining when an admission that does not meet the 2-midnight benchmark should nonetheless be payable. This is distinct from the policy that was in effect prior to the adoption of the 2-midnight rule in the form of manual guidance that stated that when a beneficiary receives a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours (less than 24 hours), the services generally should be billed as outpatient hospital services, regardless of the hour the beneficiary comes to the hospital, whether he or she uses a bed, and whether he or she remains in the hospital past midnight.

Comment: Several commenters, including MedPAC and the American Medical Association (AMA), recommended that CMS rescind the 2-midnight rule in its entirety. Some of the commenters stated that any time-based admission policy would interfere

with physician judgment. In addition, MedPAC expressed concern that the 2-midnight rule may provide hospitals with an incentive to lengthen hospital stays in order to avoid scrutiny and that longer stays generally increase costs and expose Medicare beneficiaries to greater physical risk while also conflicting with the general incentives of the prospective payment system to reduce hospital lengths of stay. MedPAC also stated that the Commission recommended that CMS withdraw the 2-midnight rule because it becomes redundant in light of MedPAC recommendations related to the Recovery Audit Program. The AMA expressed concern that the 2-midnight rule places considerable burden on the admitting physician and erodes the ability of physicians and providers to improve health outcomes through personalized, evidence-based clinical care because it detracts from admission criteria that depend upon clinical judgment.

Response: We appreciate this comment from MedPAC and others but we do not believe that rescinding the 2-midnight rule is the best course of action at this time. Specifically, we continue to believe that it is prudent and essential to continue to maintain the 2-midnight presumption whereby cases with an actual length of stay of at least 2 midnights after admission would generally not be selected for medical review. We note that stakeholders and commenters in support of the proposed policy, including several major hospital associations, have cited their support for maintaining the 2-midnight presumption because it affords hospitals and physicians some certainty that inpatient admissions spanning at least 2 midnights after admission will generally be considered to be appropriate for Medicare payment under Part A and will not be selected for medical review, absent evidence of systematic gaming, abuse, or delays in the provision of care. This provision of the 2-midnight rule would no longer be valid if the 2-midnight rule was rescinded in entirety. We understand MedPAC's concern that hospitals may lengthen hospital stays to avoid scrutiny and will continue to monitor the claims data to detect any shifts in hospital practices pertaining to beneficiaries' length of stay, or any evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption. We are cognizant of concerns related to unnecessarily elongated hospital admissions, and will be monitoring for such patterns of systematic delays indicative of fraud or abuse. If a hospital is unnecessarily holding beneficiaries to qualify for the 2- midnight presumption, CMS and/or its contractors may conduct review on any of its inpatient claims, including those which surpassed 2 midnights after admission. In addition, as we have stated above, the 2-midnight rule does not override the clinical judgment of the physician regarding the need to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital. We also believe that the documentation requirements for admitting physicians are not overly burdensome because they are consistent with Medicare's longstanding documentation requirements, which predated the adoption of the 2-midnight rule.

With respect to MedPAC's comment that the 2-midnight rule may not be necessary in light of its recommended changes to the Recovery Audit Program, we believe that the planned changes to the Recovery Audit Program will help reduce provider concerns within this arena, but should be accompanied by the outlined changes to the 2-midnight policy.

Comment: Several commenters asked that CMS not adopt any changes to the 2-midnight rule. Many of these commenters expressed concern that further changes to the existing policy would cause confusion. Many commenters requested that CMS not adopt the ''physician judgment'' exception to the 2-midnight rule without explicit instructions and detailed case examples to help them understand when physician judgment can override the 2-midnight expectation. Another commenter believed that the proposed policy will likely be used by the QIOs and RACs as a way to deny appropriate inpatient claims, thus increasing the administrative burden on providers and worsening the appeals backlog. One commenter expressed concern that the proposed policy could create an opportunity for gaming by creating a market for independent parties to create and sell ''exception'' letters to hospitals that could be used to inappropriately ''document'' case-by-case exceptions to the 2-midnight rule.

Response: While we understand commenters' desire to not have CMS adopt any changes to the current 2-midnight rule and recognize that the proposed policy allows for added discretion in determining when inpatient admission is appropriate for payment under Medicare Part A, we believed it was appropriate to address concerns raised by hospital and physician stakeholders that the current policy potentially had the unintended consequence of interfering with the practice of medicine. We maintain that neither our current policy nor the policy being adopted in this final rule interferes with the practice of medicine, but rather both policies address Medicare payment and medical review for purposes of Medicare payment. We believe that allowing greater flexibility for determining when an admission that does not meet the benchmark should nonetheless be payable is appropriate and is supported by several hospital organizations.

In response to the commenter who suggested that the proposed policy will likely be used by the QIOs and Recovery Auditors as a way to deny appropriate inpatient claims, we note that, under the proposed modification to the existing exceptions policy, we would allow Medicare Part A payment on a case-by-case basis for inpatient admissions that do not satisfy the 2-midnight benchmark, to acknowledge other patient-specific circumstances where certain admissions may nonetheless be appropriate for Medicare Part A payment. We would expect such circumstances to be supported in the medical documentation, which would be subject to medical review. Further, under the ''2-midnight presumption,'' inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are presumed to be appropriate for Medicare Part A payment and will not be the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption. We do not believe that the proposed policy will be used by any medical review contractors as a way to deny appropriate inpatient claims. Contractors are instructed to issue claim decisions that are consistent and compliant with all applicable policies and instructions, including the 2-midnight regulations.

In addition, we intend to educate all medical review entities, including the QIOs (who assumed responsibility of patient status reviews as of October 1, 2015), CERT contractor, Recovery Auditors, MACs, Supplemental Medical Review Contractor, and appeals contractors, of final policy changes and anticipate that the new policy will be interpreted consistently. CMS typically provides this type of education to its contractors through the use of interactive calls/clinical discussions or, as appropriate, technical direction. We also intend to continue to monitor our contractors through both internal and independent third party ''accuracy

reviews'' of the medical review decisions and will provide education to the review entities if areas of inconsistency in medical review decision-making or policy interpretation are identified.

In response to comments about the proposed policy increasing the appeals backlog, we believe the additional flexibility provided by the proposed policy could potentially result in fewer denials and therefore fewer appeals. The proposed policy would allow for claims that may have been denied under the previous rule to be paid if certain criteria are met, despite not meeting the 2-midnight benchmark. However, we do not anticipate a significant impact on the volume of appeals as a result of the proposed policy.

In response to the commenters' concern that the proposed policy would create an opportunity for gaming, we will continue to monitor hospital admission practices and look for any evidence of gaming. In the event that evidence of gaming is found, CMS will take appropriate action against that provider.

Comment: A number of commenters supported a proposal for a 1-midnight rule under which any Medicare beneficiary who required overnight hospital care (other than a patient in the ED or routine recovery following surgery or a procedure) would be admitted and the hospital paid by diagnosis related group (DRG) under Medicare Part A. The ''1-midnight rule'' proposal also called for the creation of an ''extended outpatient evaluation'' APC to replace outpatient observation, and for admission orders to become effective at midnight on the day the order was given, except in the case of late ED arrivals, for which the order would not be effective until the second midnight. These commenters also suggested that the admission order should not be required to be authenticated prior to discharge and instead recommended that it be authenticated prior to the claim being submitted. In addition, the ''1-midnight'' proposal suggested that the inpatient only list would no longer be necessary because any surgical patient who required a medically necessary overnight stay following routine recovery would be admitted and those patients who were stable before midnight post-surgery would be billed as outpatients. In addition, these commenters suggested that, in order to address more beneficiaries paying the inpatient deductible amount under the suggested 1-midnight rule, the inpatient deductible could be reduced such that a beneficiary would pay one-third of the deductible for the first night, two-thirds for two nights and the full inpatient deductible for three nights or more.

Response: While we appreciate this alternative policy option put forth by the commenters, we believe that a ''1-midnight rule'' would present several challenges. Generally, patients who are seen and appropriately treated and discharged without requiring an overnight stay in the hospital represent the lowest acuity patients receiving treatment in an HOPD. We are concerned that a ''1-midnight rule,'' as outlined by the commenters, could potentially create a negative incentive for hospitals to hold such low acuity patients in the hospital longer to receive higher inpatient payment under Medicare Part A and could be prone to gaming, especially in light of the suggested comments that would make changes to the inpatient order requirements. We believe that the ''1-midnight'' rule, as put forth by the commenters, would create opportunities for relatively low acuity patients who would otherwise not appropriately qualify for Medicare Part A payment, to potentially be eligible for Medicare Part A payment. We note that this is additionally troublesome due to the high volume of the aforementioned relatively low acuity patients currently treated in the hospital outpatient setting that could potentially be held in the hospital longer to receive higher inpatient payment under Medicare Part A.

In addition, this proposal could result in additional costs to the Medicare program as all overnight hospital stays (other than a patient in the ED or routine recovery following surgery or a procedure) would be newly eligible for Part A payment. In order to account for the additional costs that the program would incur under this approach, we might determine that it would be appropriate to make an even greater downward adjustment to payment rates than the original −0.2 percent adjustment currently in effect. We are not prepared to propose a further adjustment at this time, as we are still evaluating claims data to determine the impact of the original −0.2 percent adjustment. In addition, due to statutory differences in cost sharing under Medicare Part A versus Part B, the substantial influx of cases that would be newly eligible for Part A payment under this ''1-midnight rule'' proposal would potentially subject Medicare beneficiaries to greater cost-sharing requirements, as the inpatient deductible could be higher than the Part B copayment that would be applied if the services had been billed as outpatient services under Part B. The commenter's suggested fractional deduction of the inpatient deductible (one-third for 1 night, two-thirds for 2 nights, and the full deductible for a stay of 3 nights or more) is not permitted under existing statute.

In light of all of the challenges associated with this proposal for a 1-midnight rule, we are not accepting this alternative to our proposal. Moreover, as we did not propose any changes to our existing policy requiring a physician's order for hospital admission, the changes to that policy prescribed in this ''1-midnight rule'' proposal are outside the scope of the proposed rule.

Comment: Other commenters presented individual alternatives to the proposal such as: (1) CMS could eliminate the classification of hospital stays into observation or inpatient days and classify all medically necessary hospital stays on a hospital floor as inpatient stays; (2) CMS could automatically deem any beneficiary in a hospital setting, including emergency room or observation, an inpatient after 24 hours and cap beneficiary liability at the Part A inpatient deductible amount; (3) CMS could automatically deem any beneficiary in observation greater than 72 hours an inpatient and pay hospitals an MS–DRG payment; and (4) CMS could define an inpatient as a patient who requires a bed in a hospital beyond the normal recovery time or for extended testing that cannot be safely performed in a lower level of care outside the hospital, and could make certain related payment adjustments.

Response: While we appreciate the various alternatives to our proposal presented by the commenters, we note that all four of the alternative proposals would allow for an inpatient hospital admission without a signed physician order. It is our current policy that a hospital admission must be initiated by a signed physician order to admit the patient as an inpatient. We did not propose nor are we finalizing any changes to that policy at this time. Therefore, we are not accepting any of the individual alternatives to our proposal suggested by the commenters.

Comment: One commenter suggested that CMS (1) clarify that inpatient hospital admissions with expected lengths of stay less than 2 midnights are neither rare nor unusual; (2) reemphasize that inpatient care and observation services are not the same level of care and, therefore, inpatient hospital admissions are not appropriate as a substitute for lengthy (greater than 2 midnights) outpatient hospital stays; (3) allow the 2-midnight benchmark to serve exclusively as a medical review

threshold to determine the general appropriateness for claim payment; and (4) realign its policy with existing guidance by asserting that, regardless of the expected length of stay, documentation of the medical necessity as well as the need for inpatient hospital care is the requisite component of every inpatient admission appropriately paid under Medicare Part A.

Response: In light of this comment, we would like to clarify that our proposed modification to the current exceptions process does not define inpatient hospital admissions with expected lengths of stay less than 2 midnights as rare and unusual. Rather, it modifies our current ''rare and unusual'' exceptions policy to allow Medicare Part A payment on a case-by-case basis for inpatient admissions that do not satisfy the 2-midnight benchmark. This modification acknowledges other patient-specific circumstances where certain cases may nonetheless be appropriate for Part A payment, in addition to continuing to provide an opportunity for Part A payment in ''rare and unusual'' circumstances for which there is a national exception.

In addition, as previously stated in this final rule, we continue to expect it to be rare and unusual for a beneficiary to require inpatient hospital admission after having a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours and not at least overnight, and thus such admissions will be prioritized for medical review.

With respect to the comment about hospital level of care, we note that while we do not refer to ''level of care'' in guidance regarding hospital inpatient admission decisions, but, rather, have consistently provided physicians with the aforementioned time-based guidelines regarding when an inpatient hospital admission is payable under Part A, we do note that, by definition, there are differences between observation services furnished in the outpatient setting and services furnished to hospital inpatients. Specifically, observation services, as defined in Section 290 of Chapter 4 of the Medicare Claims Processing Manual, are a well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment, that are furnished while a decision is being made, regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital.

In response to the request that the 2-midnight benchmark be used exclusively for determining the appropriateness of Part A payment, we note that we continue to believe that the 2-midnight benchmark and the 2-midnight presumption are effective tools in determining general appropriateness for Medicare Part A payment and whether a claim should be subject to medical review, respectively. As stated earlier, we also believe that there may be other patient-specific circumstances where certain cases may nonetheless be appropriate for Part A payment, and, therefore, we will allow Medicare Part A payment on a case-by-case basis for inpatient admissions that do not satisfy the 2-midnight benchmark, if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care, despite an expected length of stay that is less than 2 midnights.

In response to the commenter's request that CMS realign its policy with existing guidance by asserting that regardless of the expected length of stay, documentation of the medical necessity, as well as the need for inpatient hospital care, are the requisite components of every inpatient admission appropriately paid under Medicare Part A, we note that, consistent with our longstanding policy, all inpatient admissions must be medically reasonable and necessary and be supported by documentation in the patient's medical record.

Comment: Commenters also commented on the following subject areas in their comments: Self-administered drugs; long observation stays; hospital admission orders; outpatient observation notice; and the 3-day inpatient stay requirement for Medicare skilled nursing facility (SNF) coverage.

Response: We did not include any proposals relating to these areas in the proposed rule. Therefore, we consider these comments to be outside the scope of the proposed rule and are not addressing them in this final rule.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to revise our previous ''rare and unusual'' exceptions policy to allow for Medicare Part A payment on a case-by-case basis for inpatient admissions that do not satisfy the 2-midnight benchmark, if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than 2 midnights. Accordingly, we also are finalizing our proposal to revise § 412.3(d) to reflect the above policy modification and to increase clarity.

C. Announcement Regarding Change in Medical Review Responsibilities

Shortly after adopting the 2-midnight rule, we instructed the MACs to engage in a Probe and Educate process under the 2-midnight rule from October 2013 through September 2015. We indicated in the CY 2016 OPPS/ASC proposed rule that, regardless of whether we finalize the policy proposals outlined under section XV.B. of this final rule with comment period, no later than October 1, 2015, we would be changing the medical review strategy and planned to have QIO contractors, rather than the MACs, conduct these reviews of short inpatient stays. Among the QIO's statutory duties is the review of some or all of the professional activities of providers and practitioners in the QIO's service area, subject to the terms of the QIO contracts, in the provision of health care items or services to Medicare beneficiaries. Such QIO reviews are for the purposes of determining whether providers and practitioners are delivering services that are reasonable and medically necessary, whether the quality of services meets professionally recognized standards of care, and, for inpatient services, whether the services could be effectively furnished on an outpatient basis or in a different type of inpatient facility. Section 1154(a)(1) of the Act authorizes QIOs to review whether services and items billed under Medicare are reasonable and medically necessary and whether services that are provided on an inpatient basis could be appropriately and effectively provided on an outpatient basis, while section 1154(a)(2) of the Act provides for payment determinations to be made based on these QIO reviews. Section 1154(a)(18) of the Act includes provisions that involve broad authority for the Secretary to direct additional activities by QIOs to improve the effectiveness, efficiency, economy, and quality of services under the Medicare program. These reviews are integral to the determination of whether items and services should be payable under the Medicare program.

In addition to the reviews to ensure coverage in accordance with Medicare standards under sections 1154(a)(1) and (a)(2) of the Act, QIO case review work is an effort to measurably improve the quality of health care for Medicare beneficiaries as well as all individuals protected under the Emergency Medical Treatment and Labor Act (EMTALA) and to provide peer review. QIOs have longstanding program experience in

addressing beneficiary complaints, provider-based notice appeals, violations of EMTALA, Higher Weighted Diagnosis Related-Group (HWDRG) coding reviews, and other related responsibilities as articulated in the Act. Further, in the performance of their current quality improvement activities and medical reviews, QIOs routinely collaborate and interact with State survey agencies, MACs, and Qualified Independent Contractors (QICs).

In addition to their expedited appeal and quality of care review expertise, QIOs currently perform both coding and medical necessity reviews. For example, when conducting HWDRG coding reviews, QIOs already analyze claims submitted by hospitals with proposed changes to billing codes that would allow the hospital to receive a higher weighted DRG payment for the care delivered. In these HWDRG reviews, QIOs ensure that the clinical circumstances in which the care was provided accurately matches the provider's claim for payment. Further in those instances when the HWDRG review involves a service provided during a short inpatient stay, QIOs also perform a corresponding medical review to validate adherence to the current 2-midnight policy. QIOs also currently perform reviews to confirm that all services and items provided were reasonable and medically necessary, consistent with section 1862(a)(1) or 1862(a)(9) of the Act.

As previously mentioned in this section, we are changing our medical review strategy for short hospital stays and will have QIO contractors conduct reviews of short inpatient stays. QIO contractors are well-suited to conduct these short-stay inpatient reviews because these reviews fit within the scope of the QIO statutory functions and because their quality improvement programs are aligned with the HHS' National Quality Strategy objective to provide ''better care and better health at lower cost.'' QIOs, by their design, are groups of regional and national health quality experts, clinicians, and consumers organized to improve the care delivered to people with Medicare. As indicated previously, QIOs manage a variety of beneficiary complaints and quality of care case reviews to ensure consistency in health care delivery and practice in the inpatient and outpatient setting while taking into consideration clinical practice guidelines and other local factors important to beneficiaries, providers, and practitioners, and the Department. These capabilities will be useful in making case-by-case review determinations.

To mitigate the perception of a potential conflict of interest between medical review and quality improvement functions of the QIOs, on August 1, 2014, the QIO program separated medical case review from its quality improvement activities in each State under two types of regional contracts. These include Beneficiary and Family Centered Care QIOs (BFCC–QIOs) contractors who perform medical case review, and Quality Innovation Network QIOs (QIN–QIOs) contractors who perform quality improvement activities and provide technical assistance to providers and practitioners. In addition, the restructured QIO program uses a non-QIO a contractor to assist CMS in the monitoring and oversight of the BFCC–QIO case review activities.

Under the new short-stay inpatient medical review process that we adopted beginning on October 1, 2015, BFCC–QIOs began to transition to reviewing a sample of post-payment claims and making a determination of the medical appropriateness of the admission as an inpatient. As mentioned earlier in this section, we continue to believe that when a beneficiary receives a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours (less than 24 hours), the services should generally be billed as outpatient hospital services, regardless of the hour the beneficiary comes to the hospital, whether he or she uses a bed, and whether he or she remains in the hospital past midnight (Section 10, Chapter 1 of the MBPM). Accordingly, we would expect it to be rare and unusual for a beneficiary to require inpatient hospital admission after having a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for a period of time that is only for a few hours and does not span at least overnight. We will monitor the number of these types of admissions and plan to prioritize these types of cases for medical review.

BFCC–QIOs have begun to conduct post-payment reviews of claims and refer findings to the MACs for payment adjustments. Providers' appeals of denied claims will be addressed under the provisions of section 1869 of the Act and procedures in 42 CFR part 405. BFCC–QIOs will educate hospitals about claims denied under the 2-midnight policy and collaborate with these hospitals in their development of a quality improvement framework to improve organizational processes and/or systems. Under the QIO short-stay inpatient review process, those hospitals that are found to exhibit a pattern of practices, including, but not limited to: Having high denial rates and consistently failing to adhere to the 2-midnight rule (including having frequent inpatient hospital admissions for stays that do not span one midnight), or failing to improve their performance after QIO educational intervention, will be referred to the Recovery Auditors for further medical review.

In addition to the formal QIO medical review process mentioned above, we intend to continuously monitor and evaluate the changes to the 2-midnight payment policy and medical review strategy. We will specifically examine and evaluate applicable claims data and any other data available in order to determine whether any patterns of case-by-case exceptions exist that might be appropriately announced as uniform, national exceptions, to examine the effect of the revised policy on short-stay inpatient claims and long outpatient observation stays, and to observe any other trends which might affect beneficiary access, outcomes, and quality of care. We also will monitor applicable data for signs of systematic gaming of this policy. We will continue to assess the 2-midnight payment policy in future years, and, as with all Medicare payment policies, may make future payment modifications based on the trends observed.

As mentioned earlier in this section, section 521 of Pub. L. 114–10 extended the prohibition on Recovery Auditor patient status reviews for claims with dates of admission of October 1, 2013 through September 30, 2015. Under current law, Recovery Auditors may resume such reviews for dates of admission of October 1, 2015 and later. CMS announced in August 2015 that it will not approve Recovery Auditors to conduct patient status reviews for dates of admission of October 1, 2015 through December 31, 2015. (We refer readers to the CMS Web site at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/InpatientHospitalReviews.html* for more information on this announcement.) As announced in the proposed rule, the Recovery Auditors will conduct patient status reviews focused on those providers that are referred from the QIOs based on their high denial rates. The number of claims that a Recovery Auditor will be allowed to review for patient status will be based on the claim volume of the hospital and the denial rate identified by the QIO. We stated in the proposed rule that we would adopt this new medical review strategy

regardless of whether the 2-midnight rule remains unchanged or is modified.

As stated earlier, one of the reasons we adopted the 2-midnight rule was because of concerns about the growing trend of long outpatient hospital stays. We note that preliminary data suggest that the 2-midnight rule as it relates to hospital stays spanning at least 2 midnights has been effective in reducing long outpatient hospital stays. Specifically, our data show that the proportion of outpatient long-stay encounters (more than 2 days) involving observation services decreased by 11 percent in FY 2014 compared to FY 2013. The trend in these data is consistent with our adoption of the 2-midnight rule on October 1, 2013.

As noted previously, we did not propose to change the 2-midnight presumption for purposes of medical review. That is, inpatient stays for which the patient remained in the hospital at least 2 midnights following formal admission to the hospital will continue to be presumed appropriate for inpatient hospital payment under Medicare Part A and will generally not be selected for medical review of patient status absent evidence of systematic gaming, abuse, or delays in the provision of care.

Comment: In response to whether CMS should adopt specific national criteria for medical review of inpatient hospital admissions, and what those criteria tools should be, several commenters stated that they would support criteria that took into consideration the severity of the signs and symptoms exhibited by the patient and other evidence that would be relevant in determining whether an inpatient admission that was shorter than 2 midnights would nonetheless be appropriate for Part A payment.

Several commenters did not believe that CMS should adopt national medical review standards at this time, given the differences in clinical presentation and individualized treatments for patients requiring hospital care. Other commenters suggested that medical review tools, such as InterQual or Milliman, were useful for documenting a patient's vital signs and condition at a moment in time, but would not be useful for retrospective review of the appropriateness of a hospital admission. The commenters also noted that these tools were expensive and proprietary for hospitals to use and that selection of one tool over another would impose administrative burdens on hospital facilities.

Some commenters recommended that QIO review criteria take into consideration special populations of patients, treatment locations within the hospital facility, or specific clinical situations generally considered to be at higher risk for adverse patient outcomes.

Response: We appreciate the thoughtful comments submitted in response to our comment solicitation on medical review criteria. However, even among those commenters who stated that they would support the adoption of national medical review criteria, we note that no commenters recommended specific national criteria that could be applied to medical review of all short-stay hospital cases. We agree with the commenters that, given the unique clinical circumstances of Medicare beneficiaries who require hospital care, it is difficult to adopt a set of clinical standards that are universally applicable based on diagnostic conditions and may be appropriately utilized on a retrospective basis. While we acknowledge that some providers may consider this type of commercial product useful in clinical practice, we are not adopting such guidelines as binding policy for medical review purposes. Rather, we believe that the 2-midnight benchmark captures the individualities and clinical conditions of Medicare beneficiaries, by focusing on the physician's medical judgment in forecasting an expected plan of care and corresponding hospital duration. Accordingly, we are not adopting national medical review criteria at this time.

QIOs will conduct ''Revised Determination Reviews'' (42 CFR 405.980) on hospital short-stay Medicare Part A claims. QIOs will conduct patient status reviews to determine the appropriateness of Medicare Part A payment for these short-stay inpatient hospital admissions, in accordance with section 1862(a)(1)(A) of the Act. In conducting these reviews, QIOs will use the information documented in the patient's medical record, and may use evidence-based guidelines and other relevant clinical decision support materials as components of their review activity (we refer readers to 42 CFR 476.100 relating to setting standards for QIO reviews).

Comment: One commenter suggested that CMS create a tracking mechanism, such as a condition code, to allow hospitals to attest that they used nationally recognized criteria (such as InterQual or Milliman) to determine that inpatient admission was warranted. Alternatively, one commenter proposed that CMS adopt an identifier to append to the claim which would alert the medical reviewers that an inpatient only procedure had been performed.

Response: We appreciate the thoughtful claims processing recommendations. Because we are not adopting a national set of criteria at this time, we do not believe a tracking mechanism to identify use of criteria tools would be helpful for hospitals or review entities. We acknowledge the difficulties in identifying inpatient only procedures during medical review (because inpatient only procedures are identified by the national code set used by hospital outpatient departments whereas inpatient claims are billed using a separate code set) and will consider the proposed resolution in the future.

Comment: Several commenters supported the QIO medical review strategy. However, many commenters urged CMS to delay QIO medical review activity until January 1, 2016, or later, to align with the new policy that would be adopted for CY 2016. Other commenters expressed concern whether the QIOs had the needed operational resources, such as review staff qualifications and experience, training, electronic record transfer capability, and MAC points of contact, to competently conduct the reviews. One commenter stated the need for timeliness measures associated with the review process.

Response: As stated in the proposed rule, we announced that the QIOs would begin to conduct medical review on October 1, 2015, regardless of whether we finalized the policy proposals articulated in the proposed rule. Accordingly, QIOs assumed responsibility for medical review activities on October 1, 2015, as it relates to the 2-midnight rule that is currently in effect. We anticipate that it will take time for QIOs to transition and they will incrementally increase their review activities to be fully operational with regard to these reviews early next year. Beginning January 1, 2016, QIOs will conduct medical review of short hospital stay claims under the revised 2-midnight policy adopted in this final rule with comment period.

Comment: Several commenters stated the need for transparency and for more detailed information regarding the types of claims that would be subject to QIO review, claim sample sizes, the frequency of reviews, the claim look back periods, ADR limits, and administrative burden.

Response: We will address the technical medical review questions posed by commenters in subregulatory guidance. We expect to release this information on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/*

index.html?redirect=/qualityimprovementorgs/ no later than December 31, 2015.

Comment: Several commenters recommended that CMS provide education and detailed information regarding the revised medical review criteria and documentation requirements. One commenter recommended mandatory documentation instruction for physicians in residency programs because Medicare funds graduate medical education programs.

Response: QIOs have a longstanding history of provider education and engagement, through the use of provider meetings, learning and action networks, provider discussion forums, and posting educational materials to their Web sites. QIOs may use these and other methods to educate providers about the review process. We will address technical medical review questions posed by commenters in subregulatory guidance. We expect to release this information on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html?redirect=/qualityimprovementorgs/* no later than December 31, 2015.

Comment: Some commenters recommended that the QIOs provide a discussion period prior to making referral to the MACs or Recovery Auditors.

Response: After conducting medical review, QIOs will evaluate provider performance and provide interventions that are aligned with those outcomes. Every provider will receive written claim-specific information and any corresponding denial reasons that will give the provider the opportunity to review the QIO's claim decision. The written notification will include a specific phone number and/or point of contact for use by providers to request or schedule a QIO education session.

Through the QIO education session, providers will have the opportunity to have one-on-one telephonic conferences to ask questions and receive feedback with a QIO clinician knowledgeable of the reviewed claims. After the education session, the QIO will provide a final results letter to the provider. At the completion of these activities, the QIO will refer any denied claims to the MAC for payment adjustment and, when appropriate, make a referral to the Recovery Auditors for those providers requiring further review.

Comment: Several commenters supported transitioning hospital patient status reviews to the QIOs, while directing Recovery Auditors to limit their patient status reviews to those providers with ''high denial rates.'' Tailoring the scope of Recovery Auditor reviews aligns with MedPAC's recommendation in its June 2015 report, which suggested that the extent of audits be correlated with a hospital's excessive use of short inpatient stays.

Other commenters expressed concerns that the standard to which claims would be assessed was unclear, and that the Recovery Audit Program's contingency fee payment structure could potentially incentivize inappropriate claim denials, making such referrals inappropriate.

Many commenters stated the need for transparency in the medical review process and requested additional information regarding clinical decision-making, as well as QIO operations and the process for identifying providers deemed to be appropriate for Recovery Auditor referral.

Response: We will address technical medical review questions posed by the commenters in subregulatory guidance. We expect to release this information on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html?redirect=/qualityimprovementorgs/* no later than December 31, 2015.

Comment: A few commenters suggested that, in the QIO's assessment and measurement of provider denial rates, factors such as the number of short-stay inpatient admissions occurring within a given hospital and the acuity of populations served by the hospital be taken into consideration. One commenter recommended that QIOs implement or use a review test period in order to any identify national trends in provider denials.

Response: We will address technical medical review questions posed by the commenters in subregulatory guidance. We expect to release this information on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html?redirect=/qualityimprovementorgs/* no later than December 31, 2015.

After consideration of the public comments we received, we are not adopting national medical review criteria at this time. As announced in the proposed rule, QIOs assumed medical review responsibilities of short hospital stay claims on October 1, 2015 based on the existing 2-midnight policy in effect for 2015. Beginning on January 1, 2016, QIOs will conduct these medical reviews based on the revised 2-midnight policy adopted in this final rule with comment period. In conducting these reviews, QIOs will use the information documented in the patient's medical record, and may use evidence-based clinical guidelines, and other relevant clinical decision support materials as components of their review activity in order to determine whether an inpatient admission where the patient stay is expected to be less than 2 midnights is nonetheless appropriate for Medicare Part A payment.

As mentioned previously, in response to industry feedback, including suggestions to limit the Recovery Audit Program, on December 30, 2014, we announced a number of changes to the Recovery Audit Program. We received numerous comments about the Recovery Audit Program and have summarized and included our responses to them below.

Comment: Several commenters responded to the proposed rule's announcements related to the changes to be implemented in the Recovery Audit Program and the Recovery Auditor's role in conducting patient status reviews of those providers referred by the QIOs for having high denial rates associated with hospital short stay claims for payment. Several commenters also provided additional recommendations for programmatic improvement or requested more information regarding the operational details of the Recovery Audit medical review processes. In addition, some commenters recommended delays in the proposed timeframe for Recovery Auditors to begin conducting patient status reviews.

Response: We note that, while we consider these public comments to be outside the scope of the proposed rule, we appreciate the thoughtful feedback provided for our consideration. Providers wishing to provide any additional suggestions or feedback may do so by emailing them to *RAC@cms.hhs.gov.* Any future changes or additional information related to the Recovery Audit Program would be identified through subregulatory instruction and posted on the Recovery Audit Program Web site at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/.*

Comment: Some commenters recommended that enforcement of the 2-midnight provision remain under the purview of the Recovery Auditors, as it is a payment provision, rather than a quality improvement activity.

Response: We consider these public comments to be outside the scope of the

proposed rule because we neither proposed nor sought comments on the announced changes in medical review activities. However, we point out that QIOs have previous experience in hospital reviews, and we believe their positive working relationships with hospitals will be beneficial in helping to educate providers on how to comply with the revised 2-midnight rule guidance. Recovery Auditors will review those providers that fail to comply with CMS' payment policy and, as appropriate, send claims to the MAC for adjustment.

Comment: One commenter mentioned the positive experiences it has had with the Provider Relations Coordinator established by CMS in June 2014, and suggested that the role of the coordinator would be well-suited to assist providers in the implementation of the new referral structure.

Response: We consider this comment to be outside the scope of the proposed rule. However, we appreciate the suggestion and will consider the feedback in the future. We encourage providers to utilize the Provider Relations Coordinator and support expanding this role throughout the medical review process.

D. Comment Solicitation on Potential Short-Stay Payment Policies

We again welcomed stakeholder comments on potential short-stay payment policies. The most frequent comment received in response to the proposed rule was that a 1-midnight policy would eliminate the need for a short-stay payment policy. Comments on the issue of short stay payment policies ranged from paying the IPPS amount to paying an amount in between the IPPS and OPPS payment to paying the OPPS amount. Most commenters did not provide specifics as to how the payment amount should be determined. As in past comment solicitations on this issue, there was again no consensus among the commenters who chose to respond.

We have requested public comment on three different occasions on issues related to when services are appropriately billed and paid under Medicare Part A as inpatient services or under Medicare Part B as outpatient services, including potential payment policy options to address this issue. The public comment process has not produced any consensus on a recommended payment policy.

We again thank the commenters for their suggestions on the issue of short-stay payment policies. We did not propose any short-stay payment policy, but will take these comments into account in any potential future rulemaking on the issue.

XVI. Transition for Former Medicare-Dependent, Small Rural Hospitals (MDHs) Under the Hospital Inpatient Prospective Payment System

A. Background on the Medicare-Dependent, Small Rural Hospital (MDH) Program

Section 1885(d)(5)(G) of the Act provides special payment protections under the hospital inpatient prospective payment system (IPPS) to Medicare-dependent, small rural hospitals (MDHs). Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not a sole community hospital (SCH), and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges either in its 1987 cost reporting year or in 2 of its most recent 3 settled Medicare cost reporting years). MDHs are paid for their hospital inpatient services based on the higher of the Federal rate or a blended rate based, in part, on the Federal rate and, in part, on the MDH's hospital-specific rate. Specifically, the blended rate is calculated using the Federal rate payment plus 75 percent of the amount by which the Federal rate payment is exceeded by the MDH's hospital-specific rate payments. For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50022), under prior law, as specified in section 5003(a) of Pub. L. 109–171 (DRA 2005), the MDH program was to be in effect through the end of FY 2011 only. The program has since been extended several times. Most recently, section 205 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015, provided for an extension of the MDH program through FY 2017. Specifically, section 205 of the MACRA amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act by striking the April 1, 2015 end date for the MDH program and replacing it with October 1, 2017.

B. Implementation of New OMB Delineations and Urban to Rural Reclassification

On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas (MSAs), Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. These delineations are based on 2010 decennial Census data. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49991), we adopted the new OMB labor market area delineations beginning in FY 2015. Consequently, there were 105 counties that were previously located in rural areas that became urban under the new OMB delineations (79 FR 49953). As noted above, under section 1886(d)(5)(G)(iv) of the Act, an MDH must be located in a rural area.

The transition of certain counties from rural to urban under the new OMB delineations required MDHs in those counties to apply for rural status in order to retain their MDH classifications and avoid losing the special payment protections provided to MDHs. In order to be approved for a rural reclassification, a hospital that is located in an urban area must meet one of the following four criteria under section 1886(d)(8)(E)(ii) of the Act (codified at 42 CFR 412.103):

(1) The hospital is located in a rural census tract of an MSA, as determined under the most recent version of the Goldsmith Modification, the Rural-Urban Commuting Area (RUCA) codes;

(2) The hospital is located in an area designated by any law or regulation of such State as a rural area or is designated by such State as a rural hospital;

(3) The hospital would qualify as a rural referral center (RRC) or a sole community hospital (SCH) if the hospital were located in a rural area; and

(4) The hospital meets such other criteria as the Secretary may specify.

In addition, under section 1886(d)(8)(E) of the Act, in order for a hospital to reclassify from an urban area to a rural area, the State in which the hospital is located must have a rural area. In other words, a hospital may not reclassify from urban to rural under section 1886(d)(8)(E) of the Act in an all-urban State, which, as of October 1, 2014 (when the new OMB delineations became effective), included New Jersey, Delaware, and Rhode Island. Currently, the all-urban States continue to be New Jersey, Delaware, and Rhode Island.

MDHs that shifted from rural to urban under the new OMB delineations may apply for rural reclassification under § 412.103. In a situation where a hospital could not reclassify to a rural area under § 412.103 because it is now located in an all-urban State, the hospital would have lost its MDH status and would be paid for hospital inpatient

services at the Federal rate, which may be substantially lower than the MDH's hospital-specific rate. Given that the MDH program was scheduled to expire April 1, 2015, but was extended to expire effective October 1, 2017 by section 205 of the MACRA, we stated in the CY 2016 OPPS/ASC proposed rule (80 FR 39354) that we believe it would be appropriate to provide a prospective payment rate transition period for MDHs that cannot retain such status due to their location in a newly redesignated urban area located in an all-urban State and, therefore, the lack of a rural area within their State into which they could reclassify.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39354), we proposed that, effective January 1, 2016, payments to hospitals that lost their MDH status because they are no longer in a rural area due to the adoption of the new OMB delineations and are now located in all-urban States would transition from payments based, in part, on the hospital-specific rate to payments based entirely on the Federal rate. As stated earlier, currently, an MDH receives the higher of the Federal rate or the Federal rate payment plus 75 percent of the amount by which the Federal rate payment is exceeded by its hospital-specific rate payment. We proposed that, for discharges occurring on or after January 1, 2016, and before October 1, 2016, a former MDH in an all-urban State would receive the Federal rate plus two-thirds of 75 percent of the amount by which the Federal rate payment is exceeded by its hospital-specific rate payment. For FY 2017, that is, for discharges occurring on or after October 1, 2016, and before October 1, 2017, we proposed that such a former MDH would receive the Federal rate plus one-third of 75 percent of the amount by which the Federal rate payment is exceeded by the hospital's hospital-specific rate. Beginning FY 2018, that is, for discharges occurring on or after October 1, 2017, we proposed that these former MDHs would be paid solely based on the Federal rate. Payment based on 100 percent of the Federal rate beginning October 1, 2017 would align with the statutory expiration of the MDH program on October 1, 2017.

We stated in the proposed rule that we believe it is appropriate to apply these proposed transitional payments for hospitals formerly located in rural areas and formerly classified as MDHs that are now located in all-urban States, given the potentially significant payment impacts for these hospitals and the fact that a hospital may not reclassify from urban to rural under section 1886(d)(8)(E) of the Act in an all-urban State. Allowing a transition for such hospitals from payments based, in part, on the hospital-specific rate to payments based solely on the Federal rate would minimize the negative impact of our adoption of the new OMB delineations which caused certain rural hospitals to lose their MDH status.

We invited public comments on our proposal.

Comment: Commenters supported the proposed payment transition for former MDHs in all-urban States. One commenter stated that CMS' proposal would provide a much needed transition period for hospitals losing MDH status due to location in all-urban States and would be consistent with longstanding CMS policy to adopt transition periods to mitigate significant payment impacts accompanying policy changes.

Response: We appreciate the commenters' support of our proposal.

Comment: One commenter who supported the proposed transition urged CMS to also provide such a transition to all hospitals that lost MDH status as a result of implementation of the new OMB delineations which, for reasons other than location in an all-urban State, were ineligible for reclassification. The commenter noted that only one MDH was located in an all-urban State following implementation of the new OMB delineations, and that being in an all-urban State is only one reason why a hospital cannot qualify for reclassification under § 412.103 of the regulations. The commenter stated that the other hospitals that cannot reclassify under § 412.103, if not provided with a transition period, face the same circumstances that CMS is proposing to allow other identically situated hospitals to avoid. The commenter argued that providing payment transition exclusively for that one hospital and not for all hospitals that are similarly unable to reclassify to a rural area to maintain MDH status is arbitrary and capricious. The commenter also questioned why CMS did not provide similar protection for FY 2015 for MDHs repositioned from rural to urban areas as a result of implementation of the new OMB delineations that could not qualify for reclassification under § 412.103 when that protection was requested in public comments submitted in response to the FY 2015 IPPS/LTCH PPS proposed rule.

Response: Our rationale behind our proposal to allow for transitional payment to former MDHs that are located in all-urban States due to the adoption of the OMB delineations in FY 2015 was that these hospitals did not have the option to reclassify from urban to rural under the regulations at § 412.103 due to the lack of a rural area in their States into which they could reclassify. This is in contrast to other hospitals that lost MDH status due to becoming urban and are located in States with both urban and rural areas in that these hospitals have the option to apply for rural reclassification under § 412.103. We acknowledge that, in response to the FY 2015 IPPS/LTCH PPS proposed rule, this same commenter requested that hospitals losing MDH status as a result of becoming urban under the new OMB delineations be afforded the 2-year transition period of deemed rural status provided for CAHs. In the FY 2015 IPPS/LTCH PPS final rule, we explained that we did not believe that applying a 2-year transition period of deemed rural status was necessary for provider types other than CAHs (79 FR 49983). While we agreed that there were potential payment consequences for a CAH, SCH, or MDH located in an urban area as a result of the new OMB delineations, we considered the payment consequences to be greater for CAHs because, unlike SCHs and MDHs, CAHs are entirely excluded from the IPPS and generally receive payments based on 101 percent of reasonable cost. We stated that, in addition, given the different conditions of participation (CoPs) for CAHs, and that it would be generally more difficult for a CAH to have to meet the hospital CoPs instead of the CAH CoPs, only a CAH also faces the potential loss of its ability to continue to participate in the Medicare and Medicaid programs. Furthermore, we note that, at the time of the FY 2015 IPPS/LTCH PPS final rule, the MDH program was set to expire halfway through FY 2015, on March 31, 2015. However, after consideration of this public comment and due to the fact that the MDH program has been extended through FY 2017, we believe it is appropriate to apply a transition payment to all newly urban, former MDHs. We recognize that, regardless of whether the option to apply for reclassification is available to a hospital that lost MDH status as a result of becoming urban due to implementation of the new OMB delineations in FY 2015, a hospital that cannot reclassify from urban to rural for any reason may face financial hardship as a result of losing MDH status. This would be the case if the hospital was in an all-urban State without a rural area into which it could reclassify or if the hospital could not meet the requirements for rural reclassification under § 412.103. We also note that the regulations for rural

reclassification under § 412.103 do not allow MDHs, in contrast to rural referral centers (RRCs) and SCHs, to be approved for reclassification by virtue of meeting the requirements for MDH status other than being located in a rural area. For these reasons, and after consideration of the public comments we received, we are finalizing our proposed payment transition to former MDHs with a modification. We are providing for a transition for all former MDHs now located in an urban area as a result of implementation of the new OMB delineations in FY 2015 and that have not reclassified to a rural area under the regulations at § 412.103 by January 1, 2016. We believe that this expanded payment transition will help ensure financial stability and uninterrupted patient care for all hospitals that lost MDH status due to implementation of the new OMB delineations.

Comment: One commenter supported CMS' proposal for transition payments for MDHs but encouraged CMS to retroactively extend the transition payments for the entire FY 2016 rather than beginning January 1, 2016. The commenter pointed to the various extensions of the MDH program as examples of situations where CMS has implemented the law retroactively.

Response: We appreciate the commenter's request to extend the transition period to include all of FY 2016. However, we note that the various extensions of the MDH program referred to by the commenter as an example of a retroactive implementation are distinguishable from our proposal because the MDH extensions were mandated by statute. Therefore, we are finalizing the time period for the transition as proposed, beginning January 1, 2016.

Comment: One commenter questioned the impact estimate of $9 million for the proposed transition payments and requested clarification of CMS' methodology.

Response: After further examination of the data and the methodology upon which we based our impact estimate, we found that the $9 million estimated cost of the proposed transition payments included in the proposed rule was overstated because we did not account for the fact that the transition period would be effective beginning the second quarter of FY 2016 (that is, on January 1, 2016), and would not include 12 months of transition payments. We refer the reader to section XXI.A.4.g. of this final rule with comment period for an updated estimated impact that reflects 9 months of MDH transition payments in the first year of the transition, as finalized above, and a description of the methodology used to calculate that estimate.

In summary, after consideration of the public comments we received, we are finalizing a policy that, effective January 1, 2016, payments to hospitals that (1) lost their MDH status because they are no longer in a rural area due to the implementation of the new OMB delineations in FY 2015 and (2) have not reclassified from urban to rural under the regulations at § 412.103 before January 1, 2016, will transition from payments based, in part, on the hospital-specific rate to payments based entirely on the Federal rate. For discharges occurring on or after January 1, 2016, and before October 1, 2016, these former MDHs will receive the Federal rate plus two-thirds of 75 percent of the amount by which the Federal rate payment is exceeded by the hospital's hospital-specific rate payment. For FY 2017, that is, for discharges occurring on or after October 1, 2016, and before October 1, 2017, these former MDHs will receive the Federal rate plus one-third of 75 percent of the amount by which the Federal rate payment is exceeded by the hospital's hospital-specific rate. For FY 2018, that is, for discharges occurring on or after October 1, 2017, these former MDHs will be paid based solely on the Federal rate.

XVII. Final Rule: Appropriate Claims in Provider Cost Reports; Administrative Appeals by Providers and Judicial Review

A. Proposed Changes Included in the FY 2015 IPPS/LTCH PPS Proposed Rule

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28206 through 28217; CMS–1607–P), we proposed to revise the Medicare cost reporting regulations in 42 CFR part 413, subpart B, by requiring a provider to include an appropriate claim for a specific item in its Medicare cost report in order to receive or potentially qualify for Medicare payment for the specific item. If the provider's cost report does not include an appropriate claim for a specific item, we proposed that payment for the item will not be included in the notice of program reimbursement (NPR) issued by the Medicare administrative contractor (MAC) (formerly known as fiscal intermediary and herein referred to as ''contractor'') or in any decision or order issued by a reviewing entity (as defined in 42 CFR 405.1801(a)) in an administrative appeal filed by the provider. In addition, we proposed to revise the appeals regulations in 42 CFR part 405, subpart R, by eliminating the requirement that a provider must include an appropriate claim for a specific item in its cost report in order to meet the dissatisfaction requirement for jurisdiction before the Provider Reimbursement Review Board (Board). The proposal also specified the procedures for Board review of whether the provider's cost report meets the proposed substantive reimbursement requirement of an appropriate cost report claim for a specific item. We also proposed technical revisions to other Board appeals regulations to conform those regulations to the main revisions (described above) to the cost reporting regulations and the provider appeals regulations, and proposed similar revisions to the Part 405, Subpart R regulations for appeals before the contractor hearing officers.

We received numerous public comments in response to our proposals to revise the Medicare cost reporting and provider appeals regulations. Commenters raised concerns about the breadth of the proposed provisions and questioned the interpretations we provided in the preamble to the FY 2015 IPPS/LTCH proposed rule. To allow us proper time to evaluate and respond to most of these public comments, in the FY 2015 IPPS/LTCH PPS final rule, we decided to finalize only certain related general provisions and to address the more specific public comments at a later time, in a subsequent rulemaking document, as appropriate. In section XVII.B. of this final rule, we summarize the changes we made in the FY 2015 IPPS/LTCH PPS final rule. In section XVII.C. of this final rule, we discuss the various provisions of the FY 2015 IPPS/LTCH PPS proposed rule that we did not include in the FY 2015 IPPS/LTCH PPS final rule, present summaries of the public comments we received and our responses to those comments, and specify our finalized policies.

B. Summary of Related Changes Included in the FY 2015 IPPS/LTCH PPS Final Rule

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50199 through 50201), we made related revisions to the provider appeals regulations that were, or were not, included in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28206 through 28217), as follows:

- In the FY 2015 IPPS/LTCH PPS proposed rule, we proposed to conform the terminology in Part 405, Subpart R and all subparts of Part 413 from ''intermediary'' or ''fiscal intermediary'' to ''contractor'' pursuant to sections 1816, 1874A and 1878 of the Act. We did not receive any public comments on our proposal. Therefore, we finalized

our proposal in the FY 2015 IPPS/LTCH PPS final rule.

• We revised § 405.1835 of the regulations to eliminate provider dissatisfaction as a requirement for Board jurisdiction over appeals based on untimely contractor reimbursement determinations. This revision was simply a technical correction to amend § 405.1835 to conform the regulations to the provisions in section 1878(a)(1)(B) of the Act for Board appeals based on an untimely contractor determination. In effect, this amendment to § 405.1835 restored the full conformity of the regulations with the statutory requirements for Board jurisdiction over appeals based on untimely contractor determinations—a conformity that obtained before a 2008 final rule (73 FR 30190) inadvertently imposed a provider dissatisfaction requirement for Board appeals based on untimely contractor determinations. Moreover, in order to maintain consistency between the regulations for Board appeals and the rules for contractor hearing officer appeals, we also revised § 405.1811 of the regulations to eliminate provider dissatisfaction as a requirement for contractor hearing officer jurisdiction over appeals based on untimely contractor determinations.

We found good cause to waive notice-and-comment rulemaking requirements under section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)) for these revisions because the revisions were simply technical corrections that brought § 405.1835 of the Board appeals regulations into full conformity with section 1878(a)(1)(B) of the Act, and maintained consistency between § 405.1811 of the contractor hearing officer appeals regulations and § 405.1835 of the Board appeals regulations. The revisions did not represent changes in policy, nor did they have a substantive effect, and the public interest was best served by timely correction of these technical errors.

The technical correction to § 405.1835 of the Board appeals regulations and the corresponding revision to § 405.1811 of the contractor hearing officer appeals regulations apply to appeals, based on an untimely contractor determination, that were pending or filed on or after the October 1, 2014 effective date of the FY 2015 IPPS/LTCH PPS final rule. These revisions also apply, subject to the rules of administrative finality and reopening in § 405.1807 and § 405.1885 of the regulations, to appeals pending or filed on or after the August 21, 2008 effective date of the 2008 final rule (73 FR 30190). We determined that fixing the applicability date, subject to the rules of administrative finality and reopening in § 405.1807 and § 405.1885 of the regulations, of these amendments by reference to the August 21, 2008 effective date of the 2008 final rule, was not impermissibly retroactive in effect because the amendments simply corrected and clarified longstanding agency policy and practice, and were procedural in nature. We explained that if the above-described amendments to § 405.1811 and § 405.1835 were deemed a retroactive application of a substantive change to a regulation, section 1871(e)(1)(A) of the Act permits retroactive application of a substantive change to a regulation if the Secretary determines that such retroactive application is necessary to comply with statutory requirements or that failure to apply the change retroactively would be contrary to the public interest. We determined that any retroactive application of these amendments to § 405.1811 and § 405.1835 was necessary to ensure full compliance with the statutory provisions for Board appeals based on untimely contractor determinations (under section 1878(a)(1)(B) of the Act), and that it was in the public interest to apply these amendments, subject to the rules of administrative finality and reopening in § 405.1807 and § 405.1885 of the regulations, to Board appeals and contractor hearing officer appeals that were initiated or pending on or after the August 21, 2008 effective date of the 2008 final rule.

C. Specific Provisions of the FY 2015 IPPS/LTCH PPS Proposed Rule

We have completed our consideration of the public comments on the proposed revisions to the cost reporting regulations and the provider appeals regulations in the FY 2015 IPPS/LTCH PPS proposed rule cited in section XVII.A. of this final rule. Below we present appropriate background for and summaries of each proposed provision, respond to the public comments on those proposals, and explain our finalized policies for the revisions that we are adopting in this final rule. We refer readers to the specified sections of the FY 2015 IPPS/LTCH proposed rule for a more extensive description of the proposals that were contained in the proposed rule.

1. Background for Payments and Cost Reporting Requirements

For cost reporting years beginning before October 1, 1983, all providers were reimbursed on a reasonable cost basis for Medicare Part A (hospital insurance) covered items and services that were furnished to Medicare beneficiaries. Reasonable cost is defined at section 1861(v)(1)(A) of the Act and implementing regulations at 42 CFR part 413. In the Social Security Amendments of 1983 (Pub. L. 98–21), Congress added section 1886(d) to the Act, which, effective with cost reporting periods beginning on or after October 1, 1983, changed the payment method for inpatient hospital services furnished by short-term acute care hospitals to a prospective payment system (PPS). In accordance with section 1886(d) of the Act and implementing regulations at 42 CFR part 412, a PPS payment is made at a predetermined specific rate for each hospital discharge (classified according to a list of diagnosis-related groups (DRGs)), excluding certain costs that are paid on a reasonable cost basis.

Later statutory amendments expanded the types of providers and services that are subject to a PPS. The various PPSs for inpatient hospital services are summarized in § 412.1 of the regulations. Other PPSs for different types of providers and services are summarized in §§ 413.170, 413.300, 413.330, and 419.1 of the regulations. As explained in § 413.1(b) of the regulations, if a service is not subject to a PPS when it is furnished, the provider is paid on the basis of reasonable cost. (For ease of reference, we will use the terms ''reimbursement'' and ''payment'' interchangeably unless a particular context calls for the use of one of these terms instead of the other.)

Before October 1, 2005, payments to providers were ordinarily made through private organizations known as fiscal intermediaries, under contracts with the Secretary. Section 1874A of the Act, as enacted by section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, authorized the Secretary to enter into contracts with entities known as MACs. After a 6-year transition period (§ 421.400(a)), the claims processing and payment functions of the fiscal intermediaries are now performed by MACs, under contracts with the Secretary.

For covered items and services paid on a reasonable cost basis, the contractor pays a provider during its cost reporting period interim payments that approximate the provider's actual costs. Under a PPS, providers are generally paid for each patient discharge after a bill is submitted.

Sections 1815(a) and 1833(e) of the Act provide that no payments will be made to a provider unless it has furnished the information, requested by the Secretary, needed to determine the amount of payments due the provider under the Medicare program. In general,

providers submit this information through annual cost reports that cover a 12-month period of time.

All providers participating in the Medicare program are required under § 413.20(a) to maintain sufficient financial records and statistical data for proper determination of costs. Moreover, providers must use standardized definitions and follow accounting, statistical, and reporting practices that are widely accepted in the hospital and related fields. Under the provisions of §§ 413.20(b) and 413.24(f), providers are required to submit cost reports annually, with the reporting period based on the provider's accounting year. For cost years beginning on or after October 1, 1989, section 1886(f)(1) of the Act and § 413.24(f)(4) of the regulations require hospitals to submit cost reports in a standardized electronic format, and the same requirement was later imposed for other types of providers. In addition, § 412.52 of the regulations requires all PPS hospitals to meet the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, which include the requirement that the provider must submit a cost report that generally covers a 12-month period of the provider's operations.

2. Background for Administrative Appeals by Providers and Judicial Review

Upon receipt of a provider's cost report, the contractor reviews or audits the cost report, makes any necessary adjustments to the provider's Medicare reimbursement for the cost reporting period, and finally determines the total amount of payment due the provider. This year-end reconciliation of Medicare payment for the provider's cost reporting period constitutes a contractor determination, as defined in § 405.1801(a). Under §§ 405.1801(a)(1) and (a)(2) and 405.1803, the contractor must give the provider written notice of the final contractor determination for the cost period in a notice of the total amount of program reimbursement. This notice, the NPR, is an appealable determination, and the contractor determination is final and binding unless it is revised on appeal or reopening (§ 405.1807).

Under section 1878(a) of the Act, a provider that has submitted a timely cost report may appeal to the Board a final determination of program reimbursement made by a contractor, as well as certain final determinations by the Secretary involving payment under the IPPS. The Secretary's delegate, the Administrator of CMS, may review certain Board decisions under section 1878(f)(1) of the Act and § 405.1875 of the regulations. The final decision of the Board or the Administrator is subject to judicial review under section 1878(f)(1) of the Act and § 405.1877 of the regulations. In addition, by regulation, providers are given the right to appeal to the Board or to contractor hearing officers certain other determinations. A CMS reviewing official may review some contractor hearing officer decisions under § 405.1834 of the regulations, but there is no judicial review of decisions by contractor hearing officers or a CMS reviewing official.

Under section 1878(a)(1)(A), (a)(2), and (a)(3) of the Act, and § 405.1835(a) of the regulations, a provider may obtain a Board hearing on a final contractor or Secretary determination if: (1) The provider is ''dissatisfied'' with a final determination of the contractor or the Secretary; (2) the amount in controversy is at least $10,000; and (3) the provider files a request for a hearing to the Board within 180 days of notice of the final determination of the contractor or the Secretary. The same jurisdictional requirements govern provider appeals to contractor hearing officers under § 405.1811(a) of the regulations, except that the amount in controversy requirement is at least $1,000 but less than $10,000. Under section 1878(a)(1)(A), (a)(3), and (b) of the Act and §§ 405.1835(a) and 405.1837(a) of the regulations, the same jurisdictional requirements also apply to group appeals to the Board, except the amount in controversy for a group appeal is at least $50,000.

However, as explained in section XVII.B. of this final rule, the statutory requirements for Board jurisdiction are somewhat different if the provider does not receive a final determination of the contractor on a timely basis. Under sections 1878(a)(1)(B), (a)(2), (a)(3), and (b) of the Act, a provider may obtain a Board hearing if: (1) The provider does not receive a final determination of the contractor on a timely basis, after the provider filed a cost report that complied with the cost reporting regulations; (2) the amount in controversy is at least $10,000 (at least $50,000 for a group appeal); and (3) the provider files a request for a hearing to the Board within 180 days after notice of the contractor's final determination would have been received if such contractor determination had been issued on a timely basis. Moreover, § 405.1835(c)(1) of the regulations (as amended in the FY 2015 IPPS/LTCH PPS final rule) provides that a contractor determination is not timely if it is not issued, through no fault of the provider, within 12 months of the contractor's receipt of the provider's perfected cost report or amended cost report (as specified in § 413.24(f) of the regulations). The same jurisdictional requirements govern provider appeals to contractor hearing officers, based on an untimely contractor determination, under § 405.1811(c) (as amended in the final FY 2015 IPPS/LTCH PPS final rule), except that the amount in controversy requirement is at least $1,000 but less than $10,000.

3. Background for Appropriate Claims in Provider Cost Reports

Under longstanding Medicare policy as set forth in § 413.24 of the regulations and Section 115 of the Provider Reimbursement Manual (PRM), Part 2 (CMS Pub. 15–2), a provider must make an appropriate cost report claim for a specific item in order to be reimbursed for the item, whether through the NPR issued by the contractor or as the result of an administrative appeal or judicial review. For example, as set forth in § 413.24, providers receiving payment on the basis of reimbursable cost are required to provide adequate cost data to the contractor to support payments made for services furnished to beneficiaries. In addition, as set forth in Section 115 of the PRM, Part 2, we require that providers make a specific claim for an item in its cost report, in order to meet the dissatisfaction requirement for Board jurisdiction. The Medicare cost report has always included particular ''lines'' for specific allowable costs such as interest expense and depreciation. If a provider makes a cost report claim for a cost that is allowable, and reimbursement is claimed in accordance with Medicare payment policy, the NPR will include appropriate reimbursement for the cost. (For ease of reference, we use the terms ''specific item'' or ''item'' to refer to a particular aspect of reasonable cost-based payment or a specific aspect of payment under a PPS unless a particular context calls for the use of more specific terms (for example, the term ''allowable cost'' as used in determining reasonable cost-based payment).)

If the NPR does not include reimbursement for a specific item claimed in the cost report or if the provider believes it should have received more reimbursement for the item, the provider can request a hearing before the Board (if the amount in controversy is at least $10,000) or the contractor hearing officers (if the amount in controversy is at least $1,000 but less than $10,000). However, our longstanding policy is that an appropriate cost report claim is a

jurisdictional requirement for an appeal to the Board or the contractor hearing officers. As explained earlier, section 1878(a)(1)(A) of the Act provides for a hearing before the Board if the provider has filed a timely cost report with the contractor, and the provider is ''dissatisfied'' with a final determination of the contractor or the Secretary. Our view has been that, in order for a provider to be dissatisfied with a specific aspect of the contractor determination, the provider must have included an appropriate cost report claim for the specific item so that the contractor can respond to the provider's claim in the NPR and thereby potentially produce a specific reimbursement result about which the provider is dissatisfied.

Thus, under our policy for Board jurisdiction, a provider has to make a specific claim for an item in its cost report and not be paid in accordance with that claim in order to meet the dissatisfaction requirement for Board jurisdiction. Previously, we did not permit a provider to ''self-disallow'' a specific item, even if the Medicare contractor had no discretion to award payment for the item. (In self-disallowing an item, the provider submits a cost report that complies with Medicare policy for the item and then appeals the item to the Board; the contractor's NPR then would not include any disallowance of the item, and therefore the provider would effectively self-disallow the item.) However, the Supreme Court rejected our longstanding policy in *Bethesda Hospital Association* v. *Bowen*, 485 U.S. 399 (1988). The Court held that, despite the providers' failure to claim all the reimbursement they believed should have been made, the plain language of the dissatisfaction requirement in section 1878(a)(1)(A) of the Act supported Board jurisdiction because the contractor had no authority to award reimbursement in excess of a regulation by which it was bound, and thus it would have been futile for the providers to try to persuade the contractor otherwise. The Court also stated in dicta, however, that the dissatisfaction requirement might not be met if providers were to ''bypass a clearly prescribed exhaustion requirement or . . . fail to request from the intermediary reimbursement for all costs to which they are entitled under applicable rules'' (*Bethesda Hospital Association* v. *Bowen*, 485 U.S. at 404–05).

Following the *Bethesda* decision, we no longer required providers to make a cost report claim for reimbursement of items for which the contractor did not have the discretion to award payment due to a regulation or manual provision. However, consistent with the dicta in the *Bethesda* decision, we continued to require providers to include cost report claims for allowable costs. Our policy, as revised in response to the *Bethesda* decision, was also challenged in the courts, and a ''circuit split'' resulted. *Compare Little Co. of Mary Hosp.* v. *Shalala*, 165 F.3d 1162 (7th Cir. 1999) (sustaining our interpretation of the statutory dissatisfaction requirement for Board jurisdiction) *with Loma Linda Univ. Med. Ctr.* v. *Leavitt*, 492 F.3d 1065 (9th Cir. 2007) (rejecting our interpretation of the dissatisfaction requirement); *Maine General Med. Ctr.* v. *Shalala*, 205 F.3d 493 (1st Cir. 2000) (same).

In response to the Supreme Court's *Bethesda* decision and the ensuing circuit split, we then addressed the dissatisfaction requirement in notice-and-comment rulemaking. In a 2008 final rule, we revised § 405.1811(a)(1) and § 405.1835(a)(1) for contractor and Board hearings, respectively (73 FR 30190, 30195 through 30200, 30244 through 30245, and 30249 through 30250). Under the revised regulations, in order to preserve its appeal rights, a provider must either claim an item in its cost report where it is seeking reimbursement that it believes to be in accordance with Medicare policy, or self-disallow the item if it is seeking reimbursement that it believes may not comport with Medicare policy (for example, where the contractor does not have the discretion to award the reimbursement sought by the provider). In order to self-disallow an item, the provider must follow the applicable procedures for filing a cost report under protest, which are contained currently in Section 115 of the PRM, Part 2.

As explained in the preamble to the 2008 final rule, we believe the revised dissatisfaction policy set forth in § 405.1835(a)(1) is a reasonable interpretation of the dissatisfaction requirement for Board jurisdiction in section 1878(a)(1)(A) of the Act (73 FR 30195 through 30200). The dissatisfaction requirement in § 405.1835(a)(1) comports with the Supreme Court's statement (discussed above) that the statutory dissatisfaction requirement might not be met if a provider bypassed a clearly prescribed exhaustion requirement or failed to ask the contractor for reimbursement of all costs to which it is entitled under applicable rules (*Bethesda Hospital Association* v. *Bowen*, 485 U.S. at 404–05; *see also Little Co. of Mary Hosp.* v. *Shalala*, 165 F.3d 1162 (7th Cir. 1999) (sustaining our interpretation of the statutory dissatisfaction requirement for Board jurisdiction on the basis of the forgoing statements by the Supreme Court); *Little Co. of Mary Hosp.* v. *Shalala*, 24 F.3d 984 (7th Cir. 1994) (same)).

Upon further reflection, however, we determined that the requirement that a provider either claim reimbursement for a specific cost, or expressly self-disallow the cost, in its cost report is more appropriately treated as a cost reporting requirement under sections 1815(a) and 1833(e) of the Act, as the agency cannot make payments to a provider without sufficient information on all claims for which the provider believes it should be paid. Indeed, it is eminently reasonable for the Secretary to require a provider to make an appropriate cost report claim for a specific item if the provider wants to be paid for the item. As we explain in detail in the next section, requiring a cost report claim for full reimbursement or an express self-disallowance of the cost enables the contractor to review and audit the claim, make any adjustments that seem appropriate, and include any final payment for the cost as part of the NPR. Accordingly, in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28209 through 28212 and 28306 through 28307), we proposed to revise the cost reporting regulations in Part 413, Subpart B by adding the substantive reimbursement requirement that a provider must include an appropriate claim for an item in its cost report. We proposed that the failure to account appropriately for the item in the provider's cost report would foreclose payment for the item in the NPR issued by the contractor and in any decision, order, or other action by a reviewing entity (as defined in § 405.1801(a) of the regulations) in an administrative appeal filed by the provider.

However, as explained in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28208), we recognized that the proposed addition to the cost reporting regulations of the substantive reimbursement requirement of an appropriate cost report claim for a specific item would be potentially duplicative of the existing jurisdictional requirement in the Board appeals regulations of an appropriate cost report claim. In order to avoid such duplication, we also proposed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28212 through 28213 and 28297) to revise the appeals regulations in Part 405, Subpart R by eliminating the requirement that a provider must include an appropriate claim for an item in its cost report in order to meet the

dissatisfaction requirement for Board jurisdiction.

As explained in section XVII.B. of this final rule, we subsequently included, in the FY 2015 IPPS/LTCH PPS final rule, a technical correction to § 405.1835 of the regulations, in which we eliminated provider dissatisfaction as a requirement for Board jurisdiction over appeals based on untimely contractor reimbursement determinations. As a result of this final revision to § 405.1835, the proposed revisions to this Board appeals regulation in the FY 2015 IPPS/LTCH PPS proposed rule have effectively been pared down. Under that proposed rule, the Board jurisdiction requirement of an appropriate cost report claim, which now applies only to appeals of a final contractor determination (under § 405.1835(a) of the regulations), would be eliminated. The FY 2015 IPPS/LTCH PPS proposed rule further provided that our longstanding requirement of an appropriate cost report claim would be made a substantive reimbursement requirement in the cost reporting regulations. These proposed revisions to the cost reporting regulations and the provider appeals regulations would apply, on a prospective only basis, to provider cost reporting periods beginning on or after the effective date of a final rule.

D. Addition to the Cost Reporting Regulations of the Substantive Reimbursement Requirement of an Appropriate Cost Report Claim

1. Proposed Provisions (New § 413.24(j))

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28209 through 28212, 28306 through 28307), we proposed to add a new paragraph (j) to § 413.24 of the regulations. Proposed paragraph (j)(1) of § 413.24 provided that in order to receive or potentially qualify for payment for a specific item, the provider must include in its cost report an appropriate claim for the specific item. In order to make an appropriate claim for an item in its cost report, the provider must either claim payment for the item in its cost report where it is seeking payment that it believes is consistent with Medicare policy, or self-disallow the item if the provider is seeking payment that it believes may not comport with Medicare policy (for example, where the contractor does not have the authority or discretion to award the payment sought by the provider). In order to self-disallow a specific item, the provider would have to follow the applicable procedures for filing a cost report under protest, which are now contained in Section 115 of the PRM, Part 2 and were included in proposed paragraph (j)(2) of § 413.24. Specifically, the provider would have to include an estimated payment amount for each self-disallowed item in the ''protested amount'' line of the cost report, and attach a worksheet explaining why a self-disallowance is necessary (instead of claiming payment for the item in its cost report) and describing how it determined the estimated payment amount for each self-disallowed item.

Proposed paragraph (j)(3) of § 413.24 specified the procedures for determining whether there is an appropriate cost report claim for a specific item. The default rule is that the question of whether the provider's cost report includes an appropriate claim for the specific item must be determined by reference to the cost report that the provider submits originally to, and is accepted by, the contractor, unless one of three exceptions applies. The first exception is that if the provider submits an amended cost report that is accepted by the contractor, the question of whether there is an appropriate cost report claim for the specific item must be determined by reference to such amended cost report, unless one of the two remaining exceptions applies. The second exception is that if the contractor adjusts the provider's cost report, as submitted originally by the provider and accepted by the contractor or as amended by the provider and accepted by the contractor, whichever is applicable, with respect to the specific item, the question of whether there is an appropriate cost report claim for the specific item must be determined by reference to the provider's cost report, as such cost report is adjusted for the specific item in the contractor's final determination (as defined in § 405.1801(a)), unless the remaining exception applies. The third exception is that if the contractor reopens either the final contractor determination for the provider's cost reporting period (in accordance with § 405.1885) or a revised contractor determination for such period (issued in accordance with § 405.1889) and adjusts the provider's cost report with respect to the specific item, the question of whether there is an appropriate cost report claim for the specific item must be determined by reference to the provider's cost report, as such cost report is adjusted for the specific item in the contractor's most recent revised contractor determination for such period.

In the proposed rule, we stated that providers should make every effort to comply with the default rule set forth in proposed paragraph (j)(3) of § 413.24, even though one of the exceptions to the default rule might come into play later. In order to ensure compliance with the substantive requirement of an appropriate cost report claim for a specific item, we stated that the provider should either claim full payment for, or properly self-disallow, the item in the cost report that the provider submits originally to the contractor. However, we indicated that failure to include an appropriate claim for the specific item in the provider's original ''as submitted'' cost report would not necessarily foreclose any further opportunity to meet the requirement of an appropriate cost report claim for the specific item. Under the first exception to the default rule under proposed paragraph (j)(3), the provider could include an appropriate cost report claim for the specific item in an amended cost report, but the contractor has discretion whether to accept an amended cost report by the provider. Under the second and third exceptions to the default rule under proposed paragraph (j)(3), the requirement of an appropriate cost report claim could be met through the contractor's adjustment of the provider's cost report, either in the contractor's final determination for the provider's cost reporting period (as defined in § 405.1801(a)) or, if the final contractor determination is reopened, in the contractor's revised determination. However, in preparing the final contractor determination for a provider's cost reporting period, the contractor would have the discretion as to whether to adjust the provider's cost report with respect to the specific item and, if so, how to adjust the cost report for such item. Similarly, after the final contractor determination is issued, the contractor would have the discretion as to whether to reopen the final contractor determination and, if the specific item is reopened, whether to adjust the cost report for such item and how to make any such adjustment.

In order to exemplify the workings of proposed paragraph (j)(3) of § 413.24, we included the following in the proposed rule: Consider a hospital that seeks a Medicare DSH payment adjustment that, on the provider's view, should be calculated on the basis of 2,000 Medicaid-eligible patient days in the numerator of the DSH Medicaid fraction (42 CFR 412.106(b)(4)). If the hospital's as submitted cost report claimed only 1,000 Medicaid-eligible patient days for the numerator of the DSH Medicaid fraction, and the number of Medicaid-eligible patient days was not changed in an amended cost report

by the provider or through adjustments to the cost report by the contractor, the hospital would have made an appropriate cost report claim for only 1,000 Medicaid-eligible patient days (instead of 2,000 such days). However, if the provider submitted, and the contractor accepted, an amended cost report that claimed a total of 1,500 Medicaid-eligible patient days, the provider would have made a valid cost report claim for 1,500 Medicaid-eligible patient days (instead of 2,000 such days). However, if the hospital asked the contractor, during the contractor's review and settlement of the provider's cost report, to count 250 more Medicaid-eligible patient days, and the contractor agreed to consider those days in the contractor's final determination, the provider would have made a valid cost report claim of 1,750 Medicaid-eligible patient days (instead of 2,000 such days). Finally, if the provider next requested, or the contractor initiated on its own motion, the reopening of the final contractor determination on the specific issue of the number of Medicaid-eligible patient days for the DSH Medicaid fraction's numerator, and the contractor did reopen for that specific issue and it agreed to consider still another 250 Medicaid-eligible patient days in the contractor's revised determination, the provider would have a valid cost report claim of 2,000 Medicaid-eligible patient days.[64] At that juncture, the hospital would have met the requirement of an appropriate cost report claim for all of the 2,000 Medicaid-eligible patient days, which is the number of such days that the provider believed from the outset should be used in determining the numerator of the DSH Medicaid fraction.

We stated in the proposed rule our belief that proposed paragraph (j)(3) of § 413.24 appropriately reflects the usual process in which a cost report claim that is first made in the cost report that is submitted originally to, and accepted by, the contractor, might be altered through an amended cost report by the provider (if the amended cost report is accepted by the contractor) or through adjustments of the provider's cost report claim that are made in the contractor's final determination or, in the event of a reopening, in the contractor's revised final determination. This process enables a provider to ensure compliance with the substantive requirement of an appropriate cost report claim for a specific item, by including in the cost report that the provider submits originally to, and is accepted by, the contractor, either a full claim for payment for a specific item or a proper self-disallowance of the item. In addition, this process gives a provider additional opportunities to meet the requirement of an appropriate cost report claim through an amended cost report by the provider (if the amended cost report is accepted by the contractor) and adjustments to the provider's cost report claim that are included in the contractor's final contractor determination or, if there is a reopening, in the revised final contractor determination. Unlike with the provider's original as submitted cost report, however, the contractor has discretion whether to accept an amended cost report; whether to include particular cost report claim adjustments in the final contractor determination and, if so, how to determine such adjustments; and whether to reopen a contractor determination and, if there is a reopening, how to determine any cost report claim adjustments that may be included in the revised final contractor determination. We stated that this ''back and forth'' process between the provider and the contractor, which is reflected in proposed paragraph (j)(3) of § 413.24, facilitates appropriate determinations of program payment and enhances administrative efficiency. Each of the Medicare contractors has substantial experience in reviewing and auditing cost reports and in properly determining payment amounts. The back and forth process between the provider and the contractor eliminates, or minimizes and sharpens, potential disagreements, which obviates the need to file some administrative appeals or narrows the issues in many cases.

In addition, proposed paragraph (j)(4) of § 413.24 included a provision that, to the extent a provider fails to claim a specific item appropriately in its cost report, the final contractor determination (as defined in § 405.1801(a)) may not include payment for the item. However, if the contractor determines that the provider made an appropriate cost report claim for a specific item but the contractor disagrees with material aspects of the provider's claim for the item, the contractor must make appropriate adjustments to the provider's cost report and include payment for the specific item in the final contractor determination in accordance with the contractor's adjustments to the cost report and to the extent permitted by program policy.

We proposed under proposed paragraph (j)(5) of § 413.24 that if a party to an administrative appeal questions whether the provider's cost report included an appropriate claim for the specific item under appeal, the reviewing entity (as defined in § 405.1801(a)) must follow the procedures (which we discuss in detail below) that are set forth in proposed § 405.1873 (if the appeal was filed originally with the Board), or the procedures in § 405.1832 (if the appeal was filed initially with the contractor), for review of whether the substantive reimbursement requirement of an appropriate cost report claim for the specific item is satisfied. Those regulations require the reviewing entity to follow the procedures (discussed above) that are set forth in paragraph (j)(3) of this section for determining whether the provider's cost report included an appropriate claim for the specific item under appeal. Also, the reviewing entity may permit payment for the specific item under appeal solely to the extent authorized by § 405.1873(f) (if the appeal was filed originally with the Board) or by § 405.1832(f) (if the appeal was filed initially with the contractor).

2. Statutory Authority and Rationale for Proposed § 413.24(j)

In the FY 2015 IPPS/LTCH PPS proposed rule, we stated that we believe the Medicare statute provides ample authority for the proposal (described in the preceding section of this final rule) to add a new paragraph (j) to § 413.24 of the regulations. This proposal is well within the Secretary's general rulemaking authority under sections 1102 and 1871 of the Act. Moreover, proposed § 413.24(j) is an appropriate exercise of the Secretary's broad authority under sections 1815(a), 1833(e), and 1886(f)(1) of the Act to require providers to furnish the information needed to determine the amount of payment due a provider under the Medicare program. As described above, we have relied on these particular statutory provisions in adopting regulations that require providers to submit annual cost reports; specify the requisite contents of cost reports; and impose various procedural requirements for cost reports (such as time periods for timely submission of cost reports and certification requirements for cost reports). Moreover, we have invoked the same statutory provisions in requiring

[64] In the preamble of the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28209 through 28210), this sentence inadvertently omitted the additional point regarding the contractor's acceptance of an additional 250 Medicaid-eligible patient days through a reopening and revised final contractor determination that finally resulted in the provider claiming a total of 2,000 Medicaid-eligible patient days.

providers to report other specific information as a condition for Medicare payment; we refer readers to, for example, Community Hospital of Monterey Peninsula v. Thompson, 323 F.3d 782, 790, 795–800 (9th Cir. 2003) (sustaining Medicare's policy that providers must bill ''crossover bad debts'' to the State Medicaid agency because 42 U.S.C. 1395g(a) (that is, section 1815(a) of the Act) specifically granted the Secretary broad discretion as to what information to require as a condition of payment to providers under the Medicare program; see also Maine Med. Ctr. v. Burwell, 775 F.3d 470, 480 (1st Cir. 2015) (the Secretary is authorized by 42 U.S.C. 1395g(a) (that is, section 1815(a) of the Act) to require a provider to furnish such information as the agency may request). Indeed, as explained above, the Secretary's broad discretion with respect to cost reporting requirements is also reflected in the Board appeals provisions of section 1878(a) of the Act, which makes provider compliance with cost reporting requirements a prerequisite of Board jurisdiction.

In addition to the plainly sufficient statutory authority for proposed § 413.24(j), we believe there are sound policy reasons for requiring a provider to include an appropriate claim for an item in its cost report by either claiming payment for the item (where the provider believes such claim would comport with Medicare policy), or by self-disallowing the item (if the provider is seeking payment that it believes may not be consistent with Medicare policy). This proposal has three main parts, each of which we addressed in the proposed rule.

First, we believe that if a cost is allowable and the provider does not disagree with how Medicare determines payment for the cost, the provider's cost report should include a claim for full payment of the cost in accordance with the program's payment policy. In such cases, a cost report claim for full payment of the cost enables the contractor to review the claim, make any adjustments that seem appropriate, and include final payment for the cost as part of the NPR. Requiring a cost report claim for full payment of allowable costs (where the provider does not disagree with how Medicare determines payment for the cost) facilitates the contractor's discharge of some of its principal responsibilities, which include using the contractor's expertise and experience to review and audit payment claims, making any necessary adjustments, and including final payment for the cost in the NPR. Absent some misstep by the contractor in reviewing such a cost report claim and determining final payment for the item, there would be no need for the provider to later request reopening or to file an administrative appeal regarding the item. Even if the provider disagreed with some aspect of the contractor's payment determination for the specific item, any such disagreement would be narrowed and delineated more precisely because our proposal, to require a full cost report claim for payment of allowable costs, will give the contractor an opportunity to review and audit the claim and determine the extent to which (if at all) to include payment for the claim in the NPR. Therefore, we believe that the interests of administrative finality and efficiency will be advanced if providers are required to include a cost report claim for full payment of allowable costs.

The proposed requirement under proposed § 413.24(j) of a cost report claim for full payment of allowable cost also comports with the division of responsibilities between the contractors and the Board and the other reviewing entities (as defined in § 405.1801(a)). At present, there are 12 contractors, each of which has a fairly large staff with substantial experience and expertise in reviewing and auditing cost reports and determining final payment in accordance with Medicare policy. By contrast, the Board has only five members and a relatively small staff. We believe it is a waste of scarce resources and very inefficient for a provider to first raise a clearly allowable cost in an appeal to the Board when the contractor could have considered and finally determined payment for such an allowable cost in the NPR, if the provider had simply made a timely cost report claim for full payment of the allowable cost. As indicated by the very name of the Provider Reimbursement Review Board, it is a ''review board'' or administrative appeals tribunal, not the Medicare program's front line auditors charged with making the final determination of program reimbursement for such allowable costs.

Second, there are also sound policy reasons for proposing, under a new paragraph (j) in § 413.24, that a provider must self-disallow a specific item if it is seeking payment that it believes may not comport with Medicare policy (for example, because the provider believes the contractor does not have the discretion to make the payment sought by the provider), by following the applicable procedures for filing a cost report under protest (procedures that, as explained above, are now contained in Section 115 of the PRM, Part 2, and would be set forth in proposed paragraph (j)(2) of § 413.24). When a provider self-disallows an item by accounting for it appropriately in the ''protested amount'' line of the cost report (instead of claiming payment for the item), the contractor has an opportunity to correct any misconceptions that the provider may have had about the item. For example, the contractor could determine, contrary to the provider's apparent understanding in self-disallowing a specific item, that the item in question is actually an allowable cost that is reimbursable in accordance with program policy. Another example would be that the contractor might determine, despite the provider's understanding of Medicare policy and its concomitant self-disallowance, that program policy has changed and the item is now an allowable cost or a new payment policy now applies that permits the payment methodology used by the provider in support of its self-disallowance of the item; we refer readers to, for example, 75 FR 50275 through 50286 (discussing CMS Ruling 1498–R, which revised Medicare DSH payment policy in response to adverse judicial precedent, and made such revisions applicable to open cost reports and certain pending administrative appeals). In such cases, the contractor's extensive expertise and experience and its resources can be brought to bear in reviewing self-disallowed items, making any necessary corrections, and finally allowing payment for corrected items in the NPR. Indeed, these kinds of contractor actions comport with section 1874A(a)(4) of the Act and § 413.20(b) of the regulations, which require the contractors to furnish providers with consultative services, education, training, information and instructions, and technical assistance regarding the interpretation and application of payment principles and other program policies; be available to address provider questions and problems on a daily basis; and facilitate communication between the agency and providers. Accordingly, we believe our proposed addition of a self-disallowance requirement to the cost reporting regulations will facilitate exhaustion of administrative remedies through the contractor's review and final settlement of the provider's cost report, and when the contractor corrects errors in a provider's self-disallowance, the need to appeal to the Board or request reopening could be obviated; we refer readers to *Little Co. of Mary Hospital* v. *Shalala*, 165 F.3d 1162, 1165 (7th Cir. 1999) (the Secretary's requirement of an appropriate cost report claim for an item

ensures that the contractor will have the ''first shot'' at determining any reimbursement for the item, before any appeal to the Board need be filed).

By requiring the self-disallowance of items that providers believe may not comport with Medicare policy, proposed § 413.24(j) also would contribute importantly to other aspects of program administration. For example, we believe that this proposal would facilitate provider compliance with the existing requirements in § 413.24(f) that each provider submit a complete, accurate, and timely cost report, and that the provider's administrator or chief financial officer certify that the submitted cost report is complete and accurate. We believe our proposed self-disallowance requirement also would enhance CMS' ability to accurately estimate the program's potential liabilities (for example, for purposes of the agency's preparation of required financial statements). Similarly, we believe that this proposal would improve the contractors' ability to establish audit and other workload priorities. In addition, we believe that the proposed addition of a self-disallowance requirement (for items that providers believe may not comport with Medicare policy) to the cost reporting regulations would enable us to better monitor Medicare policy and potentially adjust our policies in response to a pattern of provider self-disallowances of a given item. Indeed, the importance of requiring complete and accurate cost report information is highlighted by the fact that we use cost report data for a wide variety of purposes such as setting and refining prospective payment rates; establishing hospital market basket weights; calculating Medicare and total facility margins; determining payment for graduate medical education (GME) and indirect medical education (IME); creating projections for the President's annual budget and for the annual Medicare Trustees Report; for various research projects; and for responding to requests from the public, the Congress, OMB, and other parts of the Administration.

Third, we believe there also are sound reasons for our proposal that, under a new § 413.24(j), if a provider fails to account appropriately for an item in its cost report (by making a full claim for payment for the item or self-disallowing the item if the provider believes a payment claim would not comport with Medicare policy), the NPR issued by the contractor may not include payment for the item and payment also may not be permitted in any decision, order, or other action by a reviewing entity (as defined in § 405.1801(a)) in an administrative appeal filed by the provider. Under existing §§ 405.1835(a)(1) and 405.1840(b)(3), the consequence of not making an appropriate cost report claim for an item is that the Board would not have jurisdiction over the provider's appeal of the item. (Similarly, under §§ 405.1811(a)(1) and 405.1814(b)(3), the contractor hearing officers would lack jurisdiction for an item if the provider did not make an appropriate cost report claim for the item.) As explained below, however, we proposed the elimination of the jurisdictional requirement of an appropriate cost report claim in existing §§ 405.1835(a)(1) and 405.1840(b)(3) for Board appeals (and the corresponding jurisdictional requirement in §§ 405.1811(a)(1) and 405.1814(b)(3) for contractor hearing officer appeals), because we believe it is a requirement more appropriately placed in the cost reporting regulations. Given our longstanding policy of requiring an appropriate cost report claim for an item, proposed paragraph (j) of § 413.24 is a natural place to spell out the consequences of not abiding by this cost reporting requirement. In this regard, we note that the proposed addition of a new paragraph (j) to § 413.24 is like the existing paragraph (e) in § 413.20, which provides for the suspension of Medicare payments if a provider fails to maintain the records necessary for proper determination of Medicare reimbursement. Similarly, if a provider fails to include an appropriate claim for an item in its cost report, the NPR issued by the contractor will not include payment for the item and payment also will not be permitted in any decision, order, or other action by a reviewing entity (as defined in § 405.1801(a)) in an administrative appeal filed by the provider.

3. Summary of Public Comments, CMS Responses, and Statement of Finalized Policies for § 413.24(j)

The following public comments were received in response to the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28206 through 28217). As explained below, we are finalizing various revisions to the cost reporting regulations and the provider appeals regulations. These final revisions will apply, on a prospective only basis, to provider cost reporting periods beginning on or after the effective date of this final rule, and to provider appeals regarding provider cost reporting periods that begin on or after the effective date of this final rule.

Comment: Several commenters questioned the legitimacy of CMS' policy justifications. The commenters stated that the agency's policy justifications do not constitute a rational basis for the proposed new cost report requirements.

Response: As explained in the proposed rule (and as discussed earlier in this final rule), we believe there are several compelling policy justifications for the requirement in proposed § 413.24(j) that a provider include an appropriate claim for an item in its cost report by either claiming payment for the item (where the provider believes such claim would comport with Medicare policy), or by self-disallowing the item (if the provider is seeking payment that it believes may not be consistent with Medicare policy).

First, we believe that requiring a cost report claim for full payment of an allowable cost advances the agency's interest in administrative finality and efficiency. If a cost is allowable and the provider does not disagree with how Medicare determines payment for the item, the requirement of an appropriate cost report claim facilitates the contractor's settlement of the claim. The requirement of a cost report claim for full payment of an allowable cost also helps preserve the distinct roles of the contractor and the Board, and conserves Board resources by avoiding Board appeals involving claims that could have been considered and settled by the contractor, if the provider had simply made a timely cost report claim for full payment of the allowable cost in the cost report.

We also believe that the requirement in proposed § 413.24(j), that a provider self-disallow a specific item if it is seeking payment that it believes may not comport with Medicare policy, will facilitate exhaustion of administrative remedies. It has been our experience that providers are sometimes mistaken in their belief that payment is not allowable. This could occur, for example, where the provider misinterprets the applicable payment policies, where the policies have changed without the provider's knowledge, or where the provider has some other reason to believe (albeit erroneously) that a particular payment will be deemed not allowable. We believe that requiring a provider to self-disallow a specific item if it is seeking payment that it believes may not comport with Medicare policy ensures that the contractor will have the opportunity to employ its expertise and correct any misconceptions in the first instance, potentially avoiding unnecessary appeals and narrowing the issues in dispute. Even if the provider is correct in its belief that payment is

not allowable, the contractor may still facilitate resolution of the provider's claim through consultation, discussion, and education about the applicable Medicare policies.

In addition, we believe that the addition of a self-disallowance requirement to the cost reporting regulations will advance other aspects of program administration by facilitating provider compliance with other cost report requirements, enhancing the agency's ability to estimate potential liabilities, improving contractors' ability to establish audit and other workload priorities, and allowing the agency to better monitor Medicare policy and potentially adjust policy in response to a pattern of provider self-disallowances.

Lastly, as explained in the proposed rule, we believe the requirement of an appropriate cost report claim is more appropriately placed in the cost report regulations than in its current inclusion in the provider appeals regulations. We believe that proposed § 413.24(j) reflects our longstanding policy of requiring an appropriate cost report claim for items and that this provision is the natural place to spell out the consequences of not abiding by this cost reporting requirement.

Comment: Several commenters questioned whether the ''back and forth'' process between the provider and the contractor as described in the proposed rule reflects the reality of the cost report process. Commenters also questioned whether contractors are equipped and prepared to engage in the type of back and forth process described in the proposed rule.

Response: We believe that the back and forth process between the provider and contractor, as described in the proposed rule (79 FR 28209 through 28210), does reflect the reality of the cost report process, and contractors regularly engage in the type of back and forth process described in the proposed rule. In addition to claims processing functions, contractors regularly engage with providers to furnish consultative services, education, training, information and instructions, and technical assistance regarding the interpretation and application of payment principles and other program policies. Contractors also address providers' questions and problems on a daily basis and facilitate communication between the agency and providers. We selected the specific scenario involving a hospital seeking a Medicare DSH adjustment based on additional Medicaid-eligible patient days to exemplify the commonplace interaction between the provider and contractor. As several commenters acknowledged, contractors frequently engage with providers in determining whether to accept amended cost reports or requests for reopening under this specific circumstance. The regularity of this interaction between the contractor and the provider is reflected by the sheer volume of cost report amendments and reopening requests accepted by contractors. Contractors accepted 76 percent of requests from providers to amend cost reports during FY 2014 and 77 percent during FY 2013. In addition, as a result of a contractor reopening, 2,311 revised NPRs were issued during FY 2014 and 3,636 revised NPRs were issued during FY 2013.

Comment: Several commenters questioned whether contractors would work with providers to identify situations in which a hospital may have mistakenly claimed an item under protest, instead of affirmatively claiming payment for that item through the cost report. The commenters stated that if a contractor determines that a hospital may have mistakenly claimed an item under protest instead of affirmatively claiming payment for that item, because there is no CMS requirement directing the contractor to add that item to the allowable claims in the hospital's cost report, the contractor is free to use that error against the hospital by not reimbursing the hospital for the item in question and opposing any subsequent appeal on the ground that the protest was not proper.

Response: Contractors have been directed to work with providers to identify self-disallowed items that may actually be reimbursable in accordance with program policy. If a provider seeks payment that it mistakenly believes may not comport with Medicare policy, and follows the procedures for self-disallowing the specific item as set forth in proposed paragraph (j)(2) of § 413.24 by accounting for it appropriately in the ''protested amount'' line of the cost report, the provider has fulfilled the substantive reimbursement requirement of an appropriate cost report claim and may receive or potentially qualify for reimbursement for the specific item. If the item in question is an allowable cost that is reimbursable in accordance with Medicare policy, the contractor has the obligation to pay the provider accurately. We believe that the contractor's correction of errors in the provider's self-disallowance would obviate the need for the provider to request a contractor reopening or Board hearing. If the contractor does not correct the error, the provider could seek relief through the administrative appeals process.

Comment: Several commenters stated that the proposed rule assumes a cost reporting and appeal structure that does not reflect the reality of the hospital reimbursement process. The commenters alleged that the proposed rule ignores that providers often lack access to the information necessary to complete their cost reports in a timely fashion or otherwise may be unaware of a payment error, through no fault of their own, when the cost report is filed.

Response: We respectfully disagree with the commenters' characterization of the proposed rule. Providers have ample time, 5 months after the close of the cost reporting period, to submit cost reports with appropriate cost report claims. In most cases, the information a provider needs to make appropriate cost report claims is easily ascertainable and may be found in the provider's own records. Therefore, in most instances, providers should not have any difficulty obtaining the information necessary to complete and submit a cost report with appropriate claims for each specific item.

We have identified only one circumstance where a provider may have difficulty obtaining sufficient information to make an appropriate cost report claim within the allotted time for cost report submission. This circumstance may occur if a hospital experiences difficulty obtaining sufficient information from State agencies for the purpose of claiming DSH Medicaid-eligible patient days. Therefore, as explained below in our response to the next comment, we will instruct contractors, in this limited circumstance, that they must accept one amended cost report submitted within a 12-month period after the hospital's cost report due date, solely for the specific purpose of revising a claim for DSH by using updated Medicaid-eligible patient days, after a hospital receives updated Medicaid eligibility information from the State.

Moreover, for situations in which a provider may be unaware of a payment error when its cost report is submitted, we believe that proposed § 413.24(j)(3) offers providers several opportunities to meet the requirement of an appropriate cost report claim. As detailed in proposed paragraph (j)(3) of § 413.24, a provider may satisfy the requirement of an appropriate cost report claim through submission of an amended cost report (if the amended cost report is accepted by the contractor), through adjustments of the cost report claim that are made in the contractor's final determination or, in the event of a reopening, through cost report adjustments made in the contractor's revised determination.

Moreover, proposed § 413.24(j)(5) provides for Board review of provider compliance with the appropriate cost report claim requirement in accordance with the procedures set forth in new proposed § 405.1873.

Comment: Commenters recommended that the proposed rule include an exception for hospitals that rely on information from State agencies regarding Medicaid-eligible patient days, for the purpose of calculating DSH payments. The commenters stated that hospitals are not able to determine a final and complete count of Medicaid-eligible patient days until well after the deadline for submission of the cost report to the contractor because of State delays in providing such information. Several commenters cited retroactive State eligibility determinations and Medicaid expansion populations as complicating factors beyond a hospital's control that could substantially impact DSH payments. The commenters also pointed out that CMS has not promulgated any standards affirmatively requiring States to make Medicaid eligibility information available to hospitals for the purpose of completing the cost report, or requiring States to make this information available within any specific timeframe. One commenter stated that the proposal does not provide for an alternative of requiring States to provide accurate, timely and complete information to enable hospitals to include the Medicaid-eligible patient days in their timely submitted cost reports.

Many commenters pointed out that acceptance of an amended cost report or a reopening for the purpose of adding additional Medicaid-eligible patient days to calculate DSH payments is at the discretion of the contractor. Several commenters observed that currently, contractors typically exercise their discretion in favor of accepting amended cost reports. However, commenters also claimed that the exercise of contractor discretion under the proposal may keep a hospital from receiving the appropriate amount of payment for DSH and impede its right to appeal contractor DSH payment determinations that inappropriately omit some Medicaid-eligible patient days for a cost reporting period.

Another commenter expressed concern that the proposal may also affect payments for uncompensated care by skewing the distribution of the pool of insured low income days if additional DSH Medicaid-eligible patient days were in the calculation for some hospitals but not for other hospitals due to the sole discretion of the contractor.

Response: In claiming DSH payments, hospitals use State eligibility determinations and reporting for the purpose of calculating Medicaid-eligible patient days. In calculating the number of Medicaid-eligible patient days, the hospital must determine whether the patient was eligible for Medicaid under a State plan approved under Title XIX of the Act on the day of service by using the State's informational retrieval systems used in the administration of Title XIX of the Act, as required by CMS to provide timely and accurate data (42 CFR part 433, subpart C). The responsibility for collecting, verifying, and reporting Medicaid eligibility as part of the cost reporting process lies solely with providers. States are obligated to provide this information, although hospitals bear the burden of proof with respect to DSH Medicaid-eligible patient days claimed on the cost report. Hospitals cannot claim Medicaid-eligible patient days that have not been verified by State records. We believe that it is reasonable to continue to place the burden of furnishing the information necessary to prove eligibility for each Medicaid patient day for DSH calculation purposes on hospitals because they are best situated to provide and verify Medicaid eligibility information. Because the hospital has provided inpatient care for which they billed the relevant payers, including State Medicaid plans, they will necessarily already be in possession of much of the required information. We continue to believe that the mechanisms currently in place enable hospitals to obtain Medicaid-eligible patient days necessary to calculate DSH payments. In addition, we believe there is no need to modify State Medicaid plan regulations to require that State plans verify Medicaid eligibility for hospitals within a certain time period.

However, we recognize that, in certain limited circumstances, when the hospital submits the Medicare cost report, it may not possess sufficient information from a State agency for the purpose of reporting the total number of Medicaid-eligible patient days due to factors beyond that hospital's control. In such situations, as one commenter observed, contractors usually accept amended cost reports to account for delays a provider may have experienced in obtaining requisite information from State agencies. We will continue to afford providers the opportunity to submit amended cost reports and will instruct contractors, with new instructions in CMS Pub. 100–6, Chapter 8, that they must accept one amended cost report submitted within a 12-month period after the hospital's cost report due date, solely for the specific purpose of revising Medicaid-eligible patient days in order to calculate DSH payments after a hospital receives updated Medicaid-eligible patient days from the State. Furthermore, as we anticipate that, under this process, providers will be able to more accurately account for Medicaid-eligible patient days on their cost reports, there is little risk that the distribution pool of insured low-income days will become skewed and payments for uncompensated care will not be affected.

Comment: Several commenters pointed out that the 2008 final rule (73 FR 30190) indicated that necessary information is not always available to providers when they submit their cost reports. The commenters characterized the existing regulations as explicitly recognizing the provider's right to appeal based on information that was not available or was not known to the provider until after its cost report was submitted. The commenters stated that when the Board appeal regulations were revised in 2008, the agency acknowledged that there may be situations where a provider is uncertain about whether Medicare payment is correct because it does not have access to necessary information (for example, Medicaid eligibility information from a State agency) (73 FR 30194). The commenters stated that this admission in the 2008 rule is incompatible with the new cost report requirements in proposed § 413.24(j), which would limit reimbursement to only those items for which an ''appropriate claim'' or ''protest'' is included on the cost report.

Response: We do not see any inconsistency between our statements in the 2008 final rule and the cost report claim requirement in proposed § 413.24(j). In the 2008 rule, we stated that there may be instances where a provider does not have access to underlying data (for example, Medicaid eligibility information from a State agency) sufficient to ascertain whether Medicare payment (for example, the DSH payment) is incorrect. Consistent with the 2008 rule, we have acknowledged in this final rule the one circumstance where hospitals must rely on information from State agencies about Medicaid eligibility in order to make an appropriate DSH payment adjustment claim in its cost report. To address this limited circumstance, as discussed above, we will instruct contractors that they must accept one amended cost report submitted within a 12-month period after the hospital's original cost report due date, solely for

the specific purpose of revising and making an appropriate cost report claim for DSH Medicaid-eligible patient days after a hospital receives updated information about Medicaid-eligible patient days from the State.

Comment: Commenters expressed concern that the SSI fraction of the DSH payment determination, which is calculated by CMS, is not released until after the cost report is filed.

Response: The proposal will not have any effect on the process that CMS uses to calculate SSI fractions for acute care hospitals. CMS and its contractors will continue to use the data matching process that was referred to in CMS Ruling 1498–R and finalized at 75 FR 50275 through 50286, including all relevant provisions regarding the timing of the match process, to calculate relevant SSI fractions for acute care hospitals. Moreover, while relevant Federal fiscal year SSI ratios may not be published until after a cost report is filed, providers may use, and Medicare contractors must accept, the latest available SSI ratios that have been published to process claims, submit cost reports, and make tentative settlements (42 CFR 412.106(b)(2) and 413.64(e) and (f)), until CMS publishes the relevant Federal fiscal year SSI ratio which shall be used to issue a final determination in an NPR. In addition, the hospital could seek relief by requesting a reopening of the final contractor determination or by filing an administrative appeal.

Comment: Several commenters stated that the time period of 5 months between the end of a hospital's fiscal year and its cost report due date is too short for a hospital to capture all data necessary for direct GME and IME payments. One commenter expressed concern that direct GME or IME full-time equivalent (FTE) data relating to a prior year and/or penultimate year could be excluded from a hospital's calculation of GME or IME payments under the requirement of an appropriate cost report claim in proposed § 413.24(j). This commenter suggested that, under the proposal, if the FTE residents in a prior year's cost report are changed upon the audit or reopening of a cost report, and the current year cost report is filed using the original prior year FTE count in the IME and direct GME calculations, the 3-year rolling average and the prior year resident to bed ratio would be impacted. The commenter stated that if the contractor does not correct the current year's incorrect number upon the audit or reopening of a cost report, under the proposal, a hospital would have no recourse through the Board.

Response: We respectfully disagree with the commenters' assertion that the time period of 5 months between the end of a hospital's fiscal year and its cost report due date is too short for a hospital to capture all data necessary for GME and IME payments. Under the proposed rule, direct GME or IME FTE data relating to a prior year and/or penultimate year would not be excluded from a hospital's calculation of direct GME or IME payments. A hospital would be able to successfully resolve this issue with the contractor without needing to seek recourse through the Board.

Because 42 CFR 412.52 specifies that all hospitals participating in the prospective payment systems must meet the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, hospitals are required to maintain sufficient financial records and statistical data for proper determination of costs payable under the Medicare program, which would include direct GME and IME payments. Accordingly, such information should be maintained by the hospital and be easily ascertainable. With regard to determining FTE counts, hospitals should be able to determine FTE counts for the cost reporting year that just ended based on predetermined rotation schedules for each approved residency training program. In addition, bed counts for the IME payment and Medicare utilization for the direct GME payment are available to the hospital based on a combination of its own patient census records and on the Provider Statistical and Reimbursement System, which the hospital uses to complete its Medicare cost report after each fiscal year end. Therefore, we believe that hospitals have all the information necessary to accurately complete worksheets E, Part A, and E–4 of the Medicare cost report within the 5-month time period between the end of a hospital's fiscal year and its cost report due date.

Furthermore, if a contractor makes an adjustment to a direct GME or IME payment on a cost report for a given year, the contractor should bring forward the audit adjustment made in the prior cost year prospectively to the current cost year and make the adjustment in the NPR for the current cost year. If the hospital learned of the adjustment to the prior year shortly after filing its cost report, it could submit an amended cost report based on the contractor's adjustment. Although the acceptance of the amended cost report would ultimately be at the discretion of the contractor, such an amendment reflecting a prior year adjustment by the contractor should be accepted, as it is the contractor's responsibility to ensure that the prior year adjustment is applied prospectively. If the hospital receives an NPR where the prior adjustment is not reflected in the current cost year, it could request that the NPR be reopened. Although requests for reopening are also at the discretion of the contractor, such a request resulting from an adjustment proposed by the contractor to a prior cost report should be granted, given the contractor's responsibility to ensure that the prior year adjustment be applied prospectively. Also, the hospital could seek relief by filing an administrative appeal.

Comment: Commenters stated that the time period of 5 months between the end of a provider's fiscal year and its cost report due date is too short for a provider to capture all data necessary for bad debt payments. Several of these commenters stated that providers may not know all of their bad debt accounts at the time they initially file their cost reports and they rely on the ability to file cost report amendments to ensure accurate reimbursement.

Response: We respectfully disagree with the commenters' assertions that the time period of 5 months between the end of a provider's fiscal year and its cost report due date is too short for a provider to capture all data necessary to claim payment for bad debts. Medicare ''bad debts'' arise from uncollectible accounts and notes receivable that are created or acquired in the process of providing services to a Medicare patient (42 CFR 413.89). These uncollectible deductibles and coinsurance amounts are recognized as allowable bad debts in the reporting period in which the debts are determined to be worthless. Because bad debts are uncollectible accounts receivable and notes receivable, the provider should have the usual accounts receivable records (ledger cards and source documents) to support its claim for a bad debt for each account included in the cost report. Examples of the types of information to be retained by a provider may include, but are not limited to, the beneficiary's name and health insurance number; admission/discharge dates for Medicare Part A bills and dates of services for Medicare Part B bills; date of bills; date of write-off; and a breakdown of the uncollectible amount by deductible and coinsurance amounts. This type of information should be easily ascertainable by the provider because it is expected to be maintained by the provider in the course of normal business in accordance with § 413.20. Because uncollectible deductibles and coinsurance amounts are recognized as allowable bad debts in

the cost reporting period in which the debts are determined to be worthless by providers under § 413.89, by definition providers should have sufficient information to claim reimbursement for bad debts for a particular cost report year within that cost report year, and thus well within the 5-month time period between the close of the cost reporting year and the providers' cost report submission date. If all information needed to establish that a debt is worthless is not available within a given cost year, the account may not properly be claimed as a Medicare debt within that period, but might qualify as a bad debt in a later year.

The same is true for bad debts of dually eligible beneficiaries whose Medicaid eligibility is determined upon submission of a bill by the provider. In that situation, a provider is required to obtain a remittance advice from the State to document the liability of a State's Medicaid program for the unpaid deductible and coinsurance before a claim for bad debt can be submitted to Medicare. In this regard, providers should have the information to claim reimbursement for bad debts for a dually eligible beneficiary for a particular cost report year within the 5-month time period between the close of the cost reporting year and the providers' cost report submission date. In all situations, if for some reason the provider learns of bad debt that should have been claimed on its cost report after cost report submission, the provider may still follow the existing procedures for submitting an amended cost report to the contractor or submitting a request for reopening to the contractor. The acceptance of an amended cost report and granting of the request for reopening remain at the discretion of the contractor. However, the provider could also seek relief by filing an administrative appeal.

Comment: Many commenters asserted that the proposed rule would inappropriately limit providers' capacity to file appeals based on the discretion of the contractor. The commenters observed that, under the proposal, the question of whether the provider's cost report includes an appropriate claim for a specific item must be determined by reference to the cost report that the provider submits originally to, and is accepted by, the contractor, unless one of three exceptions apply. Noting the three exceptions in § 413.24(j)(3) of the proposed rule, several commenters stated that, under the proposal, a provider's right to appeal is dependent on the contractor's exercise of nonreviewable discretion. The commenters pointed out that the acceptance of an amended cost report or the issuance of a reopening is entirely at the discretion of the contractor under current Medicare regulations and a contractor's rejection of an amended cost report or a reopening request is not subject to judicial review. As a result, the commenters criticized the proposal as vesting contractors with overly broad authority and discretion over hospitals' right to appeal items on the cost report.

Several commenters also asserted that the proposed rule would prevent providers from correcting items on their cost reports. The commenters noted that if a hospital does not correctly list an item on its cost report, its only avenue for correction would be to file an amended report or request reopening and hope that the contractor accepts the amended cost report or reopening request. The commenters stated that if the contractor rejects the amended cost report or reopening request, the hospital would have no further administrative remedy under the proposed rule. The commenters stated that contractors routinely decline to accept amended cost reports or requests for reopening, often based on workload and resources. The commenters were concerned with the exercise of contractor discretion under the proposal and recommended that CMS develop clear and uniform standards for contractors to use in determining whether to accept an amended cost report or issue a reopening. In addition, the commenters recommended that CMS explain how it will monitor and enforce the contractors' exercise of authority to make such decisions about providers' requests to amend or reopen cost reports to ensure that the contractors are fairly and consistently applying the standards for all providers. The commenters also recommended that the proposal include an exception for instances where a provider later discovers information that should have been reported on the cost report.

Response: We acknowledge the commenters' concerns. However, as we explain in detail below in section XVII.E.1. of this final rule, we do not agree that the exercise of contractor discretion under the proposed rule would limit a provider's right to file an administrative appeal. The proposed rule eliminates the jurisdictional requirement in §§ 405.1835(a) and 405.1811(a) of an appropriate cost report claim, which makes it easier for a provider to meet the jurisdictional requirements for an appeal to the Board or the contractor, respectively. While the proposed § 413.24(j) imposes the requirement of an appropriate cost report claim as a general substantive requirement for payment, § 413.24(j) does not impose any limitations on a provider's administrative appeal rights. On the contrary, proposed § 413.24(j)(5) specifically addresses administrative appeals where a party questions provider compliance with the substantive reimbursement requirement of an appropriate cost report claim.

We proposed to require that providers include an appropriate claim for a specific item in their Medicare cost reports in order to receive or potentially qualify for Medicare payment for the specific item. In most situations, at the time of filing, the provider should possess all information needed to file an appropriate claim. We believe that, for the most part, providers should not have any significant difficulty identifying items that they believe should be paid by Medicare. Therefore, under this proposal, the question of whether the provider's cost report includes an appropriate claim for a specific item will be determined by reference to the cost report that the provider submits originally to, and is accepted by, the contractor. There may be instances where a provider learns of new and material information or needs to correct an error after filing the cost report, and in such situations, the provider may submit an amended cost report or request that the cost report be reopened. Therefore, the proposal in § 413.24(j)(3) includes exceptions where the contractor accepts an amended cost report or reopens the cost report.

We recognize that the acceptance of amended cost reports and requests for reopening is at the discretion of the contractor and not reviewable (§§ 413.24(f) and 405.1885(a)(6)). Accordingly, we understand the commenters' concerns about the potential effects of contractor discretion under the proposed rule. However, we believe that the contractors currently exercise discretion with regard to the acceptance of amended cost reports and reopening requests in an equitable and consistent manner. We respectfully disagree that contractors routinely reject amended cost reports and reopening requests based on workload and resources. This is reflected by the sheer volume of cost report amendments and reopening requests accepted by contractors. Contractors accepted 1,828 amended cost reports during FY 2014 and 1,725 amended cost reports during FY 2013. In addition, as a result of a contractor reopening, 2,311 revised NPRs were issued during FY 2014 and 3,636 revised NPRs were issued during FY 2013. We anticipate that the contractors will continue to exercise

discretion in an equitable and consistent manner under this proposal. Therefore, we see no reason to develop any new standards beyond the current guidance we provide to contractors. We also do not see a need to increase monitoring of contractor activity beyond the current monitoring that is performed as part of annual contract reviews.

Comment: One commenter alleged that the proposed rule prevents contractors from making positive adjustments to cost reports and eliminates a provider's ability to receive payments for claims that the provider may fail to include in its cost report.

Response: The proposed rule does not include any provision that would prevent a contractor from making a positive adjustment to a cost report if such an adjustment is warranted. On the contrary, proposed paragraph (j)(4) of § 413.24 provides that if the contractor determines that the provider made an appropriate cost report claim for a specific item and that all other substantive reimbursement requirements for the specific item are satisfied, the final contractor determination must include reimbursement for the item to the extent permitted by Medicare policy. Similarly, if the contractor finds an appropriate cost report claim but it disagrees with material aspects of the provider's claim for the item, the contractor must make appropriate adjustments to the provider's cost report and include payment for the specific item in the final contractor determination in accordance with the contractor's adjustment to the cost report and to the extent permitted by program policy. Such adjustments could be monetarily favorable, unfavorable, or have no reimbursement effect for the provider.

Proposed paragraph (j)(4) of § 413.24 also provides that, to the extent a provider fails to claim a specific item appropriately in its cost report, the final contractor determination may not include payment for the item. However, a provider's failure to include an appropriate claim for a specific item in the provider's original ''as submitted'' cost report does not necessarily foreclose any further opportunity for the provider to meet the requirement of an appropriate cost report claim. A provider could seek to remedy such an omission by submitting an amended cost report, if the amended cost report is accepted at the discretion of the contractor. The requirement of an appropriate cost report claim could also be met through the contractor's adjustment of the provider's cost report, either in the final contractor determination for the provider's cost reporting period or, if the final contractor determination is reopened at the discretion of the contractor, in the contractor's revised final determination. Moreover, the provider could seek relief by filing an administrative appeal.

Comment: Commenters stated that the proposed rule would prohibit providers from pursuing appeals in order to correct errors by CMS that are not known at the time the provider files the cost report. The commenters recommended that the proposal include an exception for situations in which errors in CMS calculations, which are previously unknown to the provider, are subsequently discovered after filing of the cost report.

Response: We respectfully disagree with commenters' statement that the proposed rule prohibits providers from pursuing appeals to correct errors that CMS may make in payment calculations. Assuming for the sake of argument that the agency made an error, and that such error was not known or discoverable until after the provider submitted its cost report, the proposed rule would not curtail the provider's right to file an appeal to the Board. On the contrary, proposed paragraph (j)(5) of § 413.24 provides for Board review of such an alleged CMS error in accordance with the procedures in proposed § 405.1873. The provider could first seek Board review of whether its cost report included an appropriate claim for the specific item under proposed § 405.1873(a). Proposed § 405.1873(b)(1) provides that the parties to the appeal must be given an adequate opportunity to submit factual evidence and legal argument on the question of whether the provider complied with the general reimbursement requirement of an appropriate cost report claim; the Board must make findings of fact and conclusions of law regarding that question; and those findings and conclusions of the Board must be included in the administrative record and they must be included in certain overall Board decisions regarding the appeal.

As the question of whether a provider made an appropriate cost report claim for a specific payment item is a mixed question of law and fact, it is well within the Board's decisional authority. However, the provider in this situation might also be raising a facial challenge to the lawfulness of a governing regulation for the payment item, in which case the Board would have no authority to decide that legal question. As a result, the provider could request expedited judicial review (EJR) of its facial challenge to the lawfulness of the specific payment regulation. Under proposed § 405.1873(d)(2), if the Board grants EJR regarding a question of law that is relevant to the matters at issue, its EJR decision must include the Board's findings of fact and conclusions of law (if any) about whether the provider's cost report included an appropriate claim for the matter at issue, and any such findings and conclusions are subject to the same provisions in § 405.1842(g)(1), (g)(2), (h)(1), and (h)(3) (regarding further review and finality) as ''apply to the other parts of the Board's EJR decision.'' Similarly, proposed § 405.1873(f)(2) addresses the potential reimbursement effects of an EJR decision that both grants EJR regarding a question of law that is relevant to the matters at issue, and also includes the Board's findings of fact and conclusions of law (if any) about whether the provider's cost report included an appropriate claim for the matter at issue.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to amend § 413.24 by reserving paragraph (i) and adding new paragraph (j). New § 413.24(j) requires a provider to include an appropriate claim for a specific item in its Medicare cost report in order to receive or potentially qualify for Medicare payment for the specific item. In order to make an appropriate claim for an item in its cost report, the provider must either claim payment for the item in its cost report if it is seeking payment that it believes is consistent with Medicare policy, or self-disallow the item if the provider is seeking payment that it believes may not comport with Medicare policy. If the provider's cost report does not include an appropriate claim for a specific item, payment for the item will not be included in the NPR issued by the contractor or in any decision or order issued by a reviewing entity (as defined in 42 CFR 405.1801(a)) in an administrative appeal filed by the provider.

We have identified only one circumstance where a provider may have difficulty obtaining sufficient information to make an appropriate cost report claim. This circumstance may exist when a hospital experiences difficulty obtaining sufficient information from State agencies about Medicaid-eligible patient days, which is necessary to claim a DSH payment adjustment. Of course, providers have the right to submit amended cost reports. Moreover, in this limited circumstance, we will instruct contractors, through new instructions in CMS Pub. 100–6, Chapter 8, that they

must accept one amended cost report submitted within 12 months after the due date for the hospital's cost report (which is 5 months after the last day of the hospital's fiscal year), solely for the specific purpose of revising the number of Medicaid-eligible patient days (after a hospital receives updated Medicaid-eligible patient days from the State) in order to make an appropriate cost report claim for a DSH payment adjustment. In our experience, we believe an additional 12 months is sufficient time for States to make Medicaid eligibility determinations and for hospitals to revise its number of Medicaid-eligible patient days in order to make an appropriate cost report claim for a DSH payment adjustment. In submitting such an amended cost report, the hospital must include: (1) The number of additional Medicaid-eligible patient days that the hospital is seeking to include in the DSH calculation; (2) a description of the process that the hospital used to identify and accumulate the Medicaid-eligible patient days that were reported and filed in the hospital's Medicare cost report at issue; and (3) an explanation of why the additional Medicaid-eligible patient days at issue could not be verified by the State by the time the hospital's cost report was submitted.

E. Revisions to the Provider Reimbursement Appeals Regulations

1. Elimination of the Jurisdictional Requirement of an Appropriate Cost Report Claim

a. Proposed Revisions to §§ 405.1835 and 405.1840

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28212 through 28213, and 28297 through 28298), we proposed to eliminate the requirement in existing §§ 405.1835(a)(1) and 405.1840(b)(3) of the regulations that a provider must include an appropriate claim for an item in its cost report in order to meet the dissatisfaction requirement for Board jurisdiction. We explained that there is a sound basis in law and policy for this proposal. We stated that our proposal to eliminate an appropriate cost report claim as a requirement for Board jurisdiction is well within the Secretary's general rulemaking authority under sections 1102 and 1871 of the Act. Moreover, we explained that this specific proposal is a reasonable interpretation of the ''dissatisfied'' provision in section 1878(a)(1)(A) of the Act. In our view, this statutory provision is ambiguous and the interpretation in the existing appeals regulations, which requires providers to make appropriate cost report claims in order to meet the dissatisfaction prerequisite of Board jurisdiction with respect to a specific item, is a permissible interpretation of the statute. As described above, however, providers have challenged our interpretation of the statutory dissatisfaction provision in litigation spanning more than 30 years, and in public comments on existing §§ 405.1835(a)(1) and 405.1840(b)(3) of the regulations that were adopted in the 2008 final rule (73 FR 30195 through 30200; CMS' response to public comments on the proposed Board appeals regulations, which were based on our interpretation of the statutory dissatisfaction provision). Providers have maintained throughout this litigation and in the referenced public comments that the statutory dissatisfaction provision does not support our policy of requiring an appropriate cost report claim as a prerequisite of Board jurisdiction. We continue to disagree with this view of the statute, and still believe that the existing regulations for Board appeals of timely final contractor or Secretary determinations are based on a permissible interpretation of the statutory dissatisfaction provision in section 1878(a)(1)(A) of the Act. As explained above, existing § 405.1835(a)(1) comports with the Supreme Court's statement that the statutory dissatisfaction requirement might not be met if a provider bypassed a clearly prescribed exhaustion requirement or failed to ask the contractor for payment of all costs to which it is entitled under applicable rules (Bethesda Hospital Association v. Bowen, 485 U.S. at 404–405). Furthermore, the U.S. Court of Appeals for the Seventh Circuit has twice sustained our interpretation of the statutory dissatisfaction provision, on the basis of the foregoing statements by the Supreme Court (Little Co. of Mary Hosp., 165 F.3d 1162; Little Co. of Mary Hosp., 24 F.3d 984). Nonetheless, we believe our proposal, to eliminate § 405.1835(a)(1)'s jurisdictional requirement of an appropriate cost report claim, certainly does not conflict with the ''dissatisfied'' provision in section 1878(a)(1)(A) of the Act.

Moreover, as we stated in the proposed rule, this particular proposal is supported by section 1878(a)(1)(B) of the Act, which authorizes certain Board appeals if the provider does not receive a final contractor reimbursement determination on a timely basis. (Section 405.1835(c) of the existing regulations specifies the time period and other conditions for Board appeals where the provider does not receive a final contractor determination on a timely basis.) Section 1878(a)(1)(B) of the Act does not include a dissatisfaction provision. Indeed, as explained earlier in section XVII.B. of this final rule, this was a basis for our revision of § 405.1835 of the regulations in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50199 through 50201 and 50350 through 50351) to eliminate provider dissatisfaction as a requirement for Board jurisdiction over appeals based on untimely contractor reimbursement determinations. This revision was simply a technical correction inasmuch as the amendment to § 405.1835 conformed the regulations to the provisions in section 1878(a)(1)(B) of the Act for Board appeals based on an untimely contractor determination. In effect, this amendment to § 405.1835 restored the full conformity of the regulations with the statutory requirements for Board jurisdiction over appeals based on untimely contractor determinations—a conformity that obtained before the 2008 final rule (73 FR 30195 through 30199) inadvertently imposed a provider dissatisfaction requirement for Board appeals based on untimely contractor determinations.

As a result of our elimination, in the FY 2015 IPPS/LTCH PPS final rule, of the dissatisfaction requirement for Board jurisdiction over appeals based on untimely contractor reimbursement determinations, providers no longer have to submit an appropriate cost report claim as a requirement for Board jurisdiction over such appeals. Our proposal to eliminate the requirement under § 405.1835(a)(1) of an appropriate cost report claim in order to meet the ''dissatisfied'' jurisdictional provision in section 1878(a)(1)(A) of the Act would make uniform this aspect of Board jurisdiction over both appeals of timely final contractor and Secretary determinations and appeals based on untimely final contractor determinations. Specifically, an appropriate cost report claim would no longer be required for Board jurisdiction over appeals of timely final contractor and Secretary determinations just as the same jurisdictional requirement, of an appropriate cost report claim, was previously eliminated (in the FY 2015 IPPS/LTCH PPS final rule) for appeals based on untimely final contractor determinations.

We stated in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28212) that, in addition to the sufficient statutory authority for our proposed elimination of an appropriate cost report claim as a requirement for Board jurisdiction, there

are sound policy reasons for this proposal. As explained in section XVII.D. of this final rule, we believe that, by requiring appropriate cost report claims in proposed § 413.24(j), complete and accurate determinations of provider reimbursement will be facilitated as will many other important aspects of program administration. Thus, because we would require an appropriate cost report claim in proposed § 413.24(j), it is reasonable to eliminate the Board jurisdiction requirement in existing §§ 405.1835(a)(1) and 405.1840(b)(3) of an appropriate cost report claim. We note that once this amendment to the Board appeals regulations becomes effective, this proposal will facilitate an orderly end to any litigation regarding the Board jurisdiction requirement of an appropriate cost report claim.

As explained above, our proposed revisions to the cost reporting regulations and the provider appeals regulations would apply on a prospective only basis, to provider cost reporting periods beginning on or after the effective date of this final rule. Until these proposed regulations take effect, however, the requirement of an appropriate cost report claim in §§ 405.1835(a)(1) and 405.1840(b)(3) of the regulations will continue to be a requirement for Board jurisdiction over appeals of timely final contractor reimbursement determinations. Thus, until the proposed regulations become effective, the Board and the Administrator of CMS will continue to determine Board jurisdiction over appeals of timely final contractor determinations by reference to the appropriate cost report claim requirements of §§ 405.1835(a)(1) and 405.1840(b)(3), along with other applicable jurisdictional provisions of section 1878 of the Act and §§ 405.1835 and 405.1840 of the regulations. We believe that, because it is essential to require appropriate cost report claims for the various reasons that we discussed above, it is necessary and proper to continue to require an appropriate cost report claim as a prerequisite of Board jurisdiction under §§ 405.1835(a)(1) and 405.1840(b)(3) over appeals of timely final contractor determinations until the proposed addition to the cost reporting regulations, of the substantive reimbursement requirement of an appropriate cost report claim, takes effect.

b. Summary of Public Comments and Our Responses and Finalized Policies

Comment: Some commenters stated that the proposed revisions to § 405.1835 are contrary to section 1878(a)(1)(B) of the Act, which provides for appeals to the Board if a final contractor determination is not issued timely (as specified in the Secretary's regulations at § 405.1835 (c) and (d)) and all jurisdictional requirements are satisfied. The commenters further stated that this statutory provision does not require provider dissatisfaction for appeals based on untimely final contractor determinations, and the Secretary has conceded this point in litigation.

Response: We do not believe the FY 2015 IPPS/LTCH PPS proposed rule is inconsistent with section 1878(a)(1)(B) of the Act. Under this statutory provision, a provider may appeal to the Board if a final contractor determination is not issued timely (as specified in the Secretary's regulations) and all jurisdictional requirements are satisfied. Section 1878(a)(1)(B) of the Act does not make provider dissatisfaction a jurisdictional requirement for Board appeals based on untimely final contractor determinations. By contrast, section 1878(a)(1)(A) of the Act does impose a provider dissatisfaction requirement for Board jurisdiction over appeals of a timely final contractor or Secretary determination.

As explained in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50200), a provider dissatisfaction jurisdictional requirement, for appeals based on untimely final contractor determinations, was inadvertently added to the Board appeals regulations in a 2008 final rule (73 FR 30190)—not, as the commenters asserted, in the FY 2015 IPPS/LTCH PPS proposed rule. Instead, based on the FY 2015 IPPS/LTCH PPS proposed rule and this final rule, we are eliminating our longstanding interpretation of the statutory dissatisfaction requirement for Board jurisdiction over appeals of a timely final contractor or Secretary determination, an interpretation that required the provider to establish its dissatisfaction by submitting an appropriate cost report claim. Under the FY 2015 IPPS/LTCH PPS proposed rule and this final rule, we are making an appropriate cost report claim a general substantive requirement for Medicare payment (in new § 413.24(j)), in addition to eliminating (in § 405.1835(a)) an appropriate cost report claim as a prerequisite of Board jurisdiction over appeals of a timely final contractor or Secretary determination under section 1878(a)(1)(A) of the Act.

In effect, the FY 2015 IPPS/LTCH PPS final rule addressed the commenters' concerns here about whether the regulations for Board appeals based on untimely final contractor determinations are consistent with section 1878(a)(1)(B) of the Act. As explained in section XVII.B. of this final rule, in the FY 2015 IPPS/LTCH PPS final rule, we made a technical correction to § 405.1835 of the Board appeals regulations that eliminated the dissatisfaction jurisdictional requirement for appeals based on untimely final contractor determinations. Under paragraph (c) of § 405.1835, provider dissatisfaction is no longer required for appeals based on untimely final contractor determinations. As a result of this technical correction, the regulations for Board appeals based on untimely final contractor determinations are consistent with section 1878(a)(1)(B) of the Act. Furthermore, given the amendments to § 405.1835(a)(1) in this final rule and the prior technical correction that added paragraph (c) to § 405.1835, an appropriate cost report claim is no longer required for Board jurisdiction over any appeal.

Comment: Commenters asserted that the proposed elimination of the dissatisfaction requirement for Board jurisdiction is inconsistent with section 1878(a)(1)(A) of the Act, which provides for appeals of a timely final contractor or Secretary determination if all jurisdictional requirements are satisfied. The commenters stated that the Supreme Court held in *Bethesda Hospital Association* v. *Bowen*, 485 U.S. 399 (1988) that provider dissatisfaction is a jurisdictional requirement for Board appeals based on 42 U.S.C. 1395oo(a)(1)(A) (that is, section 1878(a)(1)(A) of the Act).

Response: We did not propose in the FY 2015 IPPS/LTCH PPS proposed rule, and we are not effectuating in this final rule, the elimination of provider dissatisfaction as a requirement for Board jurisdiction over appeals of a timely final contractor or Secretary determination under section 1878(a)(1)(A) of the Act. As the Supreme Court held in *Bethesda Hospital Association*, section 1878(a)(1)(A) of the Act plainly makes provider dissatisfaction a requirement for Board jurisdiction. Also, this statutory prerequisite of Board jurisdiction over appeals of a timely final contractor or Secretary determination is clearly reiterated in the existing text of paragraph (a)(1) of § 405.1835, and in the preambles for both the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28207 through 28208 and 28212 through 28213) and the technical correction provision in the

FY 2015 IPPS/LTCH PPS final rule (79 FR 50199 through 50200).

While we are not eliminating the provider dissatisfaction requirement for Board jurisdiction over appeals of a timely final contractor or Secretary determination, we nonetheless can see some potential for confusion about this matter due to the specific text of proposed § 405.1835. In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28297), paragraph (a) of § 405.1835 retains (and renumbers the current paragraphs for) the amount in controversy and timely filing requirements for Board jurisdiction, but the statutory dissatisfaction requirement was not stated in paragraph (a). This does not mean, however, that we proposed to eliminate the provider dissatisfaction requirement for Board jurisdiction over appeals of a timely final contractor or Secretary determination. As explained above, the preamble for the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28207 through 28208 and 28212 through 28213) plainly states that provider dissatisfaction is a prerequisite for Board jurisdiction. Also, under that proposed rule (79 FR 28297), paragraph (b)(2) of § 405.1835 requires the provider to explain why it ''disagrees with'' specific aspects of the final contractor or Secretary determination. We believe the reference in paragraph (b)(2) to ''disagrees with'' is synonymous with the references to ''is dissatisfied with'' in section 1878(a)(1)(A) of the Act. Moreover, proposed paragraph (b)(2)(iii) (79 FR 28297) would require the provider's cost report to include specific details about each specific item that ''the provider self-disallows.'' Under our prior interpretation of the statutory dissatisfaction requirement for Board jurisdiction (existing paragraph (a)(1) of § 405.1835), a provider must include a self-disallowance in its cost report for a specific item that it believes may not be allowable under Medicare payment policy.

Although we did not propose the elimination of the provider dissatisfaction requirement for Board jurisdiction over appeals of a timely final contractor or Secretary determination in the FY 2015 IPPS/LTCH PPS proposed rule, we have concluded, based on consideration of the public comments we received, that technical revisions to the proposed text of paragraph (a) of § 405.1835 are warranted in order to avoid potential confusion about this matter. Accordingly, in this final rule, we are revising the proposed introductory text of paragraph (a) of § 405.1835 (79 FR 28297) by eliminating the proposed reference to items ''claimed in its cost report,'' a technical revision that further clarifies our proposed elimination of an appropriate cost report claim as a requirement for Board jurisdiction. Moreover, we are revising the proposed text of paragraph (a)(1) of § 405.1835 (79 FR 28297) by revising the dissatisfaction provision in the existing text of paragraph (a)(1) so that the provider dissatisfaction requirement for Board jurisdiction over appeals of a timely final contractor or Secretary determination in § 405.1835(a)(1) will track closely the references to ''is dissatisfied with'' in section 1878(a)(1)(A) of the Act. As a result of these technical revisions to the proposed introductory text of paragraph (a) of § 405.1835 and to the proposed text of paragraph (a)(1), § 405.1835(a) will state that the provider has a right to a Board hearing with respect to a final contractor or Secretary determination if the provider is dissatisfied with the contractor's final determination of the total amount of reimbursement due the provider, as set forth in the contractor's written notice under § 405.1803, and the other requirements for Board jurisdiction (discussed below) are also satisfied.

We also are adding paragraph (a)(1)(i) to § 405.1835, which is a technical conforming amendment to the revised dissatisfaction provision in § 405.1835(a)(1). Under paragraph (a)(1), a provider could be dissatisfied with any number of the specific aspects of Medicare payment that are finally determined in the contractor's original NPR under § 405.1803. However, under our longstanding ''issue specific'' interpretation of the reopening regulations, Board jurisdiction over an appeal involving a reopening is limited under §§ 405.1887(d) and 405.1889(b) to the specific matters that were reopened and revised in the contractor's revised NPR. We refer readers, for example, to *HCA Health Services of Oklahoma* v. *Shalala*, 27 F.3d 614 (D.C. Cir. 1994) (the reopening regulations are based on the Secretary's general rulemaking authority, and the issue specific interpretation of the reopening rules is reasonable and supportive of administrative finality). As a technical conforming amendment to the revised dissatisfaction provision in § 405.1835(a)(1), the issue specific reopening regulations are cross-referenced in paragraph (a)(1)(i) of § 405.1835, to specify that if a final contractor determination is reopened under § 405.1885, any review by the Board must be limited solely to those matters that are specifically revised in the contractor's revised final determination (§§ 405.1887(d) and 405.1889(b), and the ''Exception'' under proposed § 405.1873(c)(2)(i)). The referenced ''Exception'' in § 405.1873(c)(2)(i) is a similar cross-reference in new § 405.1873, which is addressed in section XVII.E.2.a. of this final rule.

However, we are not finalizing the proposed revisions (79 FR 28297) to paragraphs (a)(2) and (a)(3) of § 405.1835. First, our adoption of the above-described technical revision to the dissatisfaction jurisdictional requirement in current paragraph (a)(1) of § 405.1835, obviates any need to renumber either the amount in controversy jurisdictional requirement in current paragraph (a)(2) or the timely filing jurisdictional requirement in paragraph (a)(3). Second, similarly unnecessary are the proposed revisions to the text of current paragraph (a)(3), which would have reiterated (in proposed § 405.1835(a)(2)(ii)) our longstanding policy for determining whether a final contractor determination was issued timely for purposes of a Board appeal based on section 1878(a)(1)(B) of the Act. This policy is now stated appropriately in § 405.1835(c), a regulation we adopted in the technical correction provisions of the FY 2015 IPPS/LTCH PPS final rule (79 FR 50350 through 50351).

Comment: One commenter stated that proposed § 405.1835(a)(2)(ii) conflicts with the Medicare contractor manual instructions in CMS Pub. 100–6, chapter 8, sections 10.3 and 90. The commenter stated that proposed § 405.1835(a)(2)(ii) includes a 12-month period for issuance of a timely NPR by the contractor, but the two manual sections together instruct the Medicare contractor to issue an NPR within a 13-month period. The commenter recommended that CMS revise the proposed rule by adopting the same 13-month period for determining the timeliness of the contractor's NPR. The commenter also suggested an alternative approach that would change the proposed rule's beginning date for the 12-month period for determining the timeliness of the contractor's NPR.

Response: We respectfully disagree with the commenter's assertion that the two manual sections require the Medicare contractor to issue an NPR within a 13-month period. Our longstanding policy is that if the contractor does not issue an NPR within 12 months after the date of its receipt of the provider's perfected or amended cost report, the provider may appeal to the Board within 180 days after the expiration of the 12-month period for

timely issuance of the NPR. As explained in our response to the immediately preceding comment, this policy is now stated appropriately in § 405.1835(c), a regulation we adopted in the technical correction provisions of the FY 2015 IPPS/LTCH PPS final rule (79 FR 50350 through 50351). Accordingly, we do not see any reason to make any of the revisions suggested by the commenter.

Comment: A number of commenters stated that the proposed rule conflicts with section 1878(d) of the Act, which authorizes the Board to address the full range of reimbursement matters covered by a provider's cost report regardless of whether the Medicare contractor considered a particular matter in its final determination. The commenters asserted that the proposal of making an appropriate cost report claim a substantive prerequisite of reimbursement imposes a new limit on both the Board's authority and providers' appeal rights that is contrary to the Medicare statute.

Response: We respectfully disagree with the commenters for three reasons. First, based on the FY 2015 IPPS/LTCH PPS proposed rule and this final rule, we are eliminating our longstanding interpretation of the statutory dissatisfaction requirement for Board jurisdiction over appeals of a timely final contractor or Secretary determination, an interpretation that required the provider to establish its dissatisfaction by submitting an appropriate cost report claim. As explained above, the elimination of our prior interpretation of the dissatisfaction prerequisite of Board jurisdiction under section 1878(a)(1)(A) of the Act, as requiring an appropriate cost report claim, will make it easier for a provider to establish that it meets the requirements for Board jurisdiction under section 1878(a) of the Act. The Supreme Court held in *Bethesda Hospital Association* that the Board's powers under section 1878(d) of the Act are contingent on the provider first meeting the threshold requirements for Board jurisdiction as set forth in section 1878(a) of the Act. We see no reason why the Board's contingent powers under section 1878(d) of the Act would somehow be narrowed by our making it easier for a provider to meet the threshold jurisdictional requirements imposed by section 1878(a) of the Act.

Second, in the preamble to the 2008 final rule (73 FR 30225 through 30226), we addressed the Supreme Court's holding in *Bethesda Hospital Association* that the Board's powers under section 1878(d) of the Act are contingent on the provider first meeting all the requirements for Board jurisdiction in section 1878(a) of the Act. We also revised § 405.1869 of the regulations (73 FR 30261) to track closely the Supreme Court's interpretation of section 1878(d) in the *Bethesda Hospital Association* decision. However, we did not propose any revisions to § 405.1869 in the FY 2015 IPPS/LTCH PPS proposed rule, and we did not receive public comments suggesting specific revisions to that regulation. We believe that if there were a serious question about whether this final rule would somehow narrow the Board's contingent powers under section 1878(d) of the Act, commenters presumably would have suggested specific revisions to § 405.1869 in order to address any concerns about the purported effect of the FY 2015 IPPS/LTCH PPS proposed rule on the Board's powers under section 1878(d) of the Act. Given that this final rule does not narrow the Board's powers under section 1878(d) of the Act, we do not believe that revisions to § 405.1869 are necessary.

Third, as discussed below, we are adopting a new § 405.1873, which addresses in detail Board review of a provider's compliance with the general reimbursement requirement of an appropriate cost report claim (as prescribed in new § 413.24(j)). Section 405.1873 does not narrow the Board's powers under either section 1878(d) of the Act or the corresponding provisions of § 405.1869, which is not referenced in § 405.1873. Section 405.1873 provides for full review by the Board of a provider's compliance with the general reimbursement requirement of an appropriate cost report claim. Paragraph (a) of § 405.1873 provides for such Board review if any party to an appeal questions whether the provider's cost report included an appropriate claim for a specific item. Under paragraph (b)(1) of § 405.1873, the parties must be given an adequate opportunity to submit factual evidence and legal argument on the question of whether the provider complied with the general reimbursement requirement of an appropriate cost report claim; the Board must make findings of fact and conclusions of law regarding that question; and those findings and conclusions of the Board must be included in the administrative record and they must be included in certain overall Board decisions regarding the appeal. Moreover, assuming that the provider's appeal meets the requirements for Board jurisdiction under section 1878(a) of the Act and § 405.1835 of the regulations, there is no indication in § 405.1873 that the Board's contingent powers under section 1878(d) of the Act and § 405.1869 of the regulations would somehow not apply fully for purposes of Board review of whether the provider complied with the general reimbursement requirement of an appropriate cost report claim.

Comment: Several commenters stated that the proposed rule is inconsistent with section 1878(f)(1) of the Act, which authorizes EJR if the requirements for Board jurisdiction are satisfied and the Board lacks the authority to decide a question of law that is relevant to a matter at issue in the provider's appeal. The commenters stated that the purpose of the EJR statute is to avoid unnecessary delay in adjudicating payment disputes where the Board and the Medicare contractor lack the power to decide the matter at issue. The commenters further stated that, to the extent the Board and the contractor lack the power to decide a relevant legal question, it is arbitrary and capricious to require the provider to protest the matter in its cost report in order to preserve its statutory right to obtain expedited judicial review.

Response: We respectfully disagree with these comments for a number of reasons. The FY 2015 IPPS/LTCH PPS proposed rule did not propose to require a provider to protest a matter in its cost report in order to preserve its statutory right to request EJR. Under section 1878(f)(1) of the Act and § 405.1842 of the regulations, the Board must have jurisdiction over the provider's appeal before EJR can be granted as to a legal question that is relevant to a matter at issue but is beyond the Board's decisional authority. We are now eliminating our longstanding interpretation of the statutory dissatisfaction requirement for Board jurisdiction, an interpretation that required the provider to establish its dissatisfaction by submitting an appropriate cost report claim. As explained above, this revision makes it easier for a provider to demonstrate that it meets the requirements for Board jurisdiction. Given that Board jurisdiction must be established before EJR can be granted, we see no reason why the elimination of our prior interpretation of the statutory dissatisfaction requirement for Board jurisdiction (as requiring an appropriate cost report claim) would somehow impede or constrain a provider's right to seek EJR. We believe that the elimination of our prior interpretation of the statutory dissatisfaction requirement for Board jurisdiction (as requiring an appropriate cost report claim) should facilitate a provider's exercise of its

right to seek EJR because this final rule makes it easier for a provider to meet the threshold Board jurisdiction prerequisite of any request for EJR.

We also do not believe that the FY 2015 IPPS/LTCH PPS proposed rule would undermine the purpose of the EJR statute by causing improper delay in the adjudication of payment disputes where the Board lacks the authority to decide a relevant legal question. Under section 1878(f)(1) of the Act and § 405.1842 of the regulations, a grant of EJR does not necessarily resolve the entire Board appeal. Rather, section 1878(f)(1) of the Act authorizes EJR if the requirements for Board jurisdiction are satisfied, and the provider's appeal ''involves a question of law or regulations relevant to the matters in controversy'' and the Board determines ''that it is without authority to decide the question.'' While the Board might lack the authority to decide one legal question ''relevant to the matters at issue,'' the Board could also have full decisional authority over other questions that are also relevant to the matters at issue. For example, the Board has no authority to decide a facial challenge to the lawfulness of a provision of a payment regulation (42 CFR 405.1867), but the Board can decide the separate question of whether other undisputed provisions of the same payment regulation were applied properly by the contractor. The latter issue (that is, whether the payment regulation was applied properly) is a mixed question of law and fact that is within the Board's decisional authority, even though the Board lacks the authority to decide the former question of whether a provision of the same payment rule is lawful.

As discussed below, we are adopting as final the proposed new § 405.1873, which addresses Board review of a provider's compliance with the general reimbursement requirement of an appropriate cost report claim (as prescribed in new § 413.24(j)). The question of whether a provider made an appropriate cost report claim for a specific payment item is a mixed question of law and fact that is well within the Board's decisional authority. If the provider's appeal also raises a facial challenge to the lawfulness of the governing regulation for the same payment item, the Board has no authority to decide that legal question. However, the mixed question of law and fact (that is, whether the provider made an appropriate cost report claim for the specific payment item at issue), which is plainly within the Board's decisional authority, is just as ''relevant to the matters in controversy'' (section 1878(f)(1) of the Act) as the question of law (that is, whether the payment regulation is lawful) that is beyond the Board's decisional authority. Thus, the provider's statutory right to request EJR of its facial challenge to the lawfulness of the specific payment regulation is not improperly impeded or delayed by the Board's discharge of its authority to review and decide the mixed question of law and fact of whether the provider complied with the general reimbursement requirement of an appropriate cost report claim for the same payment item (as prescribed in new § 413.24(j)).

Indeed, the foregoing principles are clearly reflected in new § 405.1873. Under paragraph (d)(2) of § 405.1873, if the Board grants EJR regarding a question of law that is relevant to the matters at issue, its EJR decision must include the Board's findings of fact and conclusions of law (if any) about whether the provider's cost report included an appropriate claim for the matter at issue, and any such findings and conclusions are subject to the same provisions in § 405.1842(g)(1), (g)(2), (h)(1), and (h)(3) (regarding further review and finality) as ''apply to the other parts of the Board's EJR decision.'' Similarly, paragraph (f)(2) of § 405.1873 addresses the potential reimbursement effects of an EJR decision that both grants EJR regarding a question of law that is relevant to the matters at issue, and also includes the Board's findings of fact and conclusions of law (if any) about whether the provider's cost report included an appropriate claim for the matter at issue.

Comment: One commenter asserted that the proposed rule interferes with a provider's right to introduce evidence in a hearing before the Board.

Response: We respectfully disagree with this comment. Under section 1878(c) of the Act, a provider may be represented by counsel at a Board hearing, and introduce evidence and examine and cross-examine witnesses at such hearing. The regulations elaborate on these hearing rights (§§ 405.1845 through 405.1851, 405.1859, and 405.1861) and establish additional rights to pre-hearing discovery and subpoenas (§§ 405.1853 and 405.1857). We do not believe the FY 2015 IPPS/LTCH PPS proposed rule interferes with a provider's right to introduce evidence in a Board hearing or with any of the provider's Board procedural rights that are elaborated on, or established in, the above-referenced regulations.

None of the foregoing Board procedural regulations is mentioned in revised § 405.1835 or in new § 405.1873. As explained above, the elimination (in § 405.1835(a)) of our longstanding interpretation of the statutory dissatisfaction requirement for Board jurisdiction (an interpretation that required the provider to establish its dissatisfaction by submitting an appropriate cost report claim) makes it easier for a provider to demonstrate that it meets the requirements for Board jurisdiction. We believe this revision to § 405.1835(a), which makes it easier for the provider to establish Board jurisdiction, has no bearing on a provider's Board procedural rights under section 1878(c) of the Act or the above-referenced regulations. More specifically, we see no reason why revisions to the regulations that make it easier for a provider to establish Board jurisdiction would somehow interfere with the provider's Board procedural rights under section 1878(c) of the Act or the above-referenced regulations.

We believe the same is true of our adoption of new § 405.1873, which addresses in detail Board review of a provider's compliance with the general reimbursement requirement of an appropriate cost report claim (as prescribed in new § 413.24(j)). Far from interfering with a provider's right to introduce evidence in a Board hearing (under section 1878(c) of the Act) or with any of the provider's Board procedural rights that are elaborated on, or established in, the regulations, § 405.1873 provides for full review by the Board of provider compliance with the general reimbursement requirement of an appropriate cost report claim (as prescribed in new § 413.24(j)). Under paragraph (b)(1) of § 405.1873, the parties must be given an adequate opportunity to submit factual evidence and legal argument on the question of whether the provider complied with the general reimbursement requirement of an appropriate cost report claim; the Board must make findings of fact and conclusions of law regarding that question; and those findings and conclusions of the Board must be included in both the administrative record and in certain overall Board decisions regarding the appeal. Thus, given the broad scope of the Board's review under new § 405.1873, we see no reason to believe that this regulation would somehow interfere with a provider's right to introduce evidence in a Board hearing or with any of the provider's Board procedural rights that are elaborated on, or established in, the above-referenced regulations.

Comment: Commenters asserted that shifting the dissatisfaction provision from a Board jurisdiction requirement (in § 405.1835) to a cost reporting requirement (in new § 413.24) is

inconsistent with the PPS payment provisions of section 1886 of the Act. The commenters stated that most Board appeals now raise PPS issues, which do not involve cost-based reimbursement. The commenters further stated that the documentation of costs in provider cost reports is not relevant to PPS payment, which is set without regard to a provider's costs.

Response: We did not propose shifting the dissatisfaction provision from a Board jurisdiction requirement to a cost reporting requirement, and we are not adopting such provisions in this final rule. As explained above, the Supreme Court held in *Bethesda Hospital Association* that section 1878(a)(1)(A) of the Act clearly makes provider dissatisfaction a requirement for Board jurisdiction. This statutory prerequisite of Board jurisdiction over appeals of a timely final contractor or Secretary determination is plainly stated in the current text of paragraph (a)(1) of § 405.1835, and in the preambles for both the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28207 through 28208 and 28212 through 28213) and the technical correction provision in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50199 through 50200). Moreover, in this final rule, we are making a technical revision to the dissatisfaction provision in current paragraph (a)(1) of § 405.1835 so that the provider dissatisfaction requirement for Board jurisdiction over appeals of a timely final contractor or Secretary determination in this regulation will track closely the references to ''is dissatisfied with'' in section 1878(a)(1)(A) of the Act.

Based on the provisions of the FY 2015 IPPS/LTCH PPS proposed rule and this final rule, we are eliminating (in §§ 405.1835(a)(1) and 405.1840(b)(3)) an appropriate cost report claim as a prerequisite of Board jurisdiction over appeals of a timely final contractor or Secretary determination under section 1878(a)(1)(A) of the Act. Furthermore, we are making an appropriate cost report claim a general substantive requirement for Medicare payment (in new § 413.24(j)).

We understand that many Board appeals now present payment issues under a PPS. Also, many PPS payments are determined without reference to a provider's own costs. However, we respectfully disagree that the adoption of an appropriate cost report claim as a general substantive requirement for Medicare payment (in new § 413.24(j)) is improper simply because some PPS appeals are filed with the Board and some PPS payments are determined without reference to a provider's own costs. This notion is at odds with the statute and regulations, and with the actual workings of the Medicare program.

In accordance with 42 CFR 412.52, our longstanding policy is that hospitals subject to a PPS must meet the cost reporting and recordkeeping requirements of §§ 413.20 and 413.24. This policy fully comports with the Medicare statute. Section 1815(a) of the Act generally provides that no payments shall be made to any provider unless it has furnished such information as the Secretary may request. In addition, section 1878(a) of the Act makes Board appeal rights generally contingent on the provider having filed a required cost report within the time specified in regulations. More specifically, section 1878(a)(1)(A)(ii) of the Act provides that if a hospital receives payment under subsection (b) and (d) of section 1886 of the Act (that is, the PPS statute) and it submits such reports as the Secretary may require, the hospital may obtain a Board hearing with respect to such payment.

Contrary to the commenters' assertion, some payments to PPS hospitals are determined on a reasonable cost basis. For example, PPS hospitals are reimbursed on a reasonable cost basis for organ acquisition services (§ 412.113(d)). Because PPS hospitals receive both prospectively determined payments and cost-based payments, the requisite annual cost report accounts for both types of payment. Upon reviewing the hospital's cost report, the contractor's final determination is issued in a written NPR. The definition of ''contractor determination'' (in § 405.1801(a)) and the requirements for the NPR (in § 405.1803(a)) each refer specifically to both PPS payments and cost-based payments. Given the above-described systematic integration of PPS payments and cost-based payments under the statute and regulations and in the actual workings of the Medicare program, we believe it is entirely reasonable to make the general substantive payment requirement of an appropriate cost report claim (in new § 413.24(j)) apply to PPS payments as well as cost-based payments.

Comment: Some commenters stated that the proposed rule should only apply to appeals of a final contractor determination in an NPR, and not to challenges of final payment determinations by the Secretary such as those published in the **Federal Register**. The commenters cited IPPS rate determinations as an example, stating their belief that the statute provides a separate avenue of appeal for the Secretary's IPPS determinations under section 1886(d) of the Act, and the proposed rule should not apply to appeals from a notice of an IPPS rate determination. The commenters further stated that the U.S. Court of Appeals for the District of Columbia Circuit ruled in *Washington Hospital Center* v. *Bowen*, 795 F.2d 139 (D.C. Cir. 1986) that the filing of a cost report is not required for Board jurisdiction over an appeal of an IPPS rate determination.

Response: We respectfully disagree with these comments. First, the proposed rule does not impose new requirements for Board jurisdiction or otherwise impede Board jurisdiction. On the contrary, the propose rule eliminates our longstanding interpretation (in §§ 405.1835(a)(1) and 405.1840(b)(3)) of the dissatisfaction prerequisite of Board jurisdiction, as requiring an appropriate cost report claim, which makes it easier for providers to meet the requirements for Board jurisdiction. Moreover, our elimination of this interpretation of the dissatisfaction requirement for Board jurisdiction applies to PPS appeals based on clause (ii) of section 1878(a)(1)(A) of the Act, as well as other appeals under clause (i) of that statutory provision. Also, we are establishing an appropriate cost report claim as a general substantive requirement for payment (in new § 413.24(j)), but this regulation does not pertain to the requirements for Board jurisdiction.

Second, for the reasons set forth in our response to the immediately preceding comment, we do not believe that the general substantive payment requirement of an appropriate cost report claim (in new § 413.24(j)) should apply solely to cost-based payments but not PPS payments. By definition (in § 405.1801(a)), a final contractor determination encompasses both PPS payments and cost-based payments, and the term ''contractor determination'' is synonymous with the phrases ''intermediary's final determination'' and ''Secretary's final determination'' in clauses (i) and (ii), respectively, of section 1878(a)(1)(A) of the Act. Similarly, the requirements for the NPR (in § 405.1803(a)) include specific information about PPS payments as well as information regarding cost-based payments. These regulations comport with the actual workings of the Medicare program inasmuch as PPS hospitals receive some payments that are determined on a reasonable cost basis (§ 412.113(b)), in addition to receiving prospectively determined payments.

Third, we recognize that clause (ii) of section 1878(a)(1)(A) of the Act provides

for appeal to the Board of the Secretary's final determination of PPS payment, but this does not mean that the general substantive payment requirement of an appropriate cost report claim (in new § 413.24(j)) should not apply to PPS payments. Clause (ii) provides for a Board hearing with respect to the Secretary's final determination of PPS payment, but such Board hearings are contingent on the hospital's submission of ''such reports within such time as the Secretary may require in order to make payment under such section'' (that is, under the PPS statute). Under § 412.52, hospitals subject to PPS must satisfy the same cost reporting and recordkeeping requirements as apply to other providers pursuant to §§ 413.20 and 413.24. Moreover, the substantive payment requirement of an appropriate cost report claim (in new § 413.24(j)) is especially well-suited for some PPS payments. For example, the PPS payment adjustment for hospitals that serve a significantly disproportionate share of low income patients is determined on the basis of information about patients' eligibility for Medicaid benefits and their entitlement to Supplemental Security Income (SSI) benefits (§ 412.106(b)), but the requisite Medicaid and SSI information is not available until after the close of the hospital's cost reporting period and so this information is properly included in the hospital's cost report for such period.

Fourth, in the Washington Hospital Center decision, the U.S. Court of Appeals for the District of Columbia Circuit held that a hospital could appeal its target amount (or hospital-specific rate) to the Board under clause (ii) of section 1878(a)(1)(A) of the Act. The court reasoned that because the hospital received notice of the target amount before its cost reporting period began, it could appeal that notice under clause (ii) without waiting for the end of its fiscal period; submission of its cost report; and receipt of the contractor's NPR. However, the target amount applied during the short transition period from cost-based reimbursement to IPPS. As explained above, hospitals subject to PPS are still paid on a reasonable cost basis for some items such as the direct medical education costs of interns and residents in an approved program (§ 412.113(b)). Under PPS, hospitals can also receive certain payments that are determined on the basis of information that is not available until after the close of the hospital's cost reporting period and so such information is properly included in the hospital's cost report for such period (§ 412.106(b); determination of the payment adjustment for PPS hospitals that serve a significantly disproportionate share of low income patients is based on information about patients' eligibility for Medicaid benefits and their entitlement to SSI benefits but such information is not available until after the end of the hospital's cost reporting period).

Fifth, we understand that other PPS payment matters could arise where a hospital believes that, as with the target amount notice in Washington Hospital Center, it should be allowed to appeal to the Board under clause (ii) of section 1878(a)(1)(A) of the Act without awaiting the end of its fiscal year, submission of its cost report, and receipt of the contractor's NPR. However, we believe that, instead of trying to identify specific PPS payment matters that are arguably similar to the target amount notice in Washington Hospital Center, it is more efficient for the Board to review disputes about whether there was an appropriate cost report claim for a specific PPS item in accordance with the procedures established in new § 405.1873. Under § 405.1873, if a party to an appeal questions whether there was an appropriate cost report claim for a specific PPS item, the Board must take evidence and argument on that question; issue findings of fact and conclusions of law on such matter; and include those findings and conclusions in both the administrative record and certain types of overall Board decisions.

Comment: One commenter questioned whether the proposed rule would foreclose repayment for a claim that, based on a post-payment review, was deemed an overpayment and recouped by a contractor, but, on appeal, there was a full reversal of the overpayment determination. The commenter stated that it is a provider that is reimbursed under the periodic interim payment (PIP) method. The commenter further stated that specific claims were denied by a Medicare recovery audit contractor (RAC), and the MAC then recouped the overpayments for such claims by withholding future Medicare payments that otherwise would have been paid to the provider. The commenter also stated that when specific claim denials and overpayment determinations were reversed as a result of its administrative appeals, the MAC then reprocessed the specific claims but it did not repay the provider for the overpayment amounts on the claim denials because it is a PIP provider. The commenter stated that in order to obtain repayment of the overpayment amounts, its only option is to appeal the matter to the Board. The commenter further stated that, due to the time necessary for administrative review and reversal of the specific claim denials and overpayment determinations, it would be too late for the provider to make an appropriate claim in its cost report for repayment of the overpayment amounts on the specific claims, and so the proposed rule would foreclose any repayment of the specific claims. The commenter also stated that the proposed rule should be revised to facilitate payment pursuant to a prior decision in an appeal and, if necessary, the filing of a Board appeal.

Response: We do not agree that the proposed rule would foreclose repayment for a claim that, based on a post-payment review, was deemed an overpayment and recouped by the MAC, but, on appeal, there was a full reversal of the overpayment determination. The situation described by the commenter involved individual claims for Medicare benefits, which are subject to a separate system of claims determination procedures and administrative and judicial review under section 1869 of the Act and Subpart I of 42 CFR part 405. Under this Medicare administrative appeals process, the MAC issues an initial determination regarding coverage and any payment for a claim for Medicare benefits. If the provider is dissatisfied with the initial determination, the provider may pursue the Medicare administrative appeals process and judicial review of any final agency decision (§ 405.904(a)(2)). The initial determination is final and binding unless changed through an appeal (§ 405.928). Similarly, each decision in the administrative appeals process is final and binding unless altered through further administrative or judicial review (§§ 405.958, 405.978, 405.1048, and 405.1130).

The situation described by the commenter apparently involved the reopening of initial determinations for specific benefit claims; review and denial of the specific claims by a RAC; issuance by the MAC of revised determinations for the specific claims and demands for repayment of the overpayment for each claim (§§ 405.980 and 405.982). The commenter stated that after the overpayment amounts were recouped from the provider, the overpayment determinations for the specific claims were reversed at some stage of the administrative appeals process (§ 405.984).

When an overpayment determination for a specific claim is reversed in full through the Medicare administrative appeals process, the contractor must implement the binding and final appeals decision in accordance with the Medicare statute and regulations. In

situations like those described by the commenter, the contractor would revise the overpayment determination and credit the provider for the total overpayment amount plus interest (if any) that was recouped previously from the provider (§ 405.379(d)(8)). When crediting the provider, the contractor would not necessarily repay the provider at that time. For example, if the provider had not repaid or successfully appealed an overpayment determination for a second, different individual benefit claim, the overpayment amount for the first claim (that is, the overpayment determination that was completely reversed through the administrative appeals process) would be applied against the unpaid overpayment amount and accrued interest (if any) that might be owing for the second claim, before any excess amount is released to the provider (§§ 405.378(j) and 405.379(g)(1)(i) and (g)(4)). Thus, because the provider would receive this full credit for the recouped overpayment amount and interest (if any) that was later reversed in full through the administrative appeals process for individual benefit claims (under section 1869 of the Act and Subpart I of 42 CFR part 405), the provider would not need to appeal to the Board (under section 1878 of the Act and Subpart R of 42 CFR part 405) in order to receive full credit for the overpayment determination that had already been reversed in full through the separate appeals process for individual benefit claims.

Moreover, there are strong incentives for the contractor to promptly give the provider full credit for the previously recouped overpayment amount and interest (if any) after the overpayment determination is reversed in full through the administrative appeals process. For example, interest might accrue on the overpayment amount (§ 405.378(b) and (j)). Also, the contractor's performance review under its contract with CMS could be affected negatively (§§ 421.120(a) and 421.122(a)).

We recognize that a provider in the situation described by the commenter still might appeal to the Board in order to ensure that the provider will receive full credit for the recouped overpayment amount and interest (if any) that was reversed in full through the Medicare administrative appeals process for individual benefit claims pursuant to section 1869 of the Act and Subpart I of 42 CFR part 405. However, we believe that our proposed new § 405.1873 and other Board appeals regulations are sufficient for Board review and decision in such appeals. Under proposed new § 405.1873, if a party to such a Board appeal were to question the provider's compliance with the general substantive reimbursement requirement of an appropriate cost report claim (under new § 413.24(j)), the Board would have to receive factual evidence and legal argument on such question; issue specific findings of fact and conclusions of law on that matter; and include those findings and conclusions in the administrative record and in any hearing decision or EJR decision (if EJR is granted) regarding the matter at issue.

As explained above, the statute and regulations require Medicare contractors to fully credit the provider for any previously recouped overpayment amount and interest (if any) that is later reversed in full through the separate appeals process for individual benefit claims, and we see no reason why a contractor would not comply with these requirements. As a result, we do not believe the provider would need to appeal to the Board in order to receive such credit, and our proposed new § 405.1873 and other Board appeals regulations are sufficient for Board review and decision in such appeals. Moreover, we note that the Subpart R regulations address these kinds of issues in the context of cost reports and NPRs, similarly to how the above-described provisions in the Subpart I regulations apply to individual benefit claim determinations and appeals. Specifically, § 405.1803(d) provides that, for each final administrative appeal decision or final judicial judgment on the merits of a reimbursement issue that stems from a cost report and NPR, the contractor must determine the effect of the final administrative or judicial decision on program reimbursement for the fiscal period at issue; issue any revised final contractor determination; and make any additional payment or recoup or offset any program payment that might be due for the fiscal year at issue.

We believe that, given the similar requirements (discussed above) for contractor implementation of final administrative decisions on individual benefit claims, there is no need for a provider to appeal to the Board in order to receive full credit for an earlier final decision on such specific claims. However, if the provider still appealed to the Board, we believe our proposed new § 405.1873 and other Board appeals regulations would be sufficient for Board review and decision in such appeals.

Comment: One commenter questioned CMS' decision to continue enforcement of the Board jurisdictional requirement (in current §§ 405.1835(a)(1) and 405.1840(b)(3)) of an appropriate cost report claim until the effective date of a final rule that makes an appropriate cost report claim a general substantive reimbursement requirement.

Response: In the preambles for both the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28207 through 28208 and 28212 through 28213) and this final rule, we have explained at length the importance of requiring an appropriate cost report claim for each payment matter. Under this final rule, we are establishing (in new § 413.24(j)) an appropriate cost report claim as a general substantive reimbursement requirement that will apply to each specific payment item. However, that general reimbursement requirement will not apply until the prospective effective date of this final rule. In order to maintain our longstanding policy of requiring an appropriate cost report claim, our only recourse is to continue enforcement of the Board jurisdictional requirement (in current §§ 405.1835(a)(1) and 405.1840(b)(3)) of an appropriate cost report claim until this final rule takes effect.

After consideration of the public comments we received, we are finalizing our proposals as follows. We are adopting our proposal to eliminate our interpretation (in §§ 405.1835(a)(1) and 405.1840(b)(3)) that a provider must make an appropriate cost report claim for an item in order to meet the dissatisfaction requirement for Board jurisdiction over appeals of a timely final contractor determination or Secretary determination. More specifically, we are adopting technical revisions to the proposed introductory text for paragraph (a) of § 405.1835 and to proposed paragraph (a)(1) of § 405.1835 so that the dissatisfaction requirement in the regulations will more closely track the text of the dissatisfaction requirement in section 1878(a)(1)(A) of the Act for Board jurisdiction over appeals of a timely final contractor determination or Secretary determination. We also are adding a new conforming amendment (that is, paragraph (a)(1)(i)) to § 405.1835), which is a necessary cross-reference to certain reopening regulations (§§ 405.1887(d) and 405.1889(b)) and to a provision in new § 405.1873 (that is, paragraph (c)(2)(i)) that cross-references the same reopening regulations. In addition, we are finalizing without modification our proposal (79 FR 28298) to amend § 405.1840 by removing paragraph (b)(3).

We are not adopting the proposed revisions (79 FR 28297) to either of the other two requirements for Board jurisdiction over appeals of a timely

final contractor or Secretary determination. Our adoption of the above-described technical revision to proposed paragraph (a)(1) of § 405.1835 obviates any need to renumber the amount in controversy jurisdictional requirement in current paragraph (a)(2) or the timely filing jurisdictional requirement in current paragraph (a)(3). The proposed revisions to the text of current paragraph (a)(3) of § 405.1835 are not necessary because the essential provisions of such proposal are now contained appropriately in § 405.1835(c), a regulation we adopted in the technical correction provisions of the FY 2015 IPPS/LTCH PPS final rule (79 FR 50350 through 50351).

We are finalizing without modification the proposed revisions (79 FR 28297) to paragraphs (b)(1), (b)(2) introductory text, and (b)(2)(iii) of § 405.1835. Also, we are adopting a technical conforming revision to current paragraph (b)(3) of § 405.1835. Specifically, we are adding the term ''final'' before the phrase ''contractor or Secretary determination'' in paragraph (b)(3). This technical revision is necessary to conform paragraph (b)(3) of § 405.1835 to our revision in this final rule of the definition of ''contractor determination'' in § 405.1801(a) (discussed in section XVII.E.4.b. of this final rule).

We also are adopting, in paragraphs (e)(1) and (e)(2) of § 405.1835, the same text that we proposed (79 FR 28297) as revisions to paragraphs (c)(1) and (c)(2) of § 405.1835. When the proposed rule was published, paragraph (c) of § 405.1835 addressed the addition of issues to a pending Board appeal. However, paragraph (c) was later redesignated as paragraph (e) of § 405.1835 in the technical correction provisions of the FY 2015 IPPS/LTCH PPS final rule (79 FR 50350 through 50351). Accordingly, we are adopting the text of the proposed amendments (to paragraphs (c)(1) and (c)(2) of § 405.1835) in paragraphs (e)(1) and (e)(2) of § 405.1835 which now addresses the addition of issues to a pending Board appeal. However, we are not finalizing the proposed revision (79 FR 28297) to paragraph (c)(3) of § 405.1835, because the essential provisions of such proposal are now contained appropriately in § 405.1835(e)(3), a regulation we adopted in the technical correction provisions of the FY 2015 IPPS/LTCH PPS final rule (79 FR 50350 through 50351).

2. Board Review of Compliance With Cost Report Claim Requirements Under § 413.24(j)

a. Proposed Addition of New § 405.1873

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28213 through 28215 and 28298 through 28300), we proposed to add a new § 405.1873 to the Board appeals regulations, which would address how the Board should proceed when any party to an appeal questions whether a provider made an appropriate cost report claim (as required by proposed § 413.24(j)) for a specific item under appeal. We explained that this new regulation is necessary to forestall potential confusion about how the substantive reimbursement requirement in proposed § 413.24(j) of an appropriate cost report claim for a specific item will pertain to Board appeals of the same item.

Under paragraph (b)(1) of proposed new § 405.1873, the Board would consider timely submitted factual evidence and legal argument on, and then prepare written specific findings of fact and conclusions of law regarding, the question of whether the provider's cost report complied with proposed § 413.24(j). The Board would give these written specific factual findings and legal conclusions to each party to the appeal, and they must be included in the record of administrative proceedings for the appeal. Paragraph (b)(2) of proposed § 405.1873 provides that, upon giving the parties to the appeal the Board's written factual findings and legal conclusions on the question of whether the provider's cost report included an appropriate cost claim for the specific item under appeal, the Board then must proceed to issue one of four types of overall decisions with respect to such item. As discussed below, paragraph (d) of proposed § 405.1873 provides that, if the Board issues either of two types of overall Board decisions regarding the specific item under appeal (that is, a hearing decision or an expedited judicial review (EJR) decision where EJR is granted), the Board's written specific factual findings and legal conclusions (reached under proposed § 405.1873(b)) about whether there was an appropriate cost report claim for the item, must be included in such overall Board decision regarding the specific item, along with the other matters that are already required for a Board hearing decision or a Board EJR decision where EJR is granted. However, under paragraph (e) of proposed § 405.1873, if the Board issues either of two other types of overall Board decisions regarding the specific item under appeal (that is, a jurisdictional dismissal decision or an EJR decision where EJR is denied), the Board's written specific factual findings and legal conclusions (pursuant to proposed § 405.1873(b)) must not be included in the overall Board decision regarding the specific item. In any event, the Board's factual findings and legal conclusions about whether there was an appropriate cost report claim for the item must be included in the record of administrative proceedings for the appeal in accordance with § 405.1865 of the regulations.

We believe that, in order to ensure full and appropriate implementation of both the addition of the substantive reimbursement requirement of an appropriate cost report claim (in proposed § 413.24(j)) and the elimination of the Board jurisdiction requirement of an appropriate cost report claim (in existing §§ 405.1835(a)(1) and 405.1840(b)(3)), it is necessary to foreclose certain types of Board decisions, orders, and other actions. Accordingly, in order to give full force and effect to our proposed elimination of the Board jurisdiction requirement of an appropriate cost report claim, paragraph (c)(1) of new § 405.1873 would prohibit a denial of jurisdiction, a declination to exercise jurisdiction, the imposition of a sanction, and various other actions by the Board, if any such jurisdictional decision, order, sanction, or other specified action is based on (in whole or in part) the Board's determination that the provider's cost report did not meet the proposed substantive reimbursement requirement under proposed § 413.24(j) of an appropriate cost report claim for the specific item.

In some cases, the Board jurisdiction requirement of an appropriate cost report claim has been addressed in different but related terms. For example, Board jurisdiction has been denied based on the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal. Another example is that Board jurisdiction also has been denied due to the lack of a particular determination by the contractor or the Secretary regarding the specific item under appeal, in the final contractor determination or Secretary determination under appeal. We believe that, in order to give full force and effect to the proposed elimination of the Board jurisdiction requirement of an appropriate cost report claim, it is also necessary to address related terms such as the absence of specific adjustments and the lack of particular determinations

regarding the specific item under appeal. Accordingly, paragraph (c)(2) of proposed new § 405.1873 would prohibit a denial of jurisdiction, a declination to exercise jurisdiction, the imposition of a sanction, and various other actions by the Board, if any such jurisdictional decision, sanction, or other specified action is based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item in the final contractor determination or Secretary determination under appeal. However, paragraph (c)(2)(i) of proposed new § 405.1873 includes an important exception: if the provider's appeal of the specific item is based on the reopening of such item (under § 405.1885 of the regulations) where the specific item is not revised, adjusted, corrected, or otherwise changed in a revised final contractor determination or Secretary determination, the Board must deny jurisdiction over the specific item under appeal (as specified in §§ 405.1887(d) and 405.1889(b) of the regulations). The reopening regulations are an exercise of the Secretary's general rulemaking authority under sections 1102 and 1872 of the Act, and we believe this exception (in proposed § 405.1873(c)(2)(i)) is necessary to ensure consistency with the above-referenced reopening regulations, our longstanding ''issue specific'' interpretation of the reopening regulations, and the interests of administrative finality and efficiency. We refer readers, for example, to *HCA Health Services of Oklahoma* v. *Shalala*, 27 F.3d 614 (D.C. Cir. 1994) (the reopening regulations are based on the Secretary's general rulemaking authority, and the issue specific interpretation of the reopening rules is reasonable and supportive of administrative finality).

Under paragraph (d) of proposed § 405.1873, there are two types of Board decisions that must include any specific findings of fact and conclusions of law by the Board (reached under paragraph (b) of proposed § 405.1873), on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal. First, paragraph (d)(1) of proposed § 405.1873 provides that, if the Board issues a hearing decision on the specific item under appeal (under § 405.1871 of the regulations), the Board's specific findings of fact and conclusions of law about whether there was an appropriate cost report claim for the specific item, must be included in such a hearing decision along with the other matters prescribed in existing § 405.1871(a). A Board hearing decision addresses whether the provider has established that it should receive relief on the matter at issue (as specified in § 405.1871(a)(3)). Under proposed § 413.24(j), the requirement of an appropriate cost report claim is a substantive prerequisite of any payment for the specific item, which applies in addition to other payment requirements for the particular item (for example, the specific requirements for payment of interest expense under § 413.153 of the regulations). We believe that, because a Board hearing decision addresses whether the provider has established that it meets the substantive requirements for payment of the item under appeal whereas an appropriate cost report claim is a substantive prerequisite of any payment for the specific item (under proposed § 413.24(j)), any factual findings and legal conclusions about whether there was an appropriate cost report claim should be included in any hearing decision that might be issued by the Board regarding the specific item. In addition, we note that if the Board elects to issue a hearing decision that also includes factual findings and legal conclusions about whether the other payment requirements for the specific item were satisfied (in addition to the Board's findings and conclusions about whether there was an appropriate cost report claim for the item), such a hearing decision (addressing all the substantive reimbursement requirements for the specific item) will safeguard against piecemeal proceedings before the Board and potentially before the Administrator of CMS and a Federal court. However, paragraph (d)(1)(ii) of proposed § 405.1873 provides that, if the Board determines that the provider's cost report did not include an appropriate claim for the specific item under appeal, the Board has discretion whether or not to address in its hearing decision whether the other substantive reimbursement requirements for the specific item are also satisfied.

Second, paragraph (d)(2) of proposed § 405.1873 provides that, if the Board issues an EJR decision where EJR is granted regarding the specific item under appeal (as provided for under § 405.1842(f)(1) of the regulations), any specific findings of fact and conclusions of law by the Board (reached under paragraph (b) of proposed § 405.1873) about whether there was an appropriate cost report claim for the specific item, must be included in such an EJR decision. Section 1878(f)(1) of the Act and § 405.1842 of the regulations authorize EJR if the requirements for Board jurisdiction over a specific item are satisfied, and the Board determines that it lacks the authority to decide a legal question that is relevant to the specific item under appeal. The Administrator of CMS may review the Board's determination as to whether there is Board jurisdiction over the specific item, but the Administrator may not review the Board's determination as to whether it has the authority to decide a relevant legal question. We believe that paragraph (d)(2) of proposed § 405.1873 will also safeguard against piecemeal proceedings before the Board, the Administrator of CMS, and a Federal court. By requiring a Board EJR decision that grants EJR to include any factual findings and legal conclusions (reached under proposed § 405.1873(b)) about whether there was an appropriate cost report claim for the specific item under appeal, along with the Board's determinations that the two requirements for EJR were satisfied (that is, a finding of Board jurisdiction plus the Board's determination that it lacks the authority to decide a legal question relevant to the specific item under appeal), piecemeal proceedings would be minimized or eliminated because the Board EJR decision will encompass both the question of whether there was an appropriate cost report claim for the specific item and the relevant legal question for which EJR was granted (and for which the Board determined that it has no authority to decide such legal question). Piecemeal proceedings before the Administrator of CMS would also be minimized or eliminated because, under proposed § 405.1875(a)(2)(v) (which we discuss separately below), if the Administrator reviews and issues an EJR decision on the question of whether there is Board jurisdiction over the specific item under appeal, the Administrator will also review, and any decision will address, the Board's specific findings of fact and conclusions of law about whether there was an appropriate cost report claim for the specific item. In turn, our proposal to require an EJR decision that grants EJR to include any specific factual findings and legal conclusions under proposed § 405.1873(b) would ensure that when a Federal court exercises its EJR authority under section 1878(f)(1) of the Act and § 405.1842 of the regulations by reviewing a relevant legal question (for which the Board determined it has no decisional authority), the court's review

can also potentially encompass the final specific findings of fact and conclusions of law by the Board or the Administrator, as applicable, about whether there was an appropriate cost report claim for the specific item. If it is determined, in a final EJR decision that grants EJR, that there was an appropriate cost report claim for the specific item under appeal, the court may have no occasion to review the final specific findings of fact and conclusions of law on the question of whether there was an appropriate cost report claim for the specific item. However, if it is instead determined, in a final EJR decision that grants EJR, that the provider's cost report did not include an appropriate claim for the specific item under appeal, the court can potentially review in one proceeding the final specific findings of fact and conclusions of law about whether there was an appropriate cost report claim for the specific item, along with the relevant legal question for which EJR was granted (and for which the Board determined that it has no authority to decide such legal question).

However, paragraph (e) of proposed new § 405.1873 would provide that there are two other types of Board decisions that must not include any specific findings of fact and conclusions of law by the Board (reached under proposed § 405.1873(b)), on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal. On the one hand, paragraph (e)(1) of proposed new § 405.1873 would provide that if the Board issues a jurisdictional dismissal decision on the specific item under appeal (under § 405.1840(c)), the Board's specific findings of fact and conclusions of law about whether there was an appropriate cost report claim for the specific item must not be included in such a jurisdictional dismissal decision. When the Board issues a jurisdictional dismissal decision on a specific item under appeal, the Board's denial of jurisdiction obviates any need to address the question of whether the substantive reimbursement requirements that are specific to the particular item (for example, the specific requirements for payment for certain depreciation under § 413.134) are satisfied. Because the requirement of an appropriate cost report claim for each specific item is also a substantive prerequisite of any payment for the specific item (as prescribed in proposed § 413.24(j)), a denial of jurisdiction over the specific item also obviates any need to address the substantive reimbursement requirement of an appropriate cost report claim in the Board's jurisdictional dismissal decision.

Similarly, under paragraph (e)(2) of proposed new § 405.1873, if the Board issues an EJR decision where EJR is denied on the specific item under appeal (under § 405.1842(f)(2)), the Board's specific findings of fact and conclusions of law (reached under paragraph (b) of proposed new § 405.1873) about whether there was an appropriate cost report claim for the specific item, must not be included in such an EJR decision. If EJR is denied solely because the Board determines that it does have the authority to decide the legal question relevant to the specific item under appeal, the Board would conduct further proceedings and issue another decision (as specified in § 405.1842(h)(2)(i)). If such further decision is a hearing decision, under proposed § 405.1873(d)(1), the Board's factual findings and legal conclusions (under proposed § 405.1873(b)) about whether there was an appropriate cost report claim must be included in the Board's hearing decision; if the Board elects to also include in the hearing decision its factual findings and legal conclusions about whether the other reimbursement requirements for the specific item are satisfied, piecemeal proceedings before the Board and potentially before the Administrator of CMS and a Federal court would be minimized or eliminated. However, if EJR is denied because the Board lacked jurisdiction over the specific item under appeal, the Board's factual findings and legal conclusions about whether there was an appropriate cost report claim must not be included in such an EJR decision; as explained above regarding Board jurisdictional dismissal decisions, the denial of Board jurisdiction in such an EJR decision obviates the need to address the substantive reimbursement requirement of an appropriate cost report claim, just as there is no need to consider other payment requirements for the particular item under appeal.

Paragraph (f) of proposed new § 405.1873 addresses the various effects of the Board's factual findings and legal conclusions (reached under paragraph (b) of proposed § 405.1873) regarding whether there was an appropriate cost report claim in the two types of Board decisions where such factual findings and legal conclusions must be included—Board hearing decisions, and Board EJR decisions where EJR is granted. An appropriate cost report claim for a specific item is a necessary, but not sufficient, condition for Medicare payment for the specific item. This is because the requirement of an appropriate cost report claim for each specific item is a substantive prerequisite of any payment for the specific item (as prescribed in proposed § 413.24(j)), but all other payment requirements (for example, the particular requirements for payment for certain bad debts under § 413.89) also must be satisfied. Accordingly, under paragraph (f)(1) of proposed new § 405.1873, if the Board determines, as part of a final hearing decision, that the provider's cost report included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j)), payment for the specific item would be made in accordance with Medicare policy, but only if the Board further determines in such hearing decision that all the other substantive reimbursement requirements for the specific item are also satisfied. Conversely, if the Board determines, in a final hearing decision, that the cost report lacked an appropriate claim for the specific item under appeal, payment for the specific item would not be made, regardless of whether the Board further determines in such hearing decision that the other substantive reimbursement requirements for the specific item are satisfied.

Similarly, paragraph (f)(2) of proposed new § 405.1873 provides that, if the Board or the Administrator of CMS (as applicable) determines, as part of a final EJR decision where EJR is granted, the provider's cost report included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j)), payment for the specific item would be made in accordance with Medicare policy, but only to the extent permitted by the final decision of a Federal court under the EJR provisions of section 1878(f)(1) of the Act (see also §§ 405.1842 and 405.1877) regarding the legal question that is relevant to the specific item (but for which the Board determined it has no decisional authority). By contrast, if the Board or the Administrator of CMS (as applicable) determines, in a final EJR decision where EJR is granted, that the cost report lacked an appropriate claim for the specific item under appeal, payment for the specific item would not be made unless: (i) The specific factual findings and legal conclusions by the Board or the Administrator of CMS, as applicable, about whether there was an appropriate cost report claim for the specific item are reversed or modified by the final decision of a Federal court (in accordance with section 1878(f)(1) of the Act and § 405.1877 of the regulations)); and (ii) only to the extent permitted by the final decision of a

Federal court under the EJR provisions of section 1878(f)(1) of the Act (see also §§ 405.1842 and 405.1877 of the regulations) regarding the legal question that is relevant to the specific item (but for which the Board determined it has no decisional authority).

b. Summary of Public Comments and Our Responses and Finalized Policies

Following are summaries of public comments that were received in response to the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28206 through 28217).

Comment: One commenter stated that the proposed addition of § 405.1873 would result in an inappropriate intrusion into the Board's decision making process. The commenter stated that proposed § 405.1873 would hamper the Board's ability to serve an independent role by imposing strict requirements on the scope and content of Board review.

Response: We respectfully disagree with this comment. Section 405.1873 authorizes full Board review of provider compliance with the general substantive reimbursement requirement of an appropriate cost report claim (as prescribed in new § 413.24(j)). The criteria for Board review of such matters are set forth in § 413.24(j), but this is no different than the Board having to review a specific reimbursement claim by reference to the particular standards set forth in the pertinent payment regulation. For example, the Board must apply the specific requirements for reimbursement of interest expense pursuant to § 413.153, in order to fully consider and decide whether the specific requirements for interest expense reimbursement are satisfied. New § 413.24(j) adds the general substantive reimbursement requirement of an appropriate cost report claim, which also must be satisfied for reimbursement of interest expense or any other item. While the Board must review questions about compliance with the general substantive reimbursement requirement of an appropriate cost report claim in accordance with the procedures in proposed § 405.1873, the other provisions of section 1878 of the Act and 42 CFR part 405, subpart R also generally apply to Board review of questions about whether there was an appropriate cost report claim just as those other statutory and regulatory provisions generally apply to Board review of the specific reimbursement requirements for a particular item like interest expense.

Paragraph (b)(1) of proposed § 405.1873 does not impose specific limitations on the Board's findings of fact and conclusions of law regarding the provider's compliance with the general substantive reimbursement requirement of an appropriate cost report claim (as prescribed in new § 413.24(j)). However, after the Board reaches such factual findings and legal conclusions, paragraph (c) of proposed § 405.1873 would impose certain limits on the Board's actions with respect to those findings and conclusions. However, the restrictions on the Board's actions in paragraph (c) are simply aimed at ensuring that the requirement of an appropriate cost report claim (as prescribed in new § 413.24(j)) is applied as a general substantive reimbursement requirement instead of as a jurisdictional requirement that might otherwise underlie a potential jurisdictional dismissal decision or a declination of the exercise of jurisdiction by the Board.

The foregoing point is underscored by paragraph (e)(1) of proposed § 405.1873, which states that if the Board issues a jurisdictional dismissal decision, such a decision must not include the Board's findings of fact and conclusions of law regarding the provider's compliance with the general substantive reimbursement requirement of an appropriate cost report claim. We believe that proposed paragraph (e)(1) should further ensure that the requirement of an appropriate cost report claim (as prescribed in § 413.24(j)) is applied as a general substantive reimbursement requirement instead of as a jurisdictional requirement that might otherwise underlie a potential jurisdictional dismissal decision or a declination of the exercise of jurisdiction by the Board.

Comment: Some commenters stated that if a provider does not include an appropriate claim for a specific item in its cost report, it would not receive payment for that item and it also would lose the ability to appeal that item to the Board. The commenters stated that the Board should maintain the ability to make final determinations regarding claims disagreements.

Response: We believe that proposed new § 413.24(j) and proposed new § 405.1873 clearly state that a provider can appeal a specific item to the Board, even if the contractor previously determined that the cost report did not include an appropriate claim for the particular item. Also, under proposed § 405.1873(f)(1)(i), reimbursement for the specific item would be supported if the Board issues a hearing decision on the merits of the provider's appeal, and the Board rules that the provider complied with § 413.24(j) and all the specific requirements for payment of the particular item.

As discussed above, § 413.24(j)(4) states that if a provider's cost report does not include an appropriate claim for a specific item, the final contractor determination should not include payment for the item. However, § 413.24(j)(5) states that if the provider appeals a specific item to the Board and any party then questions the provider's compliance with the general substantive reimbursement requirement of an appropriate cost report claim for the item, the Board should review such questions in accordance with the procedures set forth in § 405.1873.

Paragraph (d)(1) of proposed § 405.1873 provides that if the Board issues a hearing decision on the merits of the provider's appeal, the hearing decision must include the Board's factual findings and legal conclusions regarding compliance with the general substantive reimbursement requirement of an appropriate cost report claim. Moreover, paragraph (f)(1)(i) of proposed § 405.1873 states that if the Board determines in such hearing decision that the provider's cost report included an appropriate claim for the specific item at issue, and that the provider satisfied all the other substantive reimbursement requirements for such item, the specific item at issue is reimbursable in accordance with Medicare policy. Thus, a Board hearing decision can support reimbursement for a specific item, even if the final contractor determination did not include reimbursement for the item because the contractor determined that an appropriate cost report claim was not made.

Comment: One commenter stated that Board jurisdiction over the appeal of an item would depend on whether the contractor accepted the provider's specific reporting of the item in its cost report.

Response: We respectfully disagree with this comment. As a result of our revisions to § 405.1835(a)(1) and removal of § 405.1840(b)(3), an appropriate cost report claim for a specific item is no longer a jurisdictional requirement for Board appeals. Moreover, as explained in our response to the preceding comment, we believe that, under new § 413.24(j) and new § 405.1873, a provider can appeal a specific item to the Board, even if the contractor previously determined that an appropriate cost report claim for the item was not made. Indeed, proposed § 405.1873(f)(1)(i) provides that reimbursement for the specific item would be supported if the Board issues a hearing decision on the merits of the

provider's appeal, and concludes that there was an appropriate cost report claim for the item at issue and that all the specific reimbursement requirements for the particular item were satisfied.

Comment: Some commenters stated that the procedures in proposed § 405.1873 for Board review of compliance with the general substantive reimbursement requirement of an appropriate cost report claim would promote piecemeal litigation instead of avoiding it.

Response: We continue to believe that proposed § 405.1873 would facilitate the avoidance of piecemeal litigation. Under paragraph (d) of § 405.1873, the Board's factual findings and legal conclusions about compliance with the general substantive reimbursement requirement of an appropriate cost report claim under new § 413.24(j) must be included in any hearing decision or EJR decision where EJR is granted. Hearing decisions, and EJR decisions where EJR is granted, end the Board's consideration of the specific item at issue (§§ 405.1842(h)(1) and 405.1871(b)(1)). Moreover, if the Administrator of CMS reviews the Board's hearing decision or the Board jurisdiction component of the two-part EJR decision (§ 405.1875(a)(2)), the Administrator's decision ends the administrative appeals proceedings regarding the specific item unless the matter is remanded to the Board for further proceedings (§ 405.1875(e)(4)(iii)). In any event, piecemeal litigation would be avoided.

Paragraph (e) of § 405.1873 provides that if the Board issues a jurisdictional dismissal decision, or an EJR decision where EJR is denied, regarding the specific matter at issue, the Board's factual findings and legal conclusions about compliance with the general substantive reimbursement requirement of an appropriate cost report claim under new § 413.24(j) must not be included in the jurisdictional dismissal decision or the EJR decision where EJR is denied. A jurisdictional dismissal decision regarding the specific item is final and binding unless the decision is reversed or modified by the CMS Administrator or a Federal court (§ 405.1840(c)(3)). If the Board's jurisdictional dismissal decision were reversed or modified on review, the matter would typically be remanded for further proceedings on the merits of the reimbursement matter at issue. This comports with the general administrative law principle that a remand is the usual remedy when one issue is finally resolved on administrative or judicial review, but other issues still must be decided in the same case.

If the Board denies EJR on jurisdictional grounds, our statements in the preceding paragraph about jurisdictional dismissal decisions would also apply to EJR decisions where EJR is denied on jurisdictional grounds. If EJR is denied because the Board determines that it has the requisite authority to decide all aspects of the matter at issue, the denial of EJR is an interlocutory decision (§ 405.1842(h)(2)). If the Board later issues a hearing decision on the specific item, its factual findings and legal conclusions regarding compliance with the general substantive reimbursement requirement of an appropriate cost report claim under new § 413.24(j) must be included in the hearing decision. As explained above, a Board hearing decision or a final decision by the CMS Administrator, as applicable, would end the administrative appeals proceedings regarding the specific item. In any event, piecemeal litigation would be avoided.

Comment: One commenter stated that it is not clear whether the Board's specific findings of fact and conclusions of law relating to § 413.24(j) are subject to judicial review.

Response: We believe that, under proposed § 405.1873, the Board's specific findings of fact and conclusions of law regarding compliance with § 413.24(j) are subject to judicial review. First, § 405.1873(b)(1) provides that the Board's factual findings and legal conclusions must be included in the administrative record. Judicial review of a final agency decision would be based on the administrative record under section 1878(f)(1) of the Act, which incorporates the ''whole record'' provision for judicial review under the Administrative Procedure Act (APA) (5 U.S.C. 706).

As explained above, the Board's specific findings of fact and conclusions of law regarding compliance with § 413.24(j) must be included in any hearing decision or EJR decision where EJR is granted. In either case, the final agency decision of the Board or the CMS Administrator, as applicable, is subject to judicial review under section 1878(f)(1) of the Act (§ 405.1877(a)).

Under proposed § 405.1873(e), the Board's specific findings of fact and conclusions of law regarding compliance with the general substantive reimbursement requirement of an appropriate cost report claim (under new § 413.24(j)) must not be included in a jurisdictional dismissal decision or an EJR decision where EJR is denied. However, a final jurisdictional dismissal decision by the Board or the CMS Administrator, as applicable, is subject to judicial review. If a Federal court reverses or modifies a final jurisdictional dismissal decision, the merits of the specific payment item at issue would be remanded. If such remand proceedings were to end with a final hearing decision or an EJR decision where EJR is granted, the Board's specific findings of fact and conclusions of law regarding compliance with § 413.24(j) would be included in such hearing decision or EJR decision under proposed § 405.1873(d). A final hearing decision or a final EJR decision where EJR is granted, including the Board's factual findings and legal conclusions regarding compliance with § 413.24(j), would be subject to judicial review under section 1878(f)(1) of the Act (§ 405.1877(a)).

After consideration of the public comments we received, we are finalizing new § 405.1873 as proposed without modification.

3. Related Revisions to § 405.1875 Regarding Administrator Review

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28215 through 28216 and 28300), we proposed two revisions to § 405.1875 of the regulations, which provides for review by the Administrator of CMS of certain Board decisions, orders, and other actions. We believe these revisions will facilitate the full and appropriate implementation of our proposals (discussed above) to add the substantive reimbursement requirement of an appropriate cost report claim (in proposed § 413.24(j)), to eliminate the Board jurisdiction requirement of an appropriate cost report claim (in existing §§ 405.1835(a)(1) and 405.1840(b)(3)), and to add specific procedures for Board review of questions about compliance with the substantive reimbursement requirement of an appropriate cost report claim (in proposed new § 405.1873).

First, under existing § 405.1875(a)(2) of the regulations, the Administrator may review a Board hearing decision, a Board dismissal decision, the Board's jurisdictional determination in an EJR decision (but not the Board's determination, in an EJR decision, of whether it has the authority to decide a relevant legal question), and any other Board decision or action deemed to be final by the Administrator. We proposed to add a new paragraph (a)(2)(v) to § 405.1875, which would provide that if the Administrator reviews a Board hearing decision, or the jurisdictional component of a Board EJR decision where EJR is granted, regarding a

specific item, the Administrator's review of such a hearing decision or such an EJR decision, as applicable, will include, and any decision issued by the Administrator under § 405.1875(e) of the regulations will address, the Board's specific findings of fact and conclusions of law in such hearing decision or EJR decision (as prescribed in proposed § 405.1873(b) and (d)) on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j)). We explained that this proposed revision to § 405.1875(a)(2) is an important additional safeguard against piecemeal proceedings in the administrative appeals process and potentially before a Federal court. As explained above with respect to proposed § 405.1873(d)(1), if the Board elects to issue a hearing decision that also includes factual findings and legal conclusions about whether the other payment requirements for the specific item were satisfied (in addition to the Board's findings and conclusions about whether there was an appropriate cost report claim for the item), all of the payment requirements for the specific item would be presented in one Board hearing decision for purposes of any review by the Administrator (under proposed § 405.1875(a)(2)(v)) and a Federal court. Moreover, for the specific reasons set forth above regarding proposed § 405.1873(d)(2), our proposal to require that the Board's factual findings and legal conclusions about whether there was an appropriate cost report claim for the item be included in an EJR decision where EJR is granted would also minimize or eliminate piecemeal proceedings before the Board and, given the proposed addition of § 405.1875(a)(2)(v), before the Administrator of CMS and a Federal court.

Second, existing § 405.1875(a) requires the Board to promptly send copies of hearing decisions and EJR decisions to the Office of the Attorney Advisor. Although the Board often (perhaps typically) sends copies of dismissal decisions to the Office of the Attorney Advisor, the Board is not required to so. We proposed to amend the last sentence of paragraph (a) of § 405.1875 by requiring the Board to promptly send copies of dismissal decisions to the Office of the Attorney Advisor. We stated that this proposed revision will facilitate the Administrator's exercise of his discretion under § 405.1875(a)(2)(ii) as to whether to review specific Board dismissal decisions. Also, given our proposals to eliminate the Board jurisdiction requirement of an appropriate cost report claim (in current §§ 405.1835(a)(1) and 405.1840(b)(3)) and to add procedures for Board review of compliance with the substantive reimbursement requirement of an appropriate cost report claim (in new § 405.1873)), we stated that our further proposal to require the Board to promptly send copies of dismissal decisions to the Office of the Attorney Advisor will enhance the Administrator's ability to ensure full and appropriate implementation of our proposed revisions to the Board appeals regulations.

We did not receive any public comments on our proposed revisions to § 405.1875. Accordingly, we are finalizing our proposed revisions to § 405.1875 without modification.

4. Conforming Changes to the Board Appeals Regulations and Corresponding Revisions to the Contractor Hearing Regulations

a. Technical Corrections to 42 CFR Part 405, Subpart R and All Subparts of 42 CFR Part 413

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28216 through 28217), we proposed a number of technical revisions and conforming changes to various provisions in part 405, subpart R and part 413. We proposed a general technical revision of certain terminology that recurs throughout 42 CFR part 405 subpart R and all subparts of 42 CFR part 413. Specifically, we proposed to conform the terminology in 42 CFR part 405 subpart R and all subparts of 42 CFR part 413, by replacing the term ''intermediary'' and its various permutations with the term ''contractor'' and its own permutations, in accordance with sections 1816, 1874A, and 1878 of the Act. We did not receive any public comments on this proposal. Accordingly, we adopted this proposal as final in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50199 and 50351).

b. Technical Corrections and Conforming Changes to §§ 405.1801 and 405.1803

In accordance with the above-described general technical revision proposal (that is, to replace the term ''intermediary'' and its various permutations with the term ''contractor'' and its own permutations throughout 42 CFR part 405 subpart R and all subparts of 42 CFR part 413), we specifically proposed (79 FR 28216) to replace the term ''intermediary determination'' in § 405.1801(a) with the term ''contractor determination.'' As a result of our ensuing adoption in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50199 and 50351) of the above-described general technical revision in terminology, the term ''intermediary determination'' has been replaced by the term ''contractor determination'' in both § 405.1801(a) and § 405.1803(a).

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28216), we also proposed to revise the definition of ''intermediary determination'' (now called ''contractor determination'') in § 405.1801(a), to clarify that such contractor determinations are final as set forth in section 1878(a) of the Act. Moreover, we proposed to revise the cross-reference in § 405.1801(b), from the existing § 413.24(f) to § 413.24 generally, a revision that we believe is appropriate due to the proposed addition of paragraph (j) to § 413.24. We also proposed to revise § 405.1803(a) to refer to the final contractor (instead of intermediary) determination as set forth in § 405.1801(a).

We did not receive any public comments on any of the above-described proposals. Accordingly, in this final rule, we are adopting as final the proposal to revise the definition of ''intermediary determination'' (now called ''contractor determination'') in § 405.1801(a), to clarify that such contractor determinations are final as set forth in section 1878(a) of the Act. Also, in this final rule, we are adopting as final the proposal to revise § 405.1801(b) to include a cross-reference to § 413.24 generally. Moreover, in this final rule, we are adopting as final the proposal to revise § 405.1803(a) to refer to the final contractor determination as set forth in § 405.1801(a).

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28216 and 28295), we proposed to revise the first cross-reference in § 405.1803(a) from paragraph (a)(3) of § 405.1835 to proposed paragraph (a)(2)(ii) of § 405.1835. Although we did not receive any public comments on this proposal, we are not adopting the proposal in this final rule.

As explained in section XVII.E.1.b. of this final rule, we are not finalizing proposed § 405.1835(a)(2)(ii), which would have reiterated our longstanding policy for determining whether a final contractor determination was issued timely for purposes of a Board appeal based on section 1878(a)(1)(B) of the Act. This policy is now stated appropriately in § 405.1835(c), a regulation we adopted in the technical correction provisions of the FY 2015

IPPS/LTCH PPS final rule (79 FR 50350 through 50351).

However, we are adopting in this final rule a conforming amendment to § 405.1803(a). Specifically, we are revising the first cross-reference in current § 405.1803(a) from paragraph (a)(3) of § 405.1835 to current paragraph (c)(1) of § 405.1835.

c. Technical Corrections and Conforming Changes to §§ 405.1811, 405.1813, and 405.1814

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28216), we also proposed revisions to the existing regulations for contractor hearing officer appeals, which are similar to the proposed revisions to the Board appeals regulations. Specifically, we proposed to eliminate an appropriate cost report claim as a jurisdictional requirement for contractor hearing officer appeals (in existing §§ 405.1811(a)(1) and 405.1814(b)(3)). As discussed in the next section, we also proposed to add a new § 405.1832 that (like new § 405.1873 for Board appeals) would detail the procedures for contractor hearing officer review of compliance with the substantive reimbursement requirement of an appropriate cost report claim (as prescribed in proposed § 413.24(j)). In addition, we proposed a technical revision to the existing cross-references in § 405.1813(a) and (b), in order to reflect the proposed revisions to § 405.1811. As explained in the proposed rule, the above-described revisions to the regulations for contractor hearing officer appeals comport with our usual practice of adopting similar regulations for both Board appeals and for contractor hearing officer appeals unless there is a sufficient reason to do otherwise.

We did not receive any public comments on these technical correction proposals to the existing regulations for contractor hearing officer appeals. In this final rule, we are revising the contractor hearing provisions of §§ 405.1811 and 405.1814 to track very closely the revisions we are adopting (in section XVII.E.1. of this final rule) to the Board hearing provisions of §§ 405.1835 and 405.1840. Accordingly, we are adopting our proposal to eliminate our interpretation (in §§ 405.1811(a)(1) and 405.1814(b)(3)) that a provider must make an appropriate cost report claim for an item in order to meet the dissatisfaction requirement for contractor hearing officer jurisdiction over appeals of a timely final contractor determination or Secretary determination. More specifically, we are adopting technical revisions to the proposed introductory text for paragraph (a) of § 405.1811 and to proposed paragraph (a)(1) of § 405.1811 for contractor hearing officer appeals that will closely track our technical revisions to the proposed introductory text for paragraph (a) of § 405.1835 and to proposed paragraph (a)(1) of § 405.1835 for Board appeals. Also, as with our adoption of the conforming amendment in paragraph (a)(1)(i) of § 405.1835 for Board appeals, we are adopting a very similar conforming amendment in paragraph (a)(1)(i) of § 405.1811. As with the corresponding technical revisions and conforming changes in the proposed introductory text for paragraph (a) of § 405.1835 and to proposed paragraphs (a)(1) and (a)(1)(i) of § 405.1835(a), these technical revisions and conforming amendment to § 405.1811(a) will dispel potential confusion about the dissatisfaction jurisdictional requirement for contractor hearing officer appeals of a timely final contractor or Secretary determination.

In addition, we are finalizing without modification our proposal to amend § 405.1814 by removing paragraph (b)(3), just as we are removing paragraph (b)(3) of § 405.1840 for Board appeals.

In this final rule, we are similarly revising various other contractor hearing officer regulations to track very closely the revisions we are adopting (in section XVII.E.1. of this final rule) to the Board appeals regulations. We are not adopting the proposed revisions (79 FR 28295) to either of the other two requirements for contractor hearing officer jurisdiction over appeals of a timely final contractor or Secretary determination. Our adoption of the above-described technical revision to proposed paragraph (a)(1) of § 405.1811 obviates any need to renumber the amount in controversy jurisdictional requirement in current paragraph (a)(2) or the timely filing jurisdictional requirement in current paragraph (a)(3). The proposed revisions to the text of current paragraph (a)(3) of § 405.1811 are not necessary because the essential provisions of such proposal are now contained appropriately in § 405.1811(c), a regulation we adopted in the technical correction provisions of the FY 2015 IPPS/LTCH PPS final rule (79 FR 50350 through 50351).

We are finalizing without modification the proposed revisions (79 FR 28297) to paragraphs (b)(1), (b)(2) introductory text, and (b)(2)(iii) of § 405.1811. Moreover, as with our adoption of a technical revision to current paragraph (b)(3) of § 405.1835, we are adding the term ''final'' before the phrase ''contractor or Secretary determination'' in paragraph (b)(3) of § 405.1811.

We also are adopting, in paragraphs (e)(1) and (e)(2) of § 405.1811, the same text that we proposed (79 FR 28295) as revisions to paragraphs (c)(1) and (c)(2) of § 405.1811. When the proposed rule was published, paragraph (c) of § 405.1811 addressed the addition of issues to a pending contractor hearing officer appeal. However, paragraph (c) was later redesignated as paragraph (e) of § 405.1811 in the technical correction provisions of the FY 2015 IPPS/LTCH PPS final rule (79 FR 50349 through 50350). Accordingly, we are adopting the text of the proposed amendments (to paragraphs (c)(1) and (c)(2) of § 405.1811) in paragraphs (e)(1) and (e)(2) of § 405.1811 which now addresses the addition of issues to a pending contractor hearing officer appeal. However, we are not finalizing the proposed revision (79 FR 28295) to paragraph (c)(3) of § 405.1811, because the essential provisions of such proposal are now contained appropriately in § 405.1811(e)(3), a regulation we adopted in the technical correction provisions of the FY 2015 IPPS/LTCH PPS final rule (79 FR 50349 through 50350).

d. Addition of New § 405.1832

In the FY 2015 IPPS/LTCH PPS proposed rule, we proposed to add new § 405.1832, which would detail the procedures for contractor hearing officer review of compliance with the substantive reimbursement requirement of an appropriate cost report claim (as prescribed in proposed § 413.24(j)). We did not receive any public comments on this proposal. Accordingly, in order to maintain uniformity with our adoption in new § 405.1873 of similar procedures for Board appeals, we are adopting in this final rule proposed new § 405.1832 as final without modification.

e. Revisions to § 405.1834

In the FY 2015 IPPS/LTCH PPS proposed rule, we proposed to amend current § 405.1834, which provides for review of contractor hearing officer decisions by the CMS reviewing official. Specifically, in accordance with proposed new paragraph (b)(2)(iii) of § 405.1834, the CMS reviewing official will review, and address in any decision, the specific factual findings and legal conclusions of contractor hearing officers regarding compliance with the substantive requirement of an appropriate cost report claim (as prescribed in proposed § 413.24(j)), as part of the CMS reviewing official's review of a contractor hearing decision.

We did not receive any public comments on this proposal. Accordingly, in this final rule, we are

adopting as final the proposed addition of new paragraph (b)(2)(iii) to § 405.1834.

f. Technical Corrections and Conforming Changes to §§ 405.1836, 405.1837, and 405.1839

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28217 and 28297), we proposed technical corrections and conforming changes to the Board appeals regulations at §§ 405.1836, 405.1837, and 405.1839. We explained that these technical revisions are necessary and appropriate to maintain consistency with our principal proposals (discussed above) to add the substantive reimbursement requirement of an appropriate cost report claim (in proposed § 413.24(j)); eliminate the Board jurisdiction requirement of an appropriate cost report claim (in existing §§ 405.1835(a)(1) and 405.1840(b)(3)); and add procedures for Board review of compliance with the substantive reimbursement requirement of an appropriate cost report claim (in proposed § 405.1873)).

We did not receive any public comments on the proposed revisions to §§ 405.1836 and 405.1839, which would revise the cross-references in each of these rules to § 405.1835. However, we are not adopting either of those proposals. As explained above, we are adopting a technical revision and a conforming change to existing paragraph (a)(1) of § 405.1835, in order to avoid any potential confusion about the dissatisfaction jurisdictional requirement for Board appeals of a timely final contractor or Secretary determination. Because we are revising the provider dissatisfaction requirement in existing paragraph (a)(1) of § 405.1835, we are not adopting the proposed renumbering (79 FR 28297) of the amount in controversy and timely filing requirements in existing paragraphs (a)(2) and (a)(3), respectively. As a result, it is not necessary to revise the existing cross-references in § 405.1836(a) and (b) to the timely filing provisions of § 405.1835(a)(3), and thus we are not adopting the proposed revisions to § 405.1836(a) and (b).

For the same reason, it is not necessary to revise the cross-references in § 405.1839(a)(1) to the amount in controversy provisions in existing § 405.1835(a)(2) (for Board appeals) and § 405.1811(a)(2) (for contractor hearing officer appeals).

However, we believe other technical revisions to the cross-references in §§ 405.1836 and 405.1839 are necessary. As explained in section XVII.B. of this final rule, the FY 2015 IPPS/LTCH PPS final rule included a technical correction to the Board appeals regulations (79 FR 50199 and 50351) that eliminated the jurisdictional requirement of provider dissatisfaction for appeals based on untimely final contractor or Secretary determinations pursuant to section 1878(a)(1)(B) of the Act. We added paragraphs (c) and (d) to § 405.1835, which govern Board appeals based on untimely final contractor or Secretary determinations. The good cause extensions provisions of § 405.1836 and the amount in controversy provisions of § 405.1839 apply to Board appeals based on untimely final contractor or Secretary determinations (under paragraphs (c) and (d) of § 405.1835) as well as appeals of timely final contractor or Secretary determinations (under paragraphs (a) and (b) of § 405.1835). Accordingly, we believe it is necessary to add, in § 405.1836(a) and (b), cross-references to the timely filing provisions of § 405.1835(c)(2), in addition to the corresponding cross-references to § 405.1835(a)(3). For the same reason, we believe it is necessary to add, in § 405.1839(a)(1), cross-references to the amount in controversy provisions in existing § 405.1835(c)(3) (for Board appeals) and § 405.1811(c)(3) (for contractor hearing officer appeals), in addition to the corresponding cross-references to § 405.1835(a)(2) and § 405.1811(a)(2).

In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28217 and 28297 through 28298), we also proposed technical corrections and conforming changes to the Board group appeal provisions of § 405.1837.

Comment: Two commenters questioned the proposed revision to paragraph (a)(1) of § 405.1837, which states that, in order to participate in a group appeal, a provider must satisfy individually the requirements for a Board hearing under § 405.1835(a)(1). The commenters noted that, under the proposed revisions to § 405.1835, the $10,000 amount in controversy requirement for a single provider appeal would be renumbered as paragraph (a)(1) (instead of its existing designation as paragraph (a)(2)). However, section 1878(b) of the Act states that the amount in controversy requirement for a single provider appeal of $10,000 or more does not apply to group appeals; instead, the amount in controversy requirement for a group appeal is $50,000 or more in the aggregate.

Response: We agree that, under section 1878(b) of the Act, the amount in controversy requirement for a single provider appeal of $10,000 or more does not apply to each group member individually; rather, the amount in controversy requirement for a group appeal is $50,000 or more in the aggregate. Therefore, in this final rule, we are not adopting the proposed revision to paragraph (a)(1) of § 405.1837. Moreover, we believe that existing paragraphs (a)(1) and (a)(3) of § 405.1837 track the amount in controversy provisions for group appeals in section 1878(b) of the Act, and therefore no revision to paragraphs (a)(1) and (a)(3) of § 405.1837(a) is necessary.

However, we believe a technical conforming revision to the introductory text of paragraph (a) of § 405.1837 (for group appeals) is warranted in order to conform this provision to our technical revision to the proposed introductory text of paragraph (a) of § 405.1835 (for single provider appeals). As explained above in section XVII.E.1. of this final rule, we are revising the proposed introductory text of paragraph (a) of § 405.1835 (79 FR 28297) by eliminating the reference to items ''claimed in its cost report,'' a technical revision that further clarifies our elimination of an appropriate cost report claim as a requirement for Board jurisdiction. We are making a technical conforming revision to the introductory text of paragraph (a) of § 405.1837 by eliminating its similar reference to items ''claimed for a cost reporting period,'' which we believe is necessary to further clarify that our elimination of an appropriate cost report claim as a requirement for Board jurisdiction applies to group appeals just like single provider appeals. Under paragraph (a)(1) of § 405.1837, the jurisdictional requirements for a group appeal are the same as the jurisdictional requirements for a single provider appeal, except for the different amount in controversy requirements for the two types of Board appeals. Thus, our technical revision to the proposed text of paragraph (a)(1) of § 405.1835(a), which will now state that the provider has a right to a Board hearing with respect to a final contractor or Secretary determination if the provider is dissatisfied with the contractor's final determination of the total amount of reimbursement due the provider, applies to group appeals as with single provider appeals. We believe that conforming the introductory text of paragraph (a) of § 405.1837 (for group appeals) to the introductory text of paragraph (a) of § 405.1835 (for single provider appeals) will further clarify that our elimination of an appropriate cost report claim as a Board jurisdiction requirement applies to group appeals as well as single provider appeals.

In addition, we believe a technical revision to a cross-reference in the text of proposed paragraphs (a)(1) and (e)(4) of § 405.1837 is necessary. As explained in section XVII.B. of this final rule, the FY 2015 IPPS/LTCH PPS final rule included a technical correction to the Board appeals regulations (79 FR 50199 and 50351) that eliminated the jurisdictional requirement of provider dissatisfaction for appeals based on untimely final contractor or Secretary determinations pursuant to section 1878(a)(1)(B) of the Act. We added paragraphs (c) and (d) to § 405.1835, which govern Board appeals based on untimely final contractor or Secretary determinations. However, the group appeal provisions of § 405.1837 apply to Board appeals based on untimely final contractor or Secretary determinations (under paragraphs (c) and (d) of § 405.1835) as well as appeals of timely final contractor or Secretary determinations (under paragraphs (a) and (b) of § 405.1835). Accordingly, in this final rule, we are adding, in paragraphs (a)(1) and (e)(4) of § 405.1837, a cross-reference to § 405.1835(c), in addition to the current cross-reference to § 405.1835(a).

F. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C 3501 through 3521).

G. Impact of Requiring Appropriate Claims in Provider Cost Reports and Eliminating That Requirement for Administrative Appeals by Providers

In section VIII. of the preamble to the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28206 through 28217), we discussed our proposal to revise the Medicare cost report regulations by requiring a provider to include an appropriate claim for an item in its cost report, which would be a general substantive requirement for payment in the Medicare contractor's final determination and in any decision by a reviewing entity in an administrative appeal. We also discussed our proposal to revise the Medicare provider appeals regulations by eliminating the requirement of an appropriate cost report claim in order to meet the dissatisfaction requirement for Provider Reimbursement Review Board jurisdiction. In Appendix A of the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28369), we set out our analyses of the impact of these proposals.

As discussed in section XVII.D. and XVII.E. of this final rule, we are finalizing our proposals to revise the Medicare cost report regulations by requiring a provider to include an appropriate claim for an item in its cost report, and to eliminate an appropriate cost report claim as a requirement for Provider Reimbursement Review Board jurisdiction. There is no impact to the provider resulting from these finalized revisions.

XVIII. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available only via the Internet on the CMS Web site. To view the Addenda to this final rule with comment period pertaining to CY 2016 payments under the OPPS, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; select ''1633–FC'' from the list of regulations. All OPPS Addenda to this final rule with comment period are contained in the zipped folder entitled ''2016 OPPS 1633–FC Addenda'' at the bottom of the page. To view the Addenda to this final rule with comment period pertaining to the CY 2016 payments under the ASC payment system, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html*; select ''1633–FC'' from the list of regulations. All ASC Addenda to this final rule with comment period are contained in the zipped folders entitled ''Addendum AA, BB, DD1, DD2, and EE''.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39253, 39211, and 39354), we proposed to add new Addenda as supporting documents for the ease of readers in comprehending the changes we were proposing: Addendum O, which listed the new and revised CY 2016 Category I and III CPT codes and their proposed assignment to new comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed APC assignment and that comments would be accepted on the proposed APC assignment and status indicator (80 FR 39253); and Addendum Q, which included a crosswalk from the existing CY 2015 APC numbers to the proposed new CY 2016 APC numbers (80 FR 39354). However, we now do not believe that Addenda O and Q are necessary for this CY 2016 OPPS/ASC final rule with comment period. Therefore, we are not including them in the files available on the CMS Web site for this final rule with comment period.

XIX. Collection of Information Requirements

A. Legislative Requirements for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and to 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.

In the CY 2016 OPPS/ASC proposed rule (80 FR 39355 through 39358), we solicited public comments on each of the issues outlined above for the information collection requirements discussed below.

B. Associated Information Collections Not Specified in Regulatory Text

In the CY 2016 OPPS/ASC proposed rule, we made reference to proposed associated information collection requirements that were not discussed in the regulation text contained in the proposed rule. The following is a discussion of those proposed requirements, any public comments we received, and our responses to those public comments.

1. Hospital OQR Program

As we stated in section XIV. of the CY 2012 OPPS/ASC final rule with comment period, the Hospital OQR Program has been generally modeled after the quality data reporting program for the Hospital IQR Program (76 FR 74451). We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72111 through 72114), the

CY 2012 OPPS/ASC final rule with comment period (76 FR 74549 through 74554), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68527 through 68532), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75170 through 75172), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 67012 through 67015) for detailed discussions of Hospital OQR Program information collection requirements we have previously finalized. The information collection requirements associated with the Hospital OQR Program are currently approved under OMB control number 0938–1009.

Below we discuss only the changes in burden resulting from the provisions in this final rule with comment period.

a. Estimated Burden of Hospital OQR Program Finalized Policies for the CY 2017 Payment Determination and Subsequent Years

In section XIII. of this final rule with comment period, we are finalizing the adoption of several changes to the Hospital OQR Program for the CY 2017 payment determination and subsequent years. Specifically, we are finalizing our proposals to: (1) Remove the OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache measure, effective January 1, 2016 (no data for this measure will be used for any payment determination); (2) change the deadline for withdrawing from the Hospital OQR Program to August 31 and revise 42 CFR 419.46(b) to reflect this change; (3) shift the quarters on which we base payment determinations; (4) change the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet Web site) to January 1 through May 15; (5) fix a typographical error to correct the name of our extension and exception policy to extension and exemption policy; (6) change the deadline for submitting a reconsideration request to the first business day on or after March 17 of the affected payment year and make a conforming change to 42 CFR 419.46(f)(1) to reflect this change; and (7) amend 42 CFR 419.46(f)(1) and 42 CFR 419.46(e)(2) to replace the term ''fiscal year'' with the term ''calendar year''. While there is burden associated with filing a reconsideration request, section 3518(c)(1)(B) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)) excludes collection activities during the conduct of administrative actions such as reconsiderations. We do not believe that any of these changes will increase burden, as further discussed below.

In addition, we are finalizing conforming changes to our validation scoring process to reflect proposed changes in the APU determination timeframes. For the CY 2017 payment determination, we are finalizing that validation will be based on three quarters of data (quarter 2, quarter 3, and quarter 4 of 2015). For this transition year, we estimate that the burden associated with validation reporting will be reduced by 25 percent because hospitals will submit validation data for three quarters instead of four.

(1) Measure Removed for the CY 2017 Payment Determination and Subsequent Years

As discussed in section XIII.B.5. of this final rule with comment period, we are finalizing our proposal to remove the OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache measure beginning with the CY 2017 payment determination. OP–15 is a claims-based measure. As we noted in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68530), we calculate claims-based measures using Medicare FFS claims data that do not require additional hospital data submissions. In addition, public reporting of OP–15 has been deferred since the CY 2013 OPPS/ASC final rule with comment period (76 FR 74456 and *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228774991461* under 1.6—Imaging Efficiency, ''OP–15 Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache''). Therefore, we estimate that there will be no change in burden based on finalizing the removal of this measure.

(2) Changes to Reporting Requirements for the CY 2017 Payment Determination and Subsequent Years

In section XIII.E. of this final rule with comment period, we are finalizing the adoption of several changes to the reporting requirements for the Hospital OQR Program. Specifically, we are finalizing our proposals to: (1) Change the deadline for withdrawing from the program to up to and including August 31 and revise 42 CFR 419.46(b) to reflect this change; (2) shift the quarters on which we base payment determinations; (3) change the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet Web site) to January 1 through May 15; (4) fix a typographical error to correct the name our extension and exception policy to extension and exemption policy; and (5) change the deadline for submitting a reconsideration request to the first business day on or after March 17 of the affected payment year and make a conforming change to 42 CFR 419.46(f)(1) to reflect this change. Although we are finalizing the adoption of our proposals to change deadlines, these date changes do not change the amount of time required to enter data. Therefore, the hourly burden and resultant financial impact will remain the same.

In addition, we are finalizing the adoption of conforming changes to our validation scoring process to reflect changes in the APU determination timeframes. For prior payment determinations, we sampled 500 hospitals for validation and estimated that it would take each hospital 12 hours to comply with the data submission requirements for four quarters. For the CY 2017 payment determination, we are transitioning to a new payment determination timeframe; as a result, only three quarters of data will be used for determining the CY 2017 payment determination, as opposed to four quarters as previously required. Specifically, for the CY 2017 payment determination, validation is based on data from validation quarter 2, validation quarter 3, and validation quarter 4 of 2015. Therefore, we estimate that data submission for three quarters reduces the number of hours required by 25 percent (from 12 hours to 9 hours per hospital). Consistent with prior years (79 FR 67013), we estimate that a hospital pays an individual approximately $30 per hour to abstract and submit these data. We estimate a total burden of approximately 4,500 hours (500 hospitals × 9 hours/hospital) and a total financial impact of $135,000 ($30/hour × 4,500 hours) for the CY 2017 payment determination. This is a reduction of 1,500 hours and $45,000 across all hospitals from last year's estimate attributable to changes in our validation scoring process.

b. Estimated Burden of Hospital OQR Program Finalized Policies for the CY 2018 Payment Determination and Subsequent Years

For the CY 2018 payment determination and subsequent years, we are finalizing the adoption of two new proposals, with a modification to the manner of data submission for one proposal. First, in section XIII.B.6.a. of this final rule with comment period, we are finalizing the adoption of one new measure for the CY 2018 payment determination and subsequent years: OP–33: External Beam Radiotherapy

(EBRT) for Bone Metastases (NQF #1822). In the CY 2016 OPPS/ASC proposed rule (80 FR 39338), we proposed that hospitals could either: (1) Report aggregate-level data for OP–33 submitted via a CMS Web-based tool (QualityNet Web site); or (2) submit an aggregate data file for OP–33 through a vendor (via the QualityNet infrastructure). As we further explain in section XIII.D.4.b. of this final rule with comment period, we are finalizing only one mode of data submission for this measure: data for OP–33 may only be submitted at an aggregate-level via a CMS Web-based tool (QualityNet Web site).

Consistent with prior years (78 FR 75171), we believe that submitting a measure through a CMS Web-based tool has two burden components: First, the time required to abstract the measure data; and second, the time required to enter these data into a CMS Web-based tool. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 67013), we estimated that it would take hospitals approximately a total of 35 minutes to collect chart-abstracted data for 12 Web-based measures. To calculate the burden associated with a collecting chart-abstracted data for a single Web-based measure, we divided the total number of minutes previously estimated (35 minutes) by the number of measures (12 measures). Therefore, we estimated the burden to collect chart-abstracted data for a single Web-based measure to be 2.92 minutes (or 0.049 hours.). Based on our most recent data (Quarter 4 2013–Quarter 3 2014) for Hospital OQR Program measures, we estimate that the average hospital will submit 48 cases per year for OP–33. Therefore, we believe that the average hospital will spend 2.352 hours (0.049 hours/measure/case × 48 cases) chart-abstracting data for this measure.

In addition, consistent with prior years (78 FR 75171 through 75172), we estimate that each participating hospital will spend 10 minutes (0.167 hours) per measure per year to collect and submit the data via a CMS Web-based tool. Therefore, we estimate that, in total, the proposed measure will increase burden by 2.519 hours (2.352 hours + 0.167 hours) per year. Consistent with prior years (79 FR 67013), we believe that approximately 3,300 hospitals will participate in the Hospital OQR Program for the CY 2018 payment determination. Therefore, we estimate a total increase in burden across all participating hospitals of approximately 8,312.7 hours (2.519 hours/hospital × 3,300 hospitals) per year. Finally, consistent with prior years (79 FR 67013), we estimate that a hospital pays an individual approximately $30 per hour to abstract and submit these data. Therefore, we estimate a total financial increase in burden to be $75.57 per hospital (2.519 hours × $30/hour) or $249,381 (8,312.7 hours × $30/hour) across all participating hospitals as a result of adopting OP–33 for the CY 2018 payment determination and subsequent years.

Second, for the CY 2018 payment determination and subsequent years, we are finalizing that validation again be based on four quarters of data. However, those quarters are validation quarter 1, validation quarter 2, validation quarter 3, and validation quarter 4. For payment determinations prior to CY 2017, we sampled 500 hospitals for validation and estimated that it would take each hospital 12 hours to comply with the data submission requirements for four quarters. Therefore, we estimate a total burden of approximately 6,000 hours (500 hospitals × 12 hours/hospital) and a total financial impact of $180,000 ($30/hour × 6,000 hours) in burden associated with the data validation process for the CY 2018 payment determination and subsequent years. This is an increase of 1,500 hours and $45,000 across all hospitals from the CY 2017 estimate because we will be sampling four quarters, as we had in prior years, instead of three quarters.

Therefore, we estimate a total financial increase in burden of $89.21 (2.97 hours × $30/hour) per hospital or $294,390 (9,813 hours × $30/hour) across all participating hospitals as a result of the proposals that we are finalizing for the CY 2018 payment determination and subsequent years.

c. Estimated Burden of Hospital OQR Program Finalized Policies for the CY 2019 Payment Determination and Subsequent Years

We are not finalizing the adoption of any new proposals for the CY 2019 payment determination and subsequent years. In the CY 2016 OPPS/ASC proposed rule (80 FR 39330), we proposed to add one new measure for the CY 2019 payment determination and subsequent years: OP–34: Emergency Department Transfer Communication (EDTC) (NQF #0291). As stated in section XIII.B.6.b. of this final rule with comment period, we are not finalizing that proposed measure. Thus, because we are not finalizing any changes specifically for the CY 2019 payment determination and subsequent years, we expect the burden to be unchanged for the CY 2019 payment determination as compared to the CY 2018 payment determination and subsequent years as discussed above.

We invited public comment on the burden associated with the proposed information collection requirements which we are finalizing. We did not receive any public comments on these requirements.

2. ASCQR Program Requirements

a. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532 through 68533), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75174), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 67015 through 67016) for detailed discussions of the ASCQR Program information collection requirements we have previously finalized.

b. Policy Proposals Finalized Effective Beginning With the CY 2017 Payment Determination

We are finalizing our proposals to codify a number of existing policies related to program participation and withdrawal, data collection and submission, public reporting, retention and removal of quality measures, measures maintenance, extraordinary circumstances extensions or waivers, and the reconsideration process. We are codifying only existing policies, with the exception of the finalized policy proposals discussed below. For existing policies for which we are finalizing codification, we do not anticipate any additional burden to ASCs affecting the CY 2017 payment determination or subsequent years because there are no changes to these policies.

We are not finalizing our proposal to implement a submission deadline with an end date of May 15 for all data submitted via a Web-based tool beginning with the CY 2017 payment determination. Instead, we are maintaining the previously finalized August 15 submission deadline for the following measures: ASC–6: Safe Surgery Checklist Use; ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures; ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF #0659); and ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following

Cataract Surgery (NQF #1536). We note that ASC–8: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) will continue under the May 15 submission deadline previously finalized for this measure. We do not anticipate additional burden because the data collection and submission requirements have not changed.

We are finalizing our proposal, beginning with the CY 2017 payment determination, to not consider IHS hospital outpatient departments that bill as ASCs to be ASCs for purposes of the ASCQR Program. This final policy will eliminate the burden associated with participation in the ASCQR Program for six IHS hospital outpatient departments that currently are required to participate in the ASCQR Program or be subject to a possible reduction in payment.

We are finalizing our proposal to make a minor change to the reconsideration request deadline to ensure our deadline for these requests will always fall on a business day effective beginning with the CY 2017 payment determination. We do not anticipate that there will be any additional burden because the materials to be submitted are unchanged and the deadline does not result in reduced time to submit a reconsideration request.

We are finalizing our proposal to publicly display data by the NPI when the data are submitted by the NPI and to publicly display data by the CCN when the data are submitted by the CCN, but are not finalizing our proposal to attribute data submitted by the CCN to all NPIs associated with the CCN. We are codifying this new revised policy at 42 CFR 416.315. Again, we do not anticipate any additional burden because this final policy does not alter the administrative or reporting requirements governing an ASC's participation in the ASCQR Program.

Finally, we are finalizing our proposal, for claims-based measures not using QDCs, to use claims for services furnished in each calendar year that have been paid by the MAC by April 30 of the following year of the ending data collection time period in the measure calculation for the payment determination year beginning with the CY 2018 payment determination. We do not anticipate any additional burden to ASCs based on this final policy affecting the CY 2017 payment determination or subsequent years because it does not alter the administrative or reporting requirements governing an ASC's participation in the ASCQR Program.

c. Claims-Based Measures for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75174), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 67015 through 67016) for detailed discussions of the information collection requirements for the six previously adopted claims-based ASCQR Program measures (five outcome measures and one process measure). The six previously adopted measures are: ASC–1: Patient Burn (NQF #0263); ASC–2: Patient Fall (NQF #0266); ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); ASC–4: Hospital Transfer/Admission (NQF #0265); ASC–5: Prophylactic Intravenous (IV) Antibiotic Timing; and ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. The first five of these measures require the reporting of Quality Data Codes (QDCs), but the sixth measure, ASC–12, while utilizing data from paid Medicare FFS claims, does not require ASCs to submit QDCs. For the reasons we discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75173) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 67016), we estimate that the reporting burden to report QDCs for the five claims-based outcome measures that utilize QDCs will be nominal. We do not anticipate that ASC–12 will create any additional burden to ASCs for the CY 2018 payment determination and for subsequent years because no additional data are required from ASCs; only information necessary for Medicare payment is utilized for calculating this measure.

d. Web-Based Measures for the CY 2018 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68532) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75172 through 75174) for detailed discussions of the information collection requirements for the five previously-adopted Web-based measures, excluding ASC–11, which we proposed for voluntary inclusion in the ASCQR Program for the CY 2017 payment determination and subsequent years. The five previously adopted measures are: ASC–6: Safe Surgery Checklist Use; ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures; ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); and ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF #0659).

For the reasons we discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173 through 75174), we estimate that the reporting burden for the ASC–6: Safe Surgery Checklist Use and the ASC–7: ASC Facility Volume measures will be 1,757 hours (5,260 ASCs × 2 measures × 0.167 hours per ASC) and $52,710 (1,757 hours × $30.00 per hour) annually for the CY 2018 payment determination and for subsequent years.

For the reasons discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173 through 75174), we estimate that the reporting burden for the ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure will be 18,005 hours (5,260 ASCs × 0.083 hours per facility = 437 hours for NHSN registration, and 5,260 ASCs × 0.167 hours per response for 20 workers per facility = 17,568 hours for data submission) and $540,150 (18,005 hours × $30.00 per hour) annually for the CY 2018 payment determination and for subsequent years.

For the reasons discussed in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75173 through 75174), we estimate that the reporting burden for ASCs with a single case per ASC for the chart-abstracted ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) and ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF #0659) measures will be 3,067 hours (5,260 ASCs × 0.583 hours per case per ASC) and $92,010 (3,067 hours × $30.00 per hour) annually for the CY 2018 payment determination and for subsequent years.

In the CY 2015 OPPS/ASC final rule with comment period, we finalized our proposal that data collection and submission be voluntary for the CY 2017 payment determination and subsequent years for ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following

Cataract Surgery (NQF #1536); that is, we will not subject ASCs to a payment reduction with respect to this measure during the period of voluntary reporting (79 FR 66984 through 66985). For the reasons discussed in the CY 2015 OPPS/ASC final rule with comment period (79 FR 67016), we estimate the total burden for this measure for ASCs with a single case per ASC to be 613 hours (1,052 ASCs × 0.583 hours per case per ASC) and $18,390 (613 hours × $30.00 per hour) annually for the CY 2018 payment determination and subsequent years.

e. Extraordinary Circumstances Extension or Exemptions Process

For a complete discussion of our ''Extraordinary Circumstances Extension or Waiver'' process under the ASCQR Program, which we retitled as the ''Extraordinary Circumstances Extensions or Exemptions'' process in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66987), we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53642 through 53643) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75140). In the CY 2016 OPPS/ASC proposed rule (80 FR 39347), we did not propose to make any changes to this process.

f. Reconsideration

In section XIV.D.8. of this final rule with comment period, we are finalizing our proposal to make a minor change to the reconsideration request deadline to ensure our deadline for these requests will always fall on a business day. We do not anticipate that there will be any additional burden because the materials to be submitted are unchanged and the deadline does not result in reduced time to submit a reconsideration request. We also are finalizing our proposal to codify our reconsideration request process at 42 CFR 416.330.

While there is burden associated with filing a reconsideration request, section 3518(c)(1)(B) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)) excludes collection activities during the conduct of administrative actions such as reconsiderations.

We invited public comments on the burden associated with these information collection requirements. We did not receive any public comments on these requirements.

XX. 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 final rule with comment period, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this final rule with comment period, 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 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Contract with America Advancement Act of 1996 (Pub. L. 104–121) (5 U.S.C. 804(2)). This section of the final rule with comment period contains the impact and other economic analyses for the provisions that we are finalizing for CY 2016.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule with comment period has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104–121). Accordingly, this final rule with comment period has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this final rule with comment period. We solicited comments on the regulatory impact analysis in the CY 2016 OPPS/ASC proposed rule (80 FR 39359), and we address the public comments we received in this section below and in other sections of this final rule with comment period as appropriate.

2. Statement of Need

This final rule with comment period is necessary to update the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2016. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are revising the APC relative payment weights using claims data for services furnished on and after January 1, 2014, through and including December 31, 2014 and processed through June 30, 2015, and updated cost report information.

This final rule with comment period also is necessary to update the ASC payment rates for CY 2016, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2016. Because ASC payment rates are based on the OPPS relative payment weights for the majority of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC not less frequently than every 2 years.

3. Overall Impacts for the OPPS and ASC Payment Provisions

We estimate that the total decrease in Federal government expenditures under the OPPS for CY 2016 compared to CY 2015 due to the changes in this final rule with comment period will be approximately $133 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate, based on the Midsession Review of the President's FY 2016 Budget, that gross Federal Government OPPS expenditures for CY 2016 will be approximately $4.1 billion higher relative to expenditures in CY 2015. This estimate reflects changes in enrollment, utilization, and case-mix, but does not include the 2.0 percent reduction to the conversion factor to

address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests that are excepted from our final CY 2014 laboratory packaging policy, as discussed in section II.B. of this final rule with comment period, or other payment changes implemented in this final rule with comment period. Because this final rule with comment period rule is economically significant as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 70 displays the distributional impact of the CY 2016 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through estimates, and the application of the frontier State wage adjustment for CY 2016) will decrease total OPPS payments by 0.3 percent in CY 2016. The changes to the APC weights, the changes to the wage indexes, the continuation of a payment adjustment for rural SCHs, including EACHs, and the payment adjustment for cancer hospitals will not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2015 and CY 2016, considering all payments, including the adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests, changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment outside of budget neutrality, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, will decrease total estimated OPPS payments by 0.4 percent.

We estimate the total increase (from changes to the ASC provisions in this final rule with comment period as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures under the ASC payment system for CY 2016 compared to CY 2015 to be approximately $128 million. Because the provisions for the ASC payment system are part of a final rule with comment period that is economically significant as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of this final rule with comment period. Table 71 and Table 72 of this final rule with comment period display the redistributive impact of the CY 2016 changes on ASC payment, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Detailed Economic Analyses

a. Estimated of OPPS Changes in This Final Rule With Comment Period

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2016 policy changes on various hospital groups. As we did for the proposed rule, we post on the CMS Web site our hospital-specific estimated payments for CY 2016 with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1633–FC'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 70 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we have not made adjustments for future changes in variables such as service volume, service-mix, or number of encounters. In the CY 2016 OPPS/ASC proposed rule (80 FR 39360), we solicited public comment and information about the anticipated effects of our proposed changes on providers and our methodology for estimating them. Any public comments that we received are addressed in the applicable sections of the final rule with comment period that discuss the specific policies.

(2) Estimated Effects of OPPS Changes on Hospitals

Table 70 below shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 70, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2016, we are finalizing our proposal to continue to pay CMHCs under renumbered APC 5851 (existing APC 0172) (Level 1 Partial Hospitalization (3 services) for CMHCs) and renumbered APC 5852 (existing APC 0173) (Level 2 Partial Hospitalization (4 or more services) for CMHCs). We also are finalizing our proposal to pay hospitals for partial hospitalization services under renumbered APC 5861 (existing APC 0175) (Level 1 Partial Hospitalization (3 services) for hospital-based PHPs) and APC 5862 (existing APC 0176) (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs). However, as discussed in section VIII.B.1. of this final rule with comment period, we are making an equitable adjustment to the actual geometric mean per diem costs so that we pay a higher payment rate for Level 2 services than Level 1 services. We also are finalizing our proposal to use a ±2 standard deviation trim for CMHCs and to apply a CCR greater than 5 (CCR>5) hospital service day trim for hospital-based PHP providers for CY 2016 and subsequent years.

The estimated decrease in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology and the adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in

section II.B. of this final rule with comment period. Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The IPPS market basket percentage increase for FY 2016 is 2.4 percent (80 FR 49510). Section 1833(t)(3)(F)(i) of the Act reduces that 2.4 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.5 percentage point for FY 2016 (which is also the MFP adjustment for FY 2016 in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49510)); and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(iv) of the Act further reduce the market basket percentage increase by 0.2 percentage point, resulting in the OPD fee schedule increase factor of 1.7 percent. We are using the OPD fee schedule increase factor of 1.7 percent in the calculation of the CY 2016 OPPS conversion factor. We also are applying a reduction of 2.0 percent to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.00. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2016 estimates in Table 70.

To illustrate the impact of the CY 2016 changes, our analysis begins with a baseline simulation model that uses the CY 2015 relative payment weights, the FY 2015 final IPPS wage indexes that include reclassifications, and the final CY 2015 conversion factor. Table 70 shows the estimated redistribution of the increase or decrease in payments for CY 2016 over CY 2015 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2015 and CY 2016 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 1.7 percent OPD fee schedule increase factor update to the conversion factor and the −2.0 percent adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests (Column 4); and the estimated impact taking into account all payments for CY 2016 relative to all payments for CY 2015, including the impact of changes in estimated outlier payments, the frontier State wage adjustment, and changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are finalizing our proposal to maintain the current adjustment percentage for CY 2016. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2016 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2015 and CY 2016 by various groups of hospitals, which CMS cannot forecast.

For hospital-based PHP APCs, the per diem rates calculated from the equitable adjustment will be budget neutral within all of the OPPS. Section 1833(t)(2)(E) of the Act states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments. The authority granted to the Secretary under this provision is broad. It would not be appropriate or equitable to pay a lower payment rate for the PHP APC for Level 2 services, under which 4 or more services are provided, than for the PHP APC for Level 1 services, under which 3 PHP services are provided. As a result, we included the equitably adjusted hospital-based PHP APC Level 1 per diem cost of $191.91, and the equitably adjusted hospital-based PHP APC Level 2 per diem cost of $222.54 in the budget neutrality process. The CMHC PHP APC Level 1 geometric mean per diem costs are $98.88, and the CMHC PHP APC Level 2 geometric mean per diem costs are $149.64.

Overall, we estimate that the rates for CY 2016 will decrease Medicare OPPS payments by an estimated 0.4 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 0.4 percent decrease in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 70 shows the total number of facilities (3,953), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2014 hospital outpatient and CMHC claims data to model CY 2015 and CY 2016 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2015 or CY 2016 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this final rule with comment period. At this time, we are unable to calculate a disproportionate share hospital (DSH) variable for hospitals that are not also paid under the IPPS, since DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,830), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 57 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience no

change, with the impact ranging from an increase of 0.3 percent to a decrease of 0.6 percent, depending on the number of beds. Rural hospitals will experience a 0.1 percent increase, with the impact ranging from an increase of 0.5 percent to a decrease of 0.1 percent, depending on the number of beds. Major teaching hospitals will experience an increase of 0.4 percent overall.

Column 3: New Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the fiscal year (FY) 2016 IPPS post-reclassification wage indexes; the cancer hospital adjustment and the rural adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2015 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the frontier State wage index adjustment, which is not budget neutral and is included in Column 5. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are finalizing our proposal to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2016, as described in section II.E. of this final rule with comment period.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2016 scaled weights and a CY 2015 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2015 and CY 2016. The FY 2016 wage policy results in modest redistributions.

We are finalizing the CY 2016 cancer hospital payment adjustment methodology as proposed. Using updated data, the payment-to-cost ratio target is 0.92. This results in a 0.1 decrease to the ''all hospitals'' category, because IPPS-exempt cancer hospitals are not included in the all hospitals category.

Column 4: All Budget Neutrality Changes Combined With the Market Basket Update and the Adjustment To Address Excess Packaged Payment for Laboratory Tests

Column 4 demonstrates the combined impact of all of the changes previously described, the update to the conversion factor of 1.7 percent, and the 2.0 percent reduction due to the adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests. Overall, these changes will decrease payments to urban hospitals by 0.4 percent and to rural hospitals by 0.6 percent. Most classes of hospitals will receive a decrease in line with the 0.4 percent overall decrease after the update and the adjustment to the conversion factor to address excess packaged payment for laboratory tests are applied to the budget neutrality adjustments.

Column 5: All Changes for CY 2016

Column 5 depicts the full impact of the CY 2016 policies on each hospital group by including the effect of all of the changes for CY 2016 and comparing them to all estimated payments in CY 2015. Column 5 shows the combined budget neutral effects of Column 2 and 3; the OPD fee schedule increase; the impact of the frontier State wage index adjustment; the impact of estimated OPPS outlier payments as discussed in section II.G. of this final rule with comment period; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIII. of this final rule with comment period); and the difference in total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2015 update (and assumed, for modeling purposes, to be the same number for CY 2016), we included 59 hospitals in our model because they had both CY 2014 claims data and recent cost report data. We estimate that the cumulative effect of all of the changes for CY 2016 will decrease payments to all facilities by 0.4 percent for CY 2016. We modeled the independent effect of all of the changes in Column 5 using the final relative payment weights for CY 2015 and the relative payment weights for CY 2016. We used the final conversion factor for CY 2015 of $74.173 and the CY 2016 conversion factor of $73.725 discussed in section II.B. of this final rule with comment period.

Column 5 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49783 through 49784) of 3.7 percent (1.037616) to increase individual costs on the CY 2014 claims, and we used the most recent overall CCR in the July 2015 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2015. Using the CY 2014 claims and a 3.7 percent charge inflation factor, we currently estimate that outlier payments for CY 2015, using a multiple threshold of 1.75 and a fixed-dollar threshold of $2,775 will be approximately 0.9 percent of total payments. The estimated current outlier payments of 0.9 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 7.7 percent (1.076647) and the CCRs in the July 2015 OPSF, with an adjustment of 0.9701, to reflect relative changes in cost and charge inflation between CY 2014 and CY 2016, to model the CY 2016 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $3,250. The charge inflation and CCR inflation factors are discussed in detail in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49783 through 49784).

We estimate that the anticipated change in payment between CY 2015 and CY 2016 for the hospitals failing to meet the Hospital OQR Program requirements will be negligible. Overall, we estimate that facilities will experience a decrease of 0.4 percent under this final rule with comment period in CY 2016 relative to total spending in CY 2015. This projected decrease (shown in Column 5) of Table 70 reflects the 1.7 percent OPD fee schedule increase factor, less 2.0 percent for the adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests, less 0.13 percent for the change in the pass-through estimate between CY 2015 and CY 2016, plus 0.1 percent for the difference in estimated outlier payments between CY 2015 (0.9 percent) and CY 2016 (1.0 percent). We estimate that the combined effect of all of the changes for CY 2016 will decrease payments to urban hospitals by 0.4 percent. Overall, we estimate that rural hospitals will experience a 0.6 percent decrease as a result of the combined effects of all of the changes for CY 2016, with the greater decrease relative to urban

hospitals primarily a result of wage index changes in CY 2016.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects of all changes will result in an increase of 0.1 percent for major teaching hospitals and a decrease of 0.7 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated decrease of 0.5 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience a decrease of 0.3 percent, proprietary hospitals will experience a decrease of 1.1 percent, and governmental hospitals will experience a decrease of 0.3 percent.

TABLE 70—ESTIMATED IMPACT OF THE CY 2016 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	APC recalibration (all changes)	New wage index and provider adjustments	All budget neutral changes (combined cols. 2, 3) with market basket update and adjustment to address excess packaged payment for laboratory tests	All changes
	(1)	(2)	(3)	(4)	(5)
ALL FACILITIES *	3,953	0.0	0.0	−0.3	−0.4
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,830	0.0	−0.1	−0.4	−0.4
URBAN HOSPITALS	2,980	0.0	0.0	−0.4	−0.4
LARGE URBAN (GT 1 MILL)	1,641	0.0	0.0	−0.3	−0.3
OTHER URBAN (LE 1 MILL.)	1,339	−0.1	0.0	−0.5	−0.5
RURAL HOSPITALS	850	0.1	−0.4	−0.6	−0.6
SOLE COMMUNITY	380	0.1	−0.4	−0.6	−0.6
OTHER RURAL	470	0.0	−0.4	−0.7	−0.7
BEDS (URBAN):					
0–99 BEDS	1,054	−0.6	−0.4	−1.2	−1.3
100–199 BEDS	847	−0.3	0.0	−0.6	−0.6
200–299 BEDS	458	−0.2	0.1	−0.4	−0.4
300–499 BEDS	406	0.0	0.0	−0.3	−0.3
500 + BEDS	215	0.3	0.0	−0.1	−0.1
BEDS (RURAL):					
0–49 BEDS	338	0.5	−0.5	−0.3	−0.2
50–100 BEDS	311	0.0	−0.3	−0.6	−0.6
101–149 BEDS	113	−0.1	−0.3	−0.8	−0.7
150–199 BEDS	48	0.1	−0.4	−0.6	−0.7
200 + BEDS	40	0.1	−0.6	−0.9	−1.0
REGION (URBAN):					
NEW ENGLAND	150	0.6	−0.7	−0.4	−0.4
MIDDLE ATLANTIC	349	−0.2	0.4	−0.1	0.0
SOUTH ATLANTIC	472	−0.1	0.0	−0.5	−0.6
EAST NORTH CENT	481	−0.1	0.1	−0.4	−0.4
EAST SOUTH CENT	185	−0.1	−0.5	−0.9	−1.0
WEST NORTH CENT	185	0.1	−0.5	−0.8	−0.7
WEST SOUTH CENT	530	0.0	−0.4	−0.7	−0.8
MOUNTAIN	200	0.0	0.0	−0.4	−0.5
PACIFIC	379	−0.2	0.7	0.2	0.3
PUERTO RICO	49	−2.5	−1.3	−4.0	−4.1
REGION (RURAL):					
NEW ENGLAND	22	0.9	−0.6	−0.1	0.1
MIDDLE ATLANTIC	56	0.3	−1.0	−1.1	−0.7
SOUTH ATLANTIC	125	−0.3	0.3	−0.3	−0.4
EAST NORTH CENT	121	−0.2	−0.2	−0.7	−0.7
EAST SOUTH CENT	163	0.1	−0.6	−0.9	−1.0
WEST NORTH CENT	103	0.3	−0.7	−0.7	−0.5
WEST SOUTH CENT	176	0.1	−1.3	−1.6	−1.7
MOUNTAIN	60	0.3	0.0	0.0	−0.3
PACIFIC	24	−0.1	1.0	0.5	0.5
TEACHING STATUS:					
NON-TEACHING	2781	−0.3	−0.1	−0.7	−0.7
MINOR	718	−0.1	0.0	−0.4	−0.5
MAJOR	331	0.4	0.0	0.1	0.1
DSH PATIENT PERCENT:					
0	20	−1.3	0.1	−1.5	−1.6
GT 0–0.10	341	−0.6	0.0	−1.0	−1.0
0.10–0.16	299	−0.2	−0.1	−0.6	−0.6
0.16–0.23	661	−0.3	−0.1	−0.7	−0.7
0.23–0.35	1120	0.0	−0.1	−0.4	−0.5
GE 0.35	806	0.2	0.1	0.0	0.0

TABLE 70—ESTIMATED IMPACT OF THE CY 2016 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	APC recalibration (all changes)	New wage index and provider adjustments	All budget neutral changes (combined cols. 2, 3) with market basket update and adjustment to address excess packaged payment for laboratory tests	All changes
	(1)	(2)	(3)	(4)	(5)
DSH NOT AVAILABLE**	583	4.5	−0.2	3.9	3.6
URBAN TEACHING/DSH:					
TEACHING & DSH	954	0.1	0.0	−0.2	−0.2
NO TEACHING/DSH	1453	−0.4	−0.1	−0.8	−0.8
NO TEACHING/NO DSH	19	−1.3	0.1	−1.5	−1.6
DSH NOT AVAILABLE**	554	4.3	−0.1	3.9	3.5
TYPE OF OWNERSHIP:					
VOLUNTARY	2010	0.0	0.0	−0.3	−0.3
PROPRIETARY	1304	−0.3	−0.3	−1.0	−1.1
GOVERNMENT	516	0.2	−0.1	−0.3	−0.3
CMHCs	57	24.5	−0.6	23.4	23.1

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all CY 2016 OPPS policies and compares those to the CY 2015 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2016 hospital inpatient wage index, including all hold harmless policies and transitional wages. The final rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 0.9994 because the payment-to-cost ratio is 0.92 for the CY 2016 OPPS.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the 1.7 percent OPD fee schedule update factor (2.4 percent reduced by 0.5 percentage points for the productivity adjustment and further reduced by 0.2 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act). Column 4 also includes the -2.0 percent adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests.

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, adding estimated outlier payments, and applying the frontier State wage adjustment.

* These 3,953 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

(3) Estimated Effects of OPPS Changes on CMHCs

The last line of Table 70 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2015, CMHCs are paid under two APCs for these services: existing APC 0172 (Level 1 Partial Hospitalization (3 services) for CMHCs) (renumbered APC 5851 for CY 2016) and existing APC 0173 (Level 2 Partial Hospitalization (4 or more services) for CMHCs) (renumbered APC 5852 for CY 2016). Hospitals are paid for partial hospitalization services under existing APC 0175 (Level 1 Partial Hospitalization (3 services) for hospital-based PHPs) (renumbered APC 5861 for CY 2016) and existing APC 0176 (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs) (renumbered APC 5862 for CY 2016). We use our standard ratesetting methodology to derive the payment rates for each APC based on the cost data derived from claims and cost data for the provider-type-specific APC. For CY 2016, we are finalizing our proposal to continue the provider-type-specific APC structure that we adopted in CY 2011. We modeled the impact of this APC policy assuming that CMHCs will continue to provide the same number of days of PHP care, with each day having either 3 services or 4 or more services, as seen in the CY 2014 claims data used for this final rule with comment period. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs will experience an overall 23.1 percent increase in payments from CY 2015 (shown in Column 5). We note that this includes the trimming methodology described in section VIII.B. of this final rule with comment period.

Column 3 shows that the estimated impact of adopting the FY 2016 wage index values will result in a small decrease of 0.6 percent to CMHCs. Column 4 shows that combining this OPD fee schedule increase factor, adjustment to the conversion to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests, along with changes in APC policy for CY 2016 and the FY 2016 wage index updates, will result in an estimated increase of 23.4 percent. Column 5 shows that adding the changes in outlier and pass-though payments will result in a total 23.1 percent increase in payment for CMHCs. This reflects all changes to CMHCs for CY 2016.

(4) Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary share of payment will increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this final rule with comment period. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage will

be 19.3 percent for all services paid under the OPPS in CY 2016. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the recalibration of the APC relative payment weights, APC reorganization, change in the portion of OPPS payments dedicated to pass-through payments, and the CY 2016 comprehensive APC payment policy discussed in section II.A.2.e. of this final rule with comment period.

(5) Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs as discussed in section XII. of this final rule with comment period. No types of providers or suppliers other than hospitals, CMHCs, and ASCs will be affected by the changes in this final rule with comment period.

(6) Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be a decrease of $133 million in program payments for OPPS services furnished in CY 2016. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We refer readers to our discussion of the impact on beneficiaries in section XXI.A. of this final rule with comment period.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are finalizing and the reasons for our selected alternatives are discussed throughout this final rule with comment period. In this section, we discuss some of the significant issues and the alternatives considered.

• Alternatives Considered for the Methodology for Assigning Skin Substitutes to High or Low Cost Groups

We refer readers to section V.B.2.c. of this final rule with comment period for a discussion of our proposal to determine the high/low cost status for each skin substitute product based on either a product's mean unit cost (MUC) exceeding the MUC threshold or the product's per day cost (PDC) exceeding the PDC threshold. As discussed in that section, we also considered, but did not propose, to determine high/low cost status for each skin substitute using just MUC or just PDC instead of both.

• Alternatives Considered for Application of the Device Offset for Discontinued Procedures for Device Intensive Procedures

We refer readers to section IV.B.4. of this final rule with comment period for a discussion of our proposal to deduct the device offset amount for procedures in device-intensive APCs that are discontinued. As discussed in that section, we considered finalizing the policy as proposed, but instead are finalizing to only apply the policy to device intensive procedures with modifier 73 (Discontinued procedure prior to anesthesia administration).

b. Estimated Effects of CY 2016 ASC Payment System Policies

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XII. of this final rule with comment period, we are setting the CY 2016 ASC relative payment weights by scaling the CY 2016 OPPS relative payment weights by the ASC scaler of 0.9332. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 71 and 72 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which currently is the CPI–U) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2016 payment determinations will be based on the application of a 2.0 percentage points reduction to the annual update factor, which currently is the CPI–U. We calculated the CY 2016 ASC conversion factor by adjusting the CY 2015 ASC conversion factor by 0.9997 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2015 and CY 2016 and by applying the CY 2016 MFP-adjusted CPI–U update factor of 0.3 percent (projected CPI–U update of 0.8 percent minus a projected productivity adjustment of 0.5 percentage point). The CY 2016 ASC conversion factor is $44.177.

(1) Limitations of Our Analysis

Presented here are the projected effects of the changes for CY 2016 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2014 and CY 2016 with precision. We believe that the net effect on Medicare expenditures resulting from the CY 2016 changes will be small in the aggregate for all ASCs. However, surgical specialty groups may be affected differently as ASCs continue to provide services to beneficiaries under the ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs will experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect of the update to the CY 2016 payments on an individual ASC will depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the CY 2016 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2014 claims data. Table 71 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2015 payments to estimated CY 2016 payments, and Table 72 shows a comparison of estimated CY 2015 payments to estimated CY 2016 payments for procedures that we estimate will receive the most Medicare payment in CY 2015.

Table 71 shows the estimated effects on aggregate Medicare payments under the ASC payment system by surgical specialty or ancillary items and services group. We have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical

specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 71.

• Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.

• Column 2—Estimated CY 2015 ASC Payments were calculated using CY 2014 ASC utilization (the most recent full year of ASC utilization) and CY 2015 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2015 ASC payments.

• Column 3—Estimated CY 2016 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that are attributable to updates to ASC payment rates for CY 2016 compared to CY 2015.

As seen in Table 71, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the update to ASC rates for CY 2016 will result in a 1-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 2-percent increase in aggregate payment amounts for digestive system procedures, a 1-percent decrease in aggregate payment amounts for nervous system procedures, a 4-percent decrease in aggregate payment amounts for musculoskeletal system procedures, a 1-percent increase in aggregate payment amounts for genitourinary system procedures, and a 2-percent increase in aggregate payment amounts for integumentary system procedures.

Also displayed in Table 71 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. We estimate that aggregate payments for these items and services will remain at $21 million for CY 2016.

TABLE 71—ESTIMATED IMPACT OF THE CY 2016 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2016 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group (1)	Estimated CY 2015 ASC payments (in millions) (2)	Estimated CY 2016 percent change (3)
Total	$3,893	0
Eye and ocular adnexa	1,534	1
Digestive system	807	2
Nervous system	617	−1
Musculoskeletal system	485	−4
Genitourinary system	176	1
Integumentary system	135	2
Respiratory system	55	3
Cardiovascular system	42	0
Ancillary items and services	21	2
Auditory system	14	5
Hematologic & lymphatic systems	6	−5

Table 72 below shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2016. The table displays 30 of the procedures receiving the greatest estimated CY 2015 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2015 program payment.

• Column 1—CPT/HCPCS code.

• Column 2—Short Descriptor of the HCPCS code.

• Column 3—Estimated CY 2015 ASC Payments were calculated using CY 2014 ASC utilization (the most recent full year of ASC utilization) and the CY 2015 ASC payment rates. The estimated CY 2015 payments are expressed in millions of dollars.

• Column 4—Estimated CY 2016 Percent Change reflects the percent differences between the estimated ASC payment for CY 2015 and the estimated payment for CY 2016 based on the update.

TABLE 72—ESTIMATED IMPACT OF THE CY 2016 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code (1)	Short descriptor (2)	Estimated CY 2015 ASC payment (in millions)	Estimated CY 2016 percent change (4)
66984	Cataract surg w/iol 1 stage	$1,092	2
43239	Egd biopsy single/multiple	177	2
45380	Colonoscopy and biopsy	181	−3
45385	Colonoscopy w/lesion removal	117	−3

TABLE 72—ESTIMATED IMPACT OF THE CY 2016 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES—Continued

CPT/HCPCS code (1)	Short descriptor (2)	Estimated CY 2015 ASC payment (in millions)	Estimated CY 2016 percent change (4)
66982	Cataract surgery complex	95	2
64483	Inj foramen epidural l/s	94	−11
62311	Inject spine lumbar/sacral	75	−11
45378	Diagnostic colonoscopy	69	−4
66821	After cataract laser surgery	65	1
64493	Inj paravert f jnt l/s 1 lev	53	25
G0105	Colorectal scrn; hi risk ind	46	17
64635	Destroy lumb/sac facet jnt	50	−3
63650	Implant neuroelectrodes	52	4
G0121	Colon ca scrn not hi rsk ind	43	17
64590	Insrt/redo pn/gastr stimul	44	−7
15823	Revision of upper eyelid	33	2
63685	Insrt/redo spine n generator	54	2
29827	Arthroscop rotator cuff repr	50	5
64721	Carpal tunnel surgery	30	3
29881	Knee arthroscopy/surgery	28	14
29824	Shoulder arthroscopy/surgery	21	−44
29880	Knee arthroscopy/surgery	24	14
43235	Egd diagnostic brush wash	24	2
62310	Inject spine cerv/thoracic	23	−11
29823	Shoulder arthroscopy/surgery	13	−44
52000	Cystoscopy	22	−3
G0260	Inj for sacroiliac jt anesth	22	−11
45384	Colonoscopy w/lesion removal	20	−3
67042	Vit for macular hole	22	5
26055	Incise finger tendon sheath	21	21

(3) Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2016 update to the ASC payment system will be generally positive for beneficiaries with respect to the new procedures that we are adding to the ASC list of covered surgical procedures and for those that we are designating as office-based for CY 2016. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with section 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services). Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. However, for those additional procedures that we are designating as office-based in CY 2016, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the MPFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

(4) Alternative ASC Payment Policies Considered

• Alternatives Considered for Application of the Device Offset for Discontinued Procedures for Device Intensive Procedures

We refer readers to section XII.C.1.d. of this final rule with comment period for a discussion of our proposal to deduct the device offset amount for device intensive procedures that are discontinued before applying any standard downward payment adjustment. We proposed that this would apply to device-intensive procedures in the ASC payment system beginning in CY 2016 with modifier ''52'' (reduced services) and modifier ''73'' (discontinued outpatient procedure prior to anesthesia administration). As discussed in that section, we considered finalizing the policy as proposed, but, based on stakeholder comments, are finalizing the policy to only apply to device-intensive procedures with modifier ''73.''

c. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget Web site at: *https://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*, we have prepared two accounting statements to illustrate the impacts of this final rule with comment period. The first accounting statement, Table 73 below, illustrates the classification of expenditures for the CY 2016 estimated hospital OPPS incurred benefit impacts associated with the CY 2016 OPD fee schedule increase, based on the Midsession Review of the President's FY 2016 Budget, and the adjustment to the conversion factor to address the

inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests. The second accounting statement, Table 74 below, illustrates the classification of expenditures associated with the 0.3 percent CY 2016 update to the ASC payment system, based on the provisions of this final rule with comment period and the baseline spending estimates for ASCs in the Midsession Review of the President's FY 2016 Budget. Lastly, the tables classify most estimated impacts as transfers.

TABLE 73—ACCOUNTING STATEMENT: CY 2016 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2015 TO CY 2016 ASSOCIATED WITH THE CY 2016 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE AND THE ADJUSTMENT TO ADDRESS EXCESS PACKAGED PAYMENT FOR LABORATORY TESTS

Category	Transfers
Annualized Monetized Transfers	−$133 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS.
Total	−$133 million.

TABLE 74—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2015 TO CY 2016 AS A RESULT OF THE CY 2016 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$10 million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Total	$10 million.

d. Effects of Requirements for the Hospital OQR Program

We refer readers to CY 2015 OPPS/ASC final rule with comment period (79 FR 67018) for the estimated effects of previously finalized OPPS changes on hospitals for the CY 2017 payment determination. In section XIII. of this final rule with comment period, we are finalizing the adoption of changes to policies affecting the Hospital OQR Program. Of the 3,292 hospitals that met eligibility requirements for the CY 2015 payment determination, we determined that 113 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor (79 FR 67018). Most of these hospitals (71 of the 113) chose not to participate in the Hospital OQR Program for the CY 2015 payment determination. We estimate that approximately 115 hospitals will not receive the full OPD fee schedule increase factor for the CY 2018 payment determination and subsequent years.

In section XIII. of this final rule with comment period, we are finalizing the adoption of our proposals to make several changes to the Hospital OQR Program for the CY 2017 payment determination and subsequent years and the CY 2018 payment determination and subsequent years. For the CY 2017 payment determination and subsequent years, we are finalizing our proposals to: (1) Remove OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache measure, effective January 1, 2016 (no data for this measure will be used for any payment determination); (2) change the deadline for withdrawing from the program to August 31 and revise 42 CFR 419.46(b) to reflect this change; (3) shift the quarters on which we base payment determinations; (4) change the data submission timeframe for measures submitted via the CMS Web-based tool (QualityNet Web site) to January 1 through May 15; (5) fix a typographical error to correct the name of our extension and exception policy to extension and exemption policy; (6) change the deadline for submitting a reconsideration request to the first business day on or after March 17 of the affected payment year and make a conforming change to 42 CFR 419.46(f)(1) to reflect this change; and (7) amend 42 CFR 419.46(f)(1) and 42 CFR 419.46(e)(2) to replace the term ''fiscal year'' with the term ''calendar year.'' While there is burden associated with filing a reconsideration request, section 3518(c)(1)(B) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)) excludes collection activities during the conduct of administrative actions such as reconsiderations. We do not believe that any of the other changes we are finalizing will increase burden, as further discussed below.

In addition, we are finalizing the adoption of our proposals to make conforming changes to our validation scoring process to reflect changes in the APU determination timeframes. For the CY 2017 payment determination, we are finalizing our proposal that validation be based on three quarters of data (validation quarter 2, validation quarter 3, and validation quarter 4 of 2015), as opposed to four quarters as previously required. For the CY 2017 transition year, we estimate that the burden associated with validation reporting will be reduced by 25 percent because hospitals will submit validation data for three quarters instead of four quarters. For prior payment determinations, we sampled 500 hospitals for validation and estimated that it would take each hospital 12 hours to comply with the data submission requirements for four quarters. We estimate that data submission for three quarters will reduce the number of hours required by 25 percent (from 12 hours to 9 hours per hospital). Consistent with prior years (79 FR 67013), we estimate that a hospital pays an individual approximately $30 per hour to abstract and submit these data. Therefore, we estimate a total burden of approximately 4,500 hours (500 hospitals × 9 hours/hospital) and a total financial impact of $135,000 ($30/hour × 4,500 hours) for the CY 2017 payment determination. This is a reduction of 1,500 hours and $45,000 across all hospitals from last year's estimate attributable to changes in our validation scoring process.

For the CY 2018 payment determination and subsequent years, we are finalizing two changes to the program. First, we are finalizing the adoption of one new measure: OP–33: External Beam Radiotherapy (EBRT) for

Bone Metastases (NQF #1822). As we further explain in section XIII.D.4.b. of this final rule with comment period, we are finalizing only one mode of data submission for this measure: data for OP–33 may only be submitted at an aggregate-level via a CMS Web based tool (QualityNet Web site). As discussed in section XIX.B.1.b. of this final rule with comment period, we believe that this measure will result in a total increase in burden across all participating hospitals of 8,312.7 hours or $249,381 per year. Second, for the CY 2018 payment determination and subsequent years, we are finalizing that validation again be based on four quarters of data. However, those quarters are validation quarter 1, validation quarter 2, validation quarter 3, and validation quarter 4. For payment determinations prior to CY 2017, we sampled 500 hospitals for validation and estimated that it would take each hospital 12 hours to comply with the data submission requirements for four quarters. Therefore, we estimate a total burden of approximately 6,000 hours (500 hospitals × 12 hours/hospital) and a total financial impact of $180,000 ($30/hour × 6,000 hours) in burden associated with validation for the CY 2018 payment determination and subsequent years. This increase in burden associated with the validation process is 1,500 hours and $45,000 across all hospitals from the CY 2017 estimate because we will be sampling four quarters, as we had in prior years, instead of three quarters.

For the CY 2019 payment determination and subsequent years, we are not making any changes to the program. We are not finalizing the proposed adoption of OP–34: Emergency Department Transfer Communication (EDTC) (NQF #0291). Thus, because we have not adopted any new measures or policy changes for the CY 2019 payment determination and subsequent years, we expect the burden to be unchanged for the CY 2019 payment determination as compared to the CY 2018 payment determination and subsequent years as discussed above.

We refer readers to the information collection requirements in section XIX.B.1. of this final rule with comment period for a detailed discussion of the financial and hourly burden of the additional requirements for submitting data to the Hospital OQR Program.

e. Effects of Requirements for the ASCQR Program

As discussed in section XIV. of this final rule with comment period, we are finalizing our proposals to adopt policies affecting the ASCQR Program. For the CY 2015 payment determination, of the 5,260 ASCs that met eligibility requirements for the ASCQR Program, 116 ASCs did not meet the requirements to receive the full annual payment update.

We are not adding any quality measures to the ASCQR measure set for the CY 2018 payment determination. We do not believe that the other measures we previously adopted will cause any additional ASCs to fail to meet the ASCQR Program requirements. (We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66978 through 66979) for a list of these measures.) In addition, we do not believe that any of the other proposals we are finalizing in this final rule with comment period will increase the number of ASCs that do not receive a full annual payment update for the CY 2018 payment determination. We expect a reduction in the number of ASCs that do not receive a full annual payment update for the CY 2018 payment determination due to our finalizing our proposal that IHS hospital outpatient departments billing as ASCs will no longer be considered ASCs for the purposes of the ASCQR Program. Thus, because CY 2016 and CY 2017 payment determination information is not yet available, using the CY 2015 payment determination numbers as a baseline, we estimate that approximately 115 ASCs will not receive the full annual payment update in CY 2018 due to failure to meet the ASCQR Program requirements.

Based on the previously finalized policies for the ASCQR program and the proposals we are finalizing in this final rule with comment period, we estimate a total burden of approximately 4.34 hours per ASC for facilities not submitting data for ASC–11 ([1,757 hours for ASC–6 and ASC–7 + 18,005 hours for ASC–8 + 3,067 hours for ASC–9 and ASC–10]/5,260 ASCs = 4.34 hours per ASC for all required measures) and approximately 4.92 hours for facilities voluntarily reporting data for ASC–11 [65] (4.34 hours for reporting all required measures + [613 hours for ASC–11/1,052 ASCs] = 4.92 hours), or approximately 23,442 hours (1,757 hours for ASC–6 and ASC–7 + 18,005 hours for ASC–8 + 3,067 hours for ASC–9 and ASC–10 + 613 hours for ASC–11 = 23,442 hours) across all ASCs associated with participating in the ASCQR Program for the CY 2018 payment determination. We further estimate a resulting total financial burden of $130 per ASC for facilities not submitting data for ASC–11 ([$52,710 for ASC–6 and ASC–7 + $540,150 for ASC–8 + $92,010 for ASC–9 and ASC–10]/5,260 ASCs = $130 per ASC for all required measures) and approximately $148 per ASC for facilities voluntarily reporting data under ASC–11 ($130 for all required measures + [$18,390/1,052 ASCs] = $148), or $703,260 ($52,710 for ASC–6 and ASC–7 + $540,150 for ASC–8 + $92,010 for ASC–9 and ASC–10 + $18,390 for ASC–11 = $703,260) across all ASCs.

We refer readers to the information collection requirements in section XIX.B.2. of this final rule with comment period for a detailed discussion of the financial and hourly burden of the ASCQR Program's current and newly finalized requirements.

We invited public comment on the burden associated with these proposals. We did not receive any public comments on these proposals.

f. Impact of the Policy Change for Medical Review of Inpatient Hospital Admissions Under Medicare Part A

As discussed in section XV. of this final rule with comment period, we are finalizing a policy change for medical review of inpatient hospital admissions under Medicare Part A. In this section, we discuss the estimate by our actuaries of the overall impact of the policy change described in section XV. of this final rule with comment period.

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27649 through 27650), we discussed our actuaries' estimate that our current 2-midnight policy would increase IPPS expenditures by approximately $220 million in FY 2014. These additional expenditures were expected to result from a net increase in hospital inpatient encounters due to some outpatient encounters spanning more than 2 midnights moving to the IPPS from the OPPS, and some inpatient encounters of less than 2 midnights moving from the IPPS to the OPPS. We also proposed to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to offset this estimated $220 million in additional expenditures with a −0.2 percent adjustment to the IPPS rates. As discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50952 through 50954), after considering the public comments we received, our actuaries continued to estimate that there would be approximately $220 million in additional expenditures resulting from the 2-midnight rule and we adopted the −0.2 percent adjustment beginning in FY 2014.

[65] As noted in the CY 2015 OPPS/ASC final rule with comment period, we anticipate that approximately 20 percent of ASCs, or 1,052 facilities, would elect to report ASC–11 on a voluntary basis (79 FR 67016).

In the CY 2016 OPPS/ASC proposed rule (80 FR 39369 through 39370), we discussed our actuaries' estimate that overall IPPS expenditures would not be significantly different under our proposed policy change for the medical review of inpatient hospital admissions under Medicare Part A. For example, our actuaries did not assume any significant additional shifts between the inpatient setting and the outpatient setting as a result of the proposed policy change relative to the shifts that had been modeled for the original −0.2 percent estimate nor did they assume any change in the assumption regarding the 30-percent outpatient/inpatient payment differential.

Although we received many public comments questioning the validity of the original −0.2 percent estimate and some commenters asserted that we should remove the −0.2 percent adjustment in light of the proposed policy change, none of these public comments specifically addressed the issue of whether or not the proposed policy change that we are adopting for the medical review of inpatient hospital admissions under Medicare Part A described in section XV. of this final rule with comment period would have a differential impact on expenditures compared to the original policy.

As a result, after consideration of the public comments we received, our actuaries do not assume any significant additional shifts between the inpatient setting and the outpatient setting as a result of the policy change we are adopting for the medical review of inpatient hospital admissions under Medicare Part A described in section XV. of this final rule with comment period. In addition, after reviewing the public comments we received, our actuaries determined that there is no change in the assumption regarding the 30-percent outpatient/inpatient payment differential at the current time. Therefore, our actuaries continue to estimate that overall IPPS expenditures would not be significantly different under the policy change we are adopting, and we are not changing the −0.2 percent adjustment at this time.

Regarding the public comments we received questioning the validity of the original −0.2 percent estimate, we note that this issue has been the subject of continuing litigation in *Shands* v. *Burwell*, No. 14–263 (D.D.C.) and consolidated cases. Since the CY 2016 OPPS/ASC proposed rule was published, the court in *Shands* has remanded the issue of the validity of the original −0.2 percent estimate to the Agency for further proceedings. Those proceedings will include publication of a notice with comment period, consideration of public comments, and publication of a final notice. As a result, we will soon be addressing the same issues regarding the validity of the original −0.2 percent adjustment in the *Shands* remand proceedings that we discussed in the proposed rule and on which we invited public comments. We do not believe it is efficient to separately respond to two sets of public comments on essentially the same issue—once now and then once again as part of the *Shands* remand proceedings. Therefore, we will respond to all public comments regarding the validity of the original −0.2 percent adjustment that we received in response to the proposed rule as part of the *Shands* remand proceedings. Commenters are invited to submit public comments as part of the *Shands* remand proceedings if they wish, whether or not they submitted public comments in response to the CY 2016 OPPS/ASC proposed rule. Commenters do not need to resubmit public comments regarding the validity of the original −0.2 percent adjustment in the *Shands* remand proceedings that they submitted in response to the proposed rule. Again, we will respond to all such public comments, in addition to public comments submitted in the *Shands* remand proceedings, as part of those proceedings.

As we indicated in the CY 2016 OPPS/ASC proposed rule, our actuaries will continue to review the claims experience under the 2-midnight rule, and we will take those reviews into account during future rulemaking, including potential future rulemaking on the issue of whether or not the proposed policy change that we are adopting for the medical review of inpatient hospital admissions under Medicare Part A described in section XV. of this final rule with comment period would have a differential impact on expenditures compared to the original policy.

g. Impact of Transition for Former MDHs Under the IPPS

In section XVI. of this final rule with comment period, we are finalizing, with modification, our proposed policy relating to a transition period under the IPPS for hospitals that lost their MDH status because they are no longer in a rural area as a result of the implementation of the new OMB labor market area delineations. A hospital is eligible for designation as an MDH only if it is either physically located in a rural area or has been reclassified to a rural area under 42 CFR 412.103. In the CY 2016 OPPS/ASC proposed rule (80 FR 39354), we proposed to provide a transition period only for hospitals that lost their MDH status because they are no longer in a rural area due to the implementation of the new OMB labor market area delineations and are now located in an all-urban State. After consideration of the public comments we received, in this final rule with comment period, we are finalizing a policy that, effective January 1, 2016, payments to hospitals that (1) lost their MDH status because they are no longer in a rural area due to the implementation of the new OMB delineations in FY 2015 and (2) have not reclassified from urban to rural under the regulations at § 412.103 before January 1, 2016, will transition from payments based, in part, on the hospital-specific rate to payments based entirely on the Federal rate. For discharges occurring on or after January 1, 2016, and before October 1, 2016, these former MDHs will receive the Federal rate plus two-thirds of 75 percent of the amount by which the Federal rate payment is exceeded by the hospital's hospital-specific rate payment. For FY 2017, that is, for discharges occurring on or after October 1, 2016, and before October 1, 2017, these former MDHs will receive the Federal rate plus one-third of 75 percent of the amount by which the Federal rate payment is exceeded by the hospital's hospital-specific rate payment. For FY 2018, that is, for discharges occurring on or after October 1, 2017, these former MDHs will be paid based solely on the Federal rate.

We are aware of eight providers that were classified as MDHs prior to the implementation of the new OMB delineations on October 1, 2014, that did not reclassify as rural under the regulations at § 412.103. In order to estimate the cost associated with the transition period for these eight providers, we used 12 months of FY 2014 MedPAR claims data and the FY 2016 payment rates. We estimated two sets of payments for affected hospitals, one calculated with MDH status in which payment is calculated based on the Federal rate plus 75 percent of the amount by which the Federal rate payment is exceeded by the hospital-specific payment (referred to as the hospital-specific payment add-on) and the other without MDH status where payment is based solely on the Federal rate. We then took the difference between these two payments to arrive at the FY 2016 hospital-specific payment add-on, that is, 75 percent of the amount by which the Federal rate payment is exceeded by the hospital-specific rate payment. For the first year of the

transition, we multiplied the hospital-specific payment add-on amount by three-quarters because the payment transition is only effective for three-quarters of FY 2016. We then multiplied that product by two-thirds to calculate the MDH transition payment for discharges on or after January 1, 2016, and before October 1, 2016. For the second year of the transition, we multiplied the hospital-specific payment add-on amount by one-third to calculate the MDH transition payment for discharges on or after October 1, 2016, and before October 1, 2017. We then added the transition payments from the first and second year to arrive at the total estimate of the costs associated with the transition period for affected former MDHs. We estimate the costs to the Government associated with the transition period for these hospitals to be approximately $9 million.

B. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $38.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $15 million or less in any single year. For details, see the Small Business Administration's ''Table of Small Business Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards*.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this final rule with comment period may have a significant impact on approximately 649 small rural hospitals. Therefore, we have prepared a regulatory impact analysis that includes the effects of the rule on small rural hospitals. The full impact analysis is reflected in Table 70 under section XXI.A. of this final rule with comment period.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $144 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are making in this final rule with comment period will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2015. Table 70 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 0.4 percent decrease in payments for all services paid under the OPPS in CY 2016, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests, wage index changes, including the frontier State wage index adjustment, estimated payment for outliers, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2016.

The updates to the ASC payment system for CY 2016 will affect each of the approximately 5,300 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 71 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted CPI–U update factor of 0.3 percent for CY 2016.

XXII. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this final rule with comment period in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 70 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would decrease payment by 0.3 percent under this final rule with comment period. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this final rule with comment period, in conjunction with the remainder of this document, demonstrate that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This final rule with comment period would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is amending 42 CFR Chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart R—Provider Reimbursement Determinations and Appeals

■ 1. The authority citation for Part 405, Subpart R continues to read as follows:

Authority: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

■ 2. Section 405.1801 is amended by—

■ a. Amending paragraph (a) by revising the definition ''Contractor determination''.

■ b. Revising paragraph (b)(1).

The revisions read as follows:

§ 405.1801 Introduction.

(a) * * *

Contractor determination means the following:

(1) With respect to a provider of services that has filed a cost report under §§ 413.20 and 413.24 of this chapter, the term means a final determination of the amount of total reimbursement due the provider, pursuant to § 405.1803 following the close of the provider's cost reporting period, for items and services furnished to beneficiaries for which reimbursement may be made on a reasonable cost basis under Medicare for the period covered by the cost report.

(2) With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (part 412 of this chapter), the term means a final determination of the total amount of payment due the hospital, pursuant to § 405.1803 following the close of the hospital's cost reporting period, under that system for the period covered by the final determination.

(3) For purposes of appeal to the Provider Reimbursement Review Board, the term is synonymous with the phrases ''intermediary's final determination,'' ''final determination of the organization serving as its fiscal intermediary,'' ''Secretary's final determination'' and ''final determination of the Secretary,'' as those phrases are used in section 1878(a) of the Act, and with the phrases ''final contractor determination'' and ''final Secretary determination'' as those phrases are used in this subpart.

(4) For purposes of § 405.376 concerning claims collection activities, the term does not include an action by CMS with respect to a compromise of a Medicare overpayment claim, or termination or suspension of collection action on an overpayment claim, against a provider or physician or other supplier.

* * * * *

(b) * * *

(1) *Providers.* In order to be paid for covered services furnished to Medicare beneficiaries, a provider must file a cost report with its contractor as specified in § 413.24 of this chapter. For purposes of this subpart, the term ''provider'' includes a hospital (as described in part 482 of this chapter), hospice program (as described in § 418.3 of this chapter), critical access hospital (CAH), comprehensive outpatient rehabilitation facility (CORF), renal dialysis facility, Federally qualified health center (FQHC), home health agency (HHA), rural health clinic (RHC), skilled nursing facility (SNF), and any other entity included under the Act. (FQHCs and RHCs are providers, for purposes of this subpart, effective with cost reporting periods beginning on or after October 1, 1991).

* * * * *

■ 3. Section 405.1803 is amended by revising the paragraph (a) introductory text to read as follows:

§ 405.1803 Contractor determination and notice of amount of program reimbursement.

(a) *General requirement.* Upon receipt of a provider's cost report, or amended cost report where permitted or required, the contractor must within a reasonable period of time (as specified in § 405.1835(c)(1)), furnish the provider and other parties as appropriate (see § 405.1805) a written notice reflecting the contractor's final determination of the total amount of reimbursement due the provider. The contractor must include the following information in the notice, as appropriate:

* * * * *

■ 4. Section 405.1811 is amended by revising paragraphs (a), (b)(1), (b)(2) introductory text, (b)(2)(iii), (b)(3), (e)(1), and (e)(2), to read as follows:

§ 405.1811 Right to contractor hearing; contents of, and adding issues to, hearing request.

(a) *Right to hearing on final contractor determination.* A provider (but no other individual, entity, or party) has a right to a contractor hearing, as a single provider appeal, with respect to a final contractor or Secretary determination for the provider's cost reporting period, if—

(1) The provider is dissatisfied with the contractor's final determination of the total amount of reimbursement due the provider, as set forth in the contractor's written notice pursuant to § 405.1803. Exception: If a final contractor determination is reopened under § 405.1885, any review by the contractor hearing officer must be limited solely to those matters that are specifically revised in the contractor's revised final determination (§§ 405.1887(d), 405.1889(b), and the ''Exception'' in § 405.1832(c)(2)(i)).

(2) The amount in controversy (as determined in accordance with § 405.1839) must be at least $1,000 but less than $10,000.

(3) Unless the provider qualifies for a good cause extension under § 405.1813, the date of receipt by the contractor of the provider's hearing request must be no later than 180 days after the date of receipt by the provider of the final contractor or Secretary determination.

(b) * * *

(1) A demonstration that the provider satisfies the requirements for a contractor hearing as specified in paragraph (a) of this section, including a specific identification of the final contractor or Secretary determination under appeal.

(2) For each specific item under appeal, a separate explanation of why, and a description of how, the provider is dissatisfied with the specific aspects of the final contractor or Secretary determination under appeal, including an account of all of the following:

* * * * *

(iii) If the provider self-disallows a specific item (as specified in § 413.24(j) of this chapter), an explanation of the nature and amount of each self-disallowed item, the reimbursement sought for the item, and why the provider self-disallowed the item instead of claiming reimbursement for the item.

(3) A copy of the final contractor or Secretary determination under appeal and any other documentary evidence the provider considers necessary to satisfy the hearing request requirements

of paragraphs (b)(1) and (b)(2) of this section.

* * * * *

(e) * * *

(1) The request to add issues complies with the requirements of paragraphs (a) and (b), or paragraphs (c) and (d), of this section as to each new specific item at issue.

(2) The specific items raised in the initial hearing request and the specific items identified in subsequent requests to add issues, when combined, satisfy the amount in controversy requirements of paragraph (a)(2) or paragraph (c)(3) of this section.

* * * * *

§ 405.1813 [Amended]

■ 5. In § 405.1813, paragraphs (a) and (b) are amended by removing the cross-reference ''§ 405.1811(a)(3) of this subpart'' and adding in its place the cross-reference ''§ 405.1811(a)(3) or § 405.1811(c)(2)''.

§ 405.1814 [Amended]

■ 6. Section 405.1814 is amended by removing paragraph (b)(3).

■ 7. A new § 405.1832 is added to read as follows:

§ 405.1832 Contractor hearing officer review of compliance with the substantive reimbursement requirement of an appropriate cost report claim.

(a) *General.* In order to receive or potentially qualify for reimbursement for a specific item, the provider must include in its cost report an appropriate claim for the specific item (as prescribed in § 413.24(j) of this chapter). If the provider files an appeal to the contractor seeking reimbursement for a specific item and any party to such appeal questions whether the provider's cost report included an appropriate claim for the specific item, the contractor hearing officer(s) must address such questions in accordance with the procedures set forth in this section.

(b) *Summary of procedures*—(1) *Preliminary steps.* The contractor hearing officer(s) must give each party to the appeal an adequate opportunity to submit factual evidence and legal argument regarding the question of whether the provider's cost report included an appropriate claim for the specific item under appeal. Upon receipt of timely submitted factual evidence and legal argument (if any), the contractor hearing officer(s) must review such evidence and argument, and prepare written specific findings of fact and conclusions of law on the question of whether the provider's cost report complied with, for the specific item under appeal, the cost report claim requirements prescribed in § 413.24(j) of this chapter. In reaching such specific factual findings and legal conclusions, the contractor hearing officer(s) must follow the procedures set forth in § 413.24(j)(3) of this chapter for determining whether the provider's cost report included an appropriate claim for the specific item under appeal. The contractor hearing officer(s) must promptly give a copy of such written specific factual findings and legal conclusions to each party to the appeal, and such factual findings and legal conclusions must be included in the record of administrative proceedings for the appeal (as prescribed in § 405.1827).

(2) *Limits on contractor hearing officer(s) actions.* The contractor hearing officer(s)'s specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section) must not be invoked or relied on by the contractor hearing officer(s) as a basis to deny, or decline to exercise, jurisdiction over a specific item or take any other of the actions specified in paragraph (c) of this section. Upon giving the parties to the appeal the contractor hearing officer(s)'s written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) on the question of whether the provider's cost report included an appropriate cost report claim for the specific item under appeal, the contractor hearing officer(s) must proceed to issue one of the two types of overall decisions specified in paragraphs (d) and (e) of this section with respect to the specific item. If the contractor hearing officer(s) issues an overall contractor hearing decision (as specified in paragraph (d) of this section) regarding the specific item under appeal, the contractor hearing officer(s)'s written specific factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) must be included in such overall contractor hearing decision regarding the specific item, along with the other matters that are required by the regulations for an overall contractor hearing decision. However, if the contractor hearing officer(s) issues an overall jurisdictional dismissal decision (as specified in paragraph (e) of this section) regarding the specific item under appeal, the contractor hearing officer(s)'s written specific factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) must not be included in the overall jurisdictional dismissal decision regarding the specific item. The contractor hearing officer(s) may permit reimbursement for the specific item under appeal, as part of an overall contractor hearing decision, but such reimbursement may be permitted only to the extent authorized by paragraph (f) of this section.

(c) *Prohibition of certain types of decisions, orders, and other actions.* (1) If the contractor hearing officer(s) determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did not include an appropriate claim for the specific item under appeal, the contractor hearing officer(s) may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the contractor hearing officer(s)'s factual findings and legal conclusions (reached under paragraph (b)(1) of this section);

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the contractor hearing officer(s)'s factual findings and legal conclusions (reached under paragraph (b)(1) of this section); or

(iii) Impose any sanction or take any other action against the interests of any party to the appeal except as provided in paragraph (f) of this section, based on (in whole or in part) the contractor hearing officer(s)'s factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section).

(2) Regardless of whether the contractor hearing officer(s) determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did or did not include an appropriate claim for the specific item under appeal, the contractor hearing officer(s) may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item. *Exception:* If the provider's appeal of the specific item is based on a reopening of such item (pursuant to § 405.1885) where the specific item is not revised, adjusted, corrected, or otherwise changed in a revised final contractor or Secretary determination, the contractor must deny jurisdiction over the specific item under appeal (as prescribed in §§ 405.1887(d) and 405.1889(b));

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the

absence, in the final contractor or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item; or

(iii) Impose any sanction or take any other action against the interests of any party to the appeal except as provided in paragraph (f) of this section, based on (in whole or in part) the absence, in the final contractor or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item.

(d) *Contractor hearing decision must include any factual findings and legal conclusions under paragraph (b)(1) of this section.* If the contractor hearing officer(s) issues a hearing decision regarding the specific item under appeal (pursuant to § 405.1831), any specific findings of fact and conclusions of law by the contractor hearing officer(s) (reached under paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must be included in such hearing decision along with the other matters prescribed by § 405.1831. The contractor hearing officer(s)'s factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) about whether there was an appropriate cost report claim for the specific item under appeal are subject to the provisions of § 405.1833 just as those provisions apply to the other parts of the contractor hearing decision. If the contractor hearing officer(s) determines that the provider's cost report—

(1) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the contractor hearing decision also must address whether the other substantive reimbursement requirements for the specific item are also satisfied; or

(2) Did not include an appropriate claim for the specific item under appeal, the contractor hearing officer(s) has discretion whether or not to address in the contractor hearing decision whether the other substantive reimbursement requirements for the specific item are also satisfied.

(e) *Contractor jurisdictional dismissal decision must not include factual findings and legal conclusions under paragraph (b)(1) of this section.* If the contractor hearing officer(s) issues a jurisdictional dismissal decision regarding the specific item under appeal (in accordance with § 405.1814(c)), the contractor hearing officer(s)'s specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section) on the question of whether the provider's cost report included an appropriate claim for the specific item must not be included in such jurisdictional dismissal decision.

(f) Effects of the contractor hearing officer(s)'s factual findings and legal conclusions under paragraph (b)(1) of this section when part of a final contractor hearing decision. If the contractor hearing officer(s) determines, as part of a final and binding contractor hearing decision (pursuant to § 405.1833 and paragraphs (b)(1) and (d) of this section), that the provider's cost report—

(1) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the specific item is reimbursable in accordance with Medicare policy, but only if the contractor hearing officer(s) further determines in such final contractor hearing decision that all the other substantive reimbursement requirements for the specific item are also satisfied; or

(2) Did not include an appropriate cost report claim for the specific item under appeal, the specific item is not reimbursable, regardless of whether the contractor hearing officer(s) further determines in such final contractor hearing decision that the other substantive reimbursement requirements for the specific item are or are not satisfied.

■ 8. Section 405.1834 is amended by adding a new paragraph (b)(2)(iii) to read as follows:

§ 405.1834 CMS reviewing official procedure.

* * * * *

(b) * * *

(2) * * *

(iii) If the CMS reviewing official reviews a contractor hearing decision regarding a specific item, then the CMS reviewing official's review of such a contractor hearing decision will include, and any decision issued by the CMS reviewing official (under paragraph (e) of this section) will address, the contractor hearing officer(s)'s specific findings of fact and conclusions of law in such contractor hearing decision (as specified in § 405.1832(b)(1) and (d)) on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal (as specified in § 413.24(j) of this chapter).

* * * * *

■ 9. Section 405.1835 is amended by revising paragraphs (a), (b)(1), (b)(2) introductory text, (b)(2)(iii), (b)(3), (e)(1), and (e)(2), to read as follows:

§ 405.1835 Right to Board hearing; contents of, and adding issues to, hearing request.

(a) Right to hearing on final contractor determination. A provider (but no other individual, entity, or party) has a right to a Board hearing, as a single provider appeal, with respect to a final contractor or Secretary determination for the provider's cost reporting period, if—

(1) The provider is dissatisfied with the contractor's final determination of the total amount of reimbursement due the provider, as set forth in the contractor's written notice specified under § 405.1803. *Exception:* If a final contractor determination is reopened under § 405.1885, any review by the Board must be limited solely to those matters that are specifically revised in the contractor's revised final determination (§§ 405.1887(d), 405.1889(b), and the ''Exception'' in § 405.1873(c)(2)(i)).

(2) The amount in controversy (as determined in accordance with § 405.1839) must be $10,000 or more.

(3) Unless the provider qualifies for a good cause extension under § 405.1836, the date of receipt by the Board of the provider's hearing request must be no later than 180 days after the date of receipt by the provider of the final contractor or Secretary determination.

(b) * * *

(1) A demonstration that the provider satisfies the requirements for a Board hearing as specified in paragraph (a) of this section, including a specific identification of the final contractor or Secretary determination under appeal.

(2) For each specific item under appeal, a separate explanation of why, and a description of how, the provider is dissatisfied with the specific aspects of the final contractor or Secretary determination under appeal, including an account of all of the following:

* * * * *

(iii) If the provider self-disallows a specific item (as specified in § 413.24(j) of this chapter), an explanation of the nature and amount of each self-disallowed item, the reimbursement sought for the item, and why the provider self-disallowed the item instead of claiming reimbursement for the item.

(3) A copy of the final contractor or Secretary determination under appeal and any other documentary evidence the provider considers necessary to satisfy the hearing request requirements

of paragraphs (b)(1) and (b)(2) of this section.

* * * * *

(e) * * *

(1) The request to add issues complies with the requirements of paragraphs (a) and (b), or paragraphs (c) and (d), of this section as to each new specific item at issue.

(2) The specific items raised in the initial hearing request and the specific items identified in subsequent requests to add issues, when combined, satisfy the amount in controversy requirements of paragraph (a)(2) or paragraph (c)(3) of this section.

* * * * *

§ 405.1836 [Amended]

■ 10. In § 405.1836, paragraph (a) is amended by removing the cross-reference ''§ 405.1835(a)(3) of this subpart'' and adding in its place the cross-reference ''§ 405.1835(a)(3) or § 405.1835(c)(2)''; and paragraph (b) is amended by removing the cross-reference ''§ 405.1835(a)(3)'' and adding in its place the cross-reference ''§ 405.1835(a)(3) or § 405.1835(c)(2)''.

■ 11. Section 405.1837 is amended by revising paragraphs (a) introductory text, (a)(1), (c)(2) introductory text, (c)(2)(iii), (c)(3), and (e)(4) to read as follows:

§ 405.1837 Group appeals.

(a) *Right to Board hearing as part of a group appeal: Criteria.* A provider (but no other individual, entity, or party) has a right to a Board hearing, as part of a group appeal with other providers, with respect to a final contractor or Secretary determination for the provider's cost reporting period, only if—

(1) The provider satisfies individually the requirements for a Board hearing under § 405.1835(a) or § 405.1835(c), except for the $10,000 amount in controversy requirement in § 405.1835(a)(2) or § 405.1835(c)(3).

* * * * *

(c) * * *

(2) An explanation (for each specific item at issue) of each provider's dissatisfaction with the final contractor or Secretary determination under appeal, including an account of—

* * * * *

(iii) If the provider self-disallows a specific item (as specified in § 413.24(j) of this chapter), an explanation of the nature and amount of each self-disallowed item, the reimbursement sought for the item, and why the provider self-disallowed the item instead of claiming reimbursement for the item.

(3) A copy of each final contractor or Secretary determination under appeal, and any other documentary evidence the providers consider to satisfy the hearing request requirements of paragraphs (c)(1) and (c)(2) of this section, and a precise description of the one question of fact or interpretation of law, regulations, or CMS Rulings that is common to the particular matter at issue in the group appeal.

* * * * *

(e) * * *

(4) A provider may submit a request to the Board to join a group appeal any time before the Board issues one of the decisions specified in § 405.1875(a)(2). By submitting a request, the provider agrees that, if the request is granted, the provider is bound by the Board's actions and decision in the appeal. If the Board denies a request, the Board's action is without prejudice to any separate appeal the provider may bring in accordance with § 405.1811, § 405.1835, or this section. For purposes of determining timeliness for the filing of any separate appeal and for the adding of issues to such appeal, the date of receipt of the provider's request to form or join the group appeal is considered the date of receipt for purposes of meeting the applicable 180-day period prescribed in § 405.1835(a)(3) or § 405.1835(c)(2).

* * * * *

§ 405.1839 [Amended]

■ 12. In § 405.1839, paragraph (a)(1) is amended by removing the cross-reference ''§ 405.1811(a)(2) of this subpart'' and adding in its place the cross-reference ''§ 405.1811(a)(2) or § 405.1811(c)(3)''; and by removing the cross-reference ''§ 405.1835(a)(2) of this subpart'' and adding in its place the cross-reference ''§ 405.1835(a)(2) or § 405.1835(c)(3)''.

§ 405.1840 [Amended]

■ 13. Section 405.1840 is amended by removing paragraph (b)(3).

■ 14. A new § 405.1873 is added to read as follows:

§ 405.1873 Board review of compliance with the reimbursement requirement of an appropriate cost report claim.

(a) *General.* In order to receive or potentially receive reimbursement for a specific item, the provider must include in its cost report an appropriate claim for the specific item (as prescribed in § 413.24(j) of this chapter). If the provider files an appeal to the Board seeking reimbursement for the specific item and any party to such appeal questions whether the provider's cost report included an appropriate claim for the specific item, the Board must address such question in accordance with the procedures set forth in this section.

(b) *Summary of procedures*—(1) *Preliminary steps.* The Board must give the parties an adequate opportunity to submit factual evidence and legal argument regarding the question of whether the provider's cost report included an appropriate claim for the specific item under appeal. Upon receipt of timely submitted factual evidence or legal argument (if any), the Board must review such evidence and argument and prepare written specific findings of fact and conclusions of law on the question of whether the provider's cost report complied with, for the specific item under appeal, the cost report claim requirements prescribed in § 413.24(j) of this chapter. In reaching such specific factual findings and legal conclusions, the Board must follow the procedures set forth in § 413.24(j)(3) of this chapter for determining whether the provider's cost report included an appropriate claim for the specific item under appeal. The Board must promptly give a copy of such written specific factual findings and legal conclusions to each party to the appeal, and such factual findings and legal conclusions must be included in the record of administrative proceedings for the appeal (as prescribed in § 405.1865).

(2) *Limits on Board actions.* The Board's specific findings of fact and conclusions of law (pursuant to paragraph (b)(1) of this section) must not be invoked or relied on by the Board as a basis to deny, or decline to exercise, jurisdiction over a specific item or take any other of the actions specified in paragraph (c) of this section. Upon giving the parties to the appeal the Board's written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) on the question of whether the provider's cost report included an appropriate cost report claim for the specific item under appeal, the Board must proceed to issue one of the four types of overall decisions specified in paragraphs (d) and (e) of this section with respect to the specific item. If the Board issues either of two types of overall Board decisions (as specified in paragraph (d) of this section) regarding the specific item under appeal, the Board's written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) must be included in such overall Board decision regarding the specific item, along with the other matters that are required by the regulations for the pertinent type of

overall Board decision. However, if the Board issues either of two other types of overall Board decisions (as specified in paragraph (e) of this section) regarding the specific item under appeal, the Board's written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) must not be included in the overall Board decision regarding the specific item. The Board may permit reimbursement for the specific item under appeal, as part of one of the two types of overall Board decisions that are specified in paragraph (d) of this section, but such reimbursement may be permitted only to the extent authorized by paragraph (f) of this section.

(c) *Prohibition of certain types of decisions, orders, and other actions.* (1) If the Board determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did not include an appropriate claim for the specific item under appeal, the Board may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section);

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section); or

(iii) Take any of the actions set forth in § 405.1868(b), (c), or (d), impose any sanction, or take any other action against the interests of any party to the appeal, except as provided in paragraph (f) of this section, based on (in whole or in part) the Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section).

(2) Regardless of whether the Board determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did or did not include an appropriate claim for the specific item under appeal, the Board may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item. *Exception:* If the provider's appeal of the specific item is based on a reopening of such item (pursuant to § 405.1885) where the specific item is not revised, adjusted, corrected, or otherwise changed in a revised final contractor or Secretary determination, the Board must deny jurisdiction over the specific item under appeal (as prescribed in §§ 405.1887(d) and 405.1889(b));

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item; or

(iii) Take any of the actions set forth in § 405.1868(b), (c), or (d), impose any sanction, or take any other action against the interests of any party to the appeal, except as provided in paragraph (f) of this section, based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item.

(d) *Two types of Board decisions that must include any factual findings and legal conclusions under paragraph (b)(1) of this section*—(1) *Board hearing decision.* If the Board issues a hearing decision regarding the specific item under appeal (pursuant to § 405.1871), any specific findings of fact and conclusions of law by the Board (in accordance with paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must be included in such hearing decision along with the other matters prescribed by § 405.1871(a). The Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section), about whether there was an appropriate cost report claim for the specific item under appeal, are subject to the provisions of § 405.1871(b) just as those provisions apply to the other parts of the Board's hearing decision. If the Board determines that the provider's cost report—

(i) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the Board's hearing decision must also address whether the other substantive reimbursement requirements for the specific item are also satisfied; or

(ii) Did not include an appropriate claim for the specific item under appeal, the Board has discretion whether or not to address in the Board's hearing decision whether the other substantive reimbursement requirements for the specific item are also satisfied.

(2) *Board expedited judicial review (EJR) decision, where EJR is granted.* If the Board issues an EJR decision where EJR is granted regarding a legal question that is relevant to the specific item under appeal (in accordance with § 405.1842(f)(1)), the Board's specific findings of fact and conclusions of law (reached under paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must be included in such EJR decision along with the other matters prescribed by § 405.1842(f)(1). The Board's factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) about whether there was an appropriate cost report claim for the specific item under appeal are subject to the provisions of § 405.1842(g)(1), (g)(2), (h)(1), and (h)(3) in the same manner as those provisions apply to the other parts of the Board's EJR decision.

(e) *Two other types of Board decisions that must not include the Board's factual findings and legal conclusions under paragraph (b)(1) of this section*—(1) *Board jurisdictional dismissal decision.* If the Board issues a jurisdictional dismissal decision regarding the specific item under appeal (pursuant to § 405.1840(c)), the Board's specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must not be included in such jurisdictional dismissal decision.

(2) *Board expedited judicial review (EJR) decision, where EJR is denied.* If the Board issues an EJR decision where EJR is denied regarding a legal question that is relevant to the specific item under appeal (in accordance with § 405.1842(f)(2)), the Board's specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the same item, must not be included in such EJR decision. If the Board conducts further proceedings and issues another decision (as specified in § 405.1842(h)(2)(i)), the Board's specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section)—

(i) Must be included in any further hearing decision or EJR decision where EJR is granted regarding the specific item under appeal (as specified in paragraph (d) of this section); but

(ii) Must not be included in any further jurisdictional dismissal decision or EJR decision where EJR is denied

regarding the specific item under appeal (as prescribed in paragraph (e) of this section).

(f) *Effects of the Board's factual findings and legal conclusions under paragraph (b)(1) of this section in two types of final decisions*—(1) *When part of a final hearing decision.* If the Board determines, or the Administrator of CMS determines (pursuant to § 405.1875(a)(2)(v)), as applicable, in a final and binding hearing decision (in accordance with § 405.1871(b) and paragraphs (b)(1) and (d)(1) of this section), that the provider's cost report—

(i) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the specific item is reimbursable in accordance with Medicare policy, but only if the Board further determines in such final hearing decision that all the other substantive reimbursement requirements for the specific item are also satisfied; or

(ii) Did not include an appropriate cost report claim for the specific item under appeal, the specific item is not reimbursable, regardless of whether the Board further determines in such final hearing decision that the other substantive reimbursement requirements for the specific item are or are not satisfied.

(2) *When part of a final EJR decision that grants EJR.* If the Board determines or the Administrator of CMS determines (pursuant to § 405.1875(a)(2)(v)), as applicable, in a final and binding EJR decision that grants EJR regarding a legal question that is relevant to the specific item under appeal (in accordance with § 405.1842(g)(1) and paragraphs (b)(1) and (d)(2) of this section), that the provider's cost report—

(i) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the specific item is reimbursable in accordance with Medicare policy, but only to the extent permitted by the final decision of a Federal court pursuant to the EJR provisions of section 1878(f)(1) of the Act (refer also to §§ 405.1842 and 405.1877); or

(ii) Did not include an appropriate claim for the specific item under appeal, the specific item is not reimbursable, unless—

(A) The specific factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) of the Board or the Administrator, as applicable, on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal, are reversed or modified by the final decision of a Federal court (in accordance with section 1878(f)(1) of the Act and § 405.1877); and

(B) Only to the extent otherwise permitted by the final decision of a Federal court pursuant to the EJR provisions of section 1878(f)(1) of the Act (refer also to §§ 405.1842 and 405.1877) and by Medicare policy.

■ 15. Section 405.1875 is amended by revising the last sentence of paragraph (a) introductory text and adding a new paragraph (a)(2)(v) to read as follows:

§ 405.1875 Administrator review.

(a) * * * The Board is required to send to the Office of the Attorney Advisor a copy of each decision specified in paragraphs (a)(2)(i), (ii), and (iii) of this section upon issuance of the decision.

* * * * *

(2) * * *

(v) If the Administrator reviews a Board hearing decision regarding a specific item, or for a Board EJR decision the question of whether there is Board jurisdiction over a specific item, the Administrator's review of such a hearing decision or EJR decision, as applicable, will include, and any decision issued by the Administrator (under paragraph (e) of this section) will address, the Board's specific findings of fact and conclusions of law in such hearing decision or EJR decision (as prescribed in § 405.1873(b)(1) and (d)) on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter).

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 16. The authority citation for Part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

■ 17. Section 410.29 is amended by revising paragraph (a) to read as follows:

§ 410.29 Limitations on drugs and biologicals.

* * * * *

(a) Except as provided in § 410.28(a) for outpatient diagnostic services and § 410.63(b) for blood clotting factors, and except for EPO, any drug or biological which is usually self-administered by the patient.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 18. The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Pub. L. 113–67, and sec 112 of Pub. L. 113–93.

■ 19. Section 412.3 is amended by revising paragraph (d) to read as follows:

§ 412.3 Admissions.

* * * * *

(d)(1) Except as specified in paragraphs (d)(2) and (3) of this section, an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights.

(i) The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

(ii) If an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis, and payment for an inpatient hospital stay may be made under Medicare Part A.

(2) An inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) of this chapter is generally appropriate for payment under Medicare Part A, regardless of the expected duration of care.

(3) Where the admitting physician expects a patient to require hospital care for only a limited period of time that does not cross 2 midnights, an inpatient admission may be appropriate for payment under Medicare Part A based on the clinical judgment of the admitting physician and medical record support for that determination. The physician's decision should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In these cases, the factors that lead to the decision to admit the patient as an inpatient must be supported by the

medical record in order to be granted consideration.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 20. The authority citation for Part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 3201 of Pub. L. 112–96 (126 Stat. 156), sec. 632 of Pub. L. 112–240 (126 Stat. 2354), and sec. 217 of Pub. L. 113–93.

■ 21. Section 413.24 is amended by adding and reserving paragraph (i), and adding a new paragraph (j), to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(i) [Reserved]

(j) *Substantive reimbursement requirement of an appropriate cost report claim*—(1) *General requirement.* In order for a provider to receive or potentially qualify for reimbursement for a specific item for its cost reporting period, the provider's cost report, whether determined on an as submitted, as amended, or as adjusted basis (as prescribed in paragraph (j)(3) of this section), must include an appropriate claim for the specific item, by either—

(i) Claiming full reimbursement in the provider's cost report for the specific item in accordance with Medicare policy, if the provider seeks payment for the item that it believes comports with program policy; or

(ii) Self-disallowing the specific item in the provider's cost report, if the provider seeks payment that it believes may not be allowable or may not comport with Medicare policy (for example, if the provider believes the contractor lacks the authority or discretion to award the reimbursement the provider seeks for the item), by following the procedures (set forth in paragraph (j)(2) of this section) for properly self-disallowing the specific item in the provider's cost report as a protested amount.

(2) *Self-disallowance procedures.* In order to properly self-disallow a specific item, the provider must—

(i) Include an estimated reimbursement amount for each specific self-disallowed item in the protested amount line (or lines) of the provider's cost report; and

(ii) Attach a separate work sheet to the provider's cost report for each specific self-disallowed item, explaining why the provider self-disallowed each specific item (instead of claiming full reimbursement in its cost report for the specific item) and describing how the provider calculated the estimated reimbursement amount for each specific self-disallowed item.

(3) *Procedures for determining whether there is an appropriate cost report claim.* Whether the provider's cost report for its cost reporting period includes an appropriate claim for a specific item (as prescribed in paragraph (j)(1) of this section) must be determined by reference to the cost report that the provider submits originally to, and was accepted by, the contractor for such period, provided that none of the following exceptions applies:

(i) If the provider submits an amended cost report for its cost reporting period and such amended cost report is accepted by the contractor, then whether there is an appropriate cost report claim for the specific item must be determined by reference to such amended cost report, provided that neither of the exceptions set forth in paragraphs (j)(3)(ii) and (iii) of this section applies;

(ii) If the contractor adjusts the provider's cost report, as submitted originally by the provider and accepted by the contractor or as amended by the provider and accepted by the contractor, whichever is applicable, with respect to the specific item, then whether there is an appropriate cost report claim for the specific item must be determined by reference to the provider's cost report, as such cost report claim is adjusted for the specific item in the final contractor determination (as defined in § 405.1801(a) of this chapter) for the provider's cost reporting period, provided that the exception set forth in paragraph (j)(3)(iii) of this section does not apply;

(iii) If the contractor reopens either the final contractor determination for the provider's cost reporting period (pursuant to § 405.1885 of this chapter) or a revised final contractor determination for such period (issued pursuant to § 405.1889 of this chapter) and the contractor adjusts the provider's cost report with respect to the specific item, then whether there is an appropriate cost report claim for the specific item must be determined by reference to the provider's cost report, as such cost report claim is adjusted for the specific item in the most recent revised final contractor determination for such period.

(4) *Reimbursement effects of contractor's determination of whether there is an appropriate cost report claim.* If the contractor determines that the provider's cost report included an appropriate claim for a specific item (as specified in paragraphs (j)(1), (2), and (3) of this section) and that all the other substantive reimbursement requirements for the specific item are also satisfied, the final contractor determination (as defined in § 405.1801(a) of this chapter) must include reimbursement for the specific item to the extent permitted by Medicare policy. If the contractor determines that the provider made an appropriate cost report claim for a specific item but the contractor disagrees with material aspects of the provider's claim for the specific item, the contractor must make appropriate adjustments to the provider's cost report and include reimbursement for the specific item in the final contractor determination in accordance with such cost report adjustments and to the extent permitted by program policy. If the contractor determines that the provider did not make an appropriate cost report claim for a specific item, the final contractor determination must not include any reimbursement for the specific item, regardless of whether the other substantive reimbursement requirements for the specific item are or are not satisfied.

(5) *Administrative review of whether there is an appropriate cost report claim.* If the provider files an administrative appeal (pursuant to Part 405, Subpart R of this chapter) seeking reimbursement for a specific item and any party to such appeal questions whether the provider's cost report included an appropriate claim for the specific item under appeal (as specified in paragraphs (j)(1), (2), (3), and (4) of this section), the reviewing entity (as defined in § 405.1801(a) of this chapter) must follow the procedures prescribed in § 405.1873 of this chapter (if the appeal was filed originally with the Board), or the procedures set forth in § 405.1832 of this chapter (if the appeal was filed initially with the contractor), for review of whether the substantive reimbursement requirement of an appropriate cost report claim for the specific item under appeal is satisfied. The reviewing entity must follow the procedures set forth in paragraph (j)(3) of this section in determining whether the provider's cost report included an appropriate claim for the specific item under appeal. The reviewing entity may permit reimbursement for the specific

item under appeal solely to the extent authorized by § 405.1873(f) of this chapter (if the appeal was filed originally with the Board) or by § 405.1832(f) of this chapter (if the appeal was filed initially with the contractor).

PART 416—AMBULATORY SURGICAL SERVICES

■ 22. The authority citation for Part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 23. Section 416.164 is amended by revising paragraph (b)(3) to read as follows:

§ 416.164 Scope of ASC services.

* * * * *

(b) * * *

(3) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the acquisition or procurement of corneal tissue for corneal transplant procedures;

* * * * *

■ 24. Section 416.172 is amended by revising paragraph (f) to read as follows:

§ 416.172 Adjustments to national payment rates.

* * * * *

(f) *Interrupted procedures.* (1) Subject to the provisions of paragraph (f)(2) of this section, when a covered surgical procedure or covered ancillary service is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary coinsurance amount are based on one of the following:

(i) The full program and beneficiary coinsurance amounts if the procedure for which anesthesia is planned is discontinued after the induction of anesthesia or after the procedure is started;

(ii) One-half of the full program and beneficiary coinsurance amounts if the procedure for which anesthesia is planned is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed but before the anesthesia is induced; or

(iii) One-half of the full program and beneficiary coinsurance amounts if a covered surgical procedure or covered ancillary service for which anesthesia is not planned is discontinued after the patient is prepared and taken to the room where the service is to be provided.

(2) Beginning CY 2016, if the covered surgical procedure is a device-intensive procedure, the full device portion of the ASC device-intensive procedure is removed prior to determining the Medicare program payment amount and the beneficiary coinsurance amount identified in paragraph (f)(1)(ii) of this section.

* * * * *

■ 25. Section 416.195 is amended by revising paragraph (a)(1) to read as follows:

§ 416.195 Determination of membership in new classes of new technology IOLs.

(a) * * *

(1) The IOL is considered new. CMS will evaluate an application for a new technology IOL only if the IOL type has received initial FDA premarket approval within the 3 years prior to the new technology IOL application submission date.

* * * * *

■ 26. Subpart H is added to read as follows:

Subpart H—Requirements Under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

Sec.
416.300 Basis and scope of subpart.
416.305 Participation and withdrawal requirements under the ASCQR Program.
416.310 Data collection and submission requirements under the ASCQR Program.
416.315 Public reporting of data under the ASCQR Program.
416.320 Retention and removal of quality measures under the ASCQR Program.
416.325 Measure maintenance under the ASCQR Program.
416.330 Reconsiderations under the ASCQR Program.

Subpart H—Requirements Under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

§ 416.300 Basis and scope of subpart.

(a) *Statutory basis.* Section 1833(i)(2)(D)(iv) and (i)(7) of the Act authorizes the Secretary to implement a revised ASC payment system in a manner so as to provide for a 2.0 percentage point reduction in any annual update for an ASC's failure to report on quality measures in accordance with the Secretary's requirements.

(b) *Scope.* This subpart contains specific requirements and standards for the ASCQR Program.

§ 416.305 Participation and withdrawal requirements under the ASCQR Program.

(a) *Participation in the ASCQR Program.* Except as provided in paragraph (c) of this section, an ambulatory surgical center (ASC) is considered as participating in the ASCQR Program once the ASC submits any quality measure data to the ASCQR Program and has been designated as open in the Certification and Survey Provider Enhanced Reporting system for at least four months prior to the beginning of data collection for a payment determination.

(b) *Withdrawal from the ASCQR Program.* (1) An ASC may withdraw from the ASCQR Program by submitting to CMS a withdrawal of participation form that can be found in the secure portion of the QualityNet Web site.

(2) An ASC may withdraw from the ASCQR Program any time up to and including August 31 of the year preceding a payment determination.

(3) Except as provided in paragraph (c) of this section, an ASC will incur a 2.0 percentage point reduction in its ASC annual payment update for that payment determination year and any subsequent payment determinations in which it is withdrawn.

(4) An ASC will be considered as rejoining the ASCQR Program if it begins to submit any quality measure data again to the ASCQR Program.

(c) *Minimum case volume for program participation.* ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) per year during an annual reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent annual reporting period for that subsequent payment determination year.

(d) *Indian Health Service hospital outpatient department participation.* Beginning with the CY 2017 payment determination, Indian Health Service hospital outpatient departments that bill Medicare under the Ambulatory Surgical Center payment system are not considered ASCs for the purposes of the ASCQR Program. These facilities are not required to meet ASCQR Program requirements and will not receive payment reductions under the ASCQR Program.

§ 416.310 Data collection and submission requirements under the ASCQR Program.

(a) *Requirements for claims-based measures using quality data codes (QDCs).* (1) ASCs must submit complete data on individual claims-based quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims.

(2) The data collection period for claims-based quality measures reported using QDCs is the calendar year 2 years prior to the payment determination year. Only claims for services furnished in each calendar year paid by the Medicare Administrative Contractor

(MAC) by April 30 of the following year of the ending data collection time period will be included in the data used for the payment determination year.

(3) For ASCQR Program purposes, data completeness for claims-based measures using QDCs is determined by comparing the number of Medicare claims (where Medicare is the primary or secondary payer) meeting measure specifications that contain the appropriate QDCs with the number of Medicare claims that meet measure specifications, but do not have the appropriate QDCs on the submitted Medicare claim. The minimum threshold for successful reporting is that at least 50 percent of Medicare claims meeting measure specifications contain the appropriate QDCs. ASCs that meet this minimum threshold are regarded as having provided complete data for the claims-based measures using QDCs for the ASCQR Program.

(b) *Requirements for claims-based measures not using QDCs.* The data collection period for claims-based quality measures not using QDCs is paid Medicare fee-for-service claims from the calendar year 2 years prior to the payment determination year. Only claims for services furnished in each calendar year paid by the MAC by April 30 of the following year of the ending data collection time period will be included in the data used for the payment determination.

(c) *Requirements for data submitted via an online data submission tool*—(1) *Requirements for data submitted via a CMS online data submission tool*—(i) *QualityNet account for Web-based measures.* ASCs must maintain a QualityNet account in order to submit quality measure data to the QualityNet Web site for all Web-based measures submitted via a CMS online data submission tool. A QualityNet security administrator is necessary to set-up such an account for the purpose of submitting this information.

(ii) *Data collection requirements.* The data collection time period for quality measures for which data are submitted via a CMS online data submission tool is for services furnished during the calendar year 2 years prior to the payment determination year. Data collected must be submitted during the time period of January 1 to August 15 in the year prior to the payment determination year.

(2) *Requirements for data submitted via a non-CMS online data submission tool.* The data collection time period for ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel is from October 1 of the year 2 years prior to the payment determination year to March 31 during the year prior to the payment determination year. Data collected must be submitted by May 15 in the year prior to the payment determination year.

(d) *Extension or exemption.* CMS may grant an extension or exemption for the submission of information in the event of extraordinary circumstances beyond the control of an ASC, or a systematic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an extension or exemption as follows:

(1) Upon request of the ASC. Specific requirements for submission of a request for an extension or exemption are available on the QualityNet Web site; or

(2) At the discretion of CMS. CMS may grant extensions or exemptions to ASCs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

§ 416.315 Public reporting of data under the ASCQR Program.

Data that an ASC submitted for the ASCQR Program will be made publicly available on a CMS Web site after providing the ASC an opportunity to review the data to be made public. CMS will publicly display ASC data by the National Provider Identifier (NPI) when data are submitted by the NPI. CMS will publicly display ASC data by the CMS Certification Number (CCN) when data are submitted by the CCNs.

§ 416.320 Retention and removal of quality measures under the ASCQR Program.

(a) *General rule for the retention of quality measures.* Quality measures adopted for an ASCQR Program measure set for a previous payment determination year are retained in the ASCQR Program for measure sets for subsequent payment determination years, except when they are removed, suspended, or replaced as set forth in paragraphs (b) and (c) of this section.

(b) *Immediate measure removal.* In cases where CMS believes that the continued use of a measure as specified raises patient safety concerns, CMS will immediately remove a quality measure from the ASCQR Program and will promptly notify ASCs and the public of the removal of the measure and the reasons for its removal through the ASCQR Program ListServ and the ASCQR Program QualityNet Web site. CMS will confirm the removal of the measure for patient safety concerns in the next ASCQR Program rulemaking.

(c) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (b) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the ASCQR Program to allow for public comment.

(1) *Criteria for removal of quality measures.* (i) CMS will use the following criteria to determine whether to remove a measure from the ASCQR Program:

(A) Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (topped-out measures);

(B) Availability of alternative measures with a stronger relationship to patient outcomes;

(C) A measure does not align with current clinical guidelines or practice;

(D) The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and

(G) Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(ii) The benefits of removing a measure from the ASCQR Program will be assessed on a case-by-case basis. A measure will not be removed solely on the basis of meeting any specific criterion.

(2) *Criteria to determine topped-out measures.* For the purposes of the ASCQR Program, a measure is considered to be topped-out under paragraph (c)(1)(i)(A) of this section when it meets both of the following criteria:

(i) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an ASC's measure is within two times the standard error of the full data set); and

(ii) A truncated coefficient of variation less than or equal to 0.10.

§ 416.325 Measure maintenance under the ASCQR Program.

(a) *Measure maintenance under the ASCQR Program.* CMS follows different procedures to update the measure specifications under the ASCQR Program based on whether the change is substantive or nonsubstantive. CMS will determine what constitutes a substantive versus a nonsubstantive change to a measure's specifications on a case-by-case basis.

(b) *Substantive changes.* CMS will continue to use rulemaking to adopt substantive updates to measures in the ASCQR Program.

(c) *Nonsubstantive changes.* If CMS determines that a change to a measure previously adopted in the ASCQR Program is nonsubstantive, CMS will use a subregulatory process to revise the ASCQR Program Specifications Manual so that it clearly identifies the changes to that measure and provide links to where additional information on the changes can be found. When a measure undergoes subregulatory maintenance, CMS will provide notification of the measure specification update on the QualityNet Web site and in the ASCQR Program Specifications Manual, and will provide sufficient lead time for ASCs to implement the revisions where changes to the data collection systems would be necessary.

§ 416.330 Reconsiderations under the ASCQR Program.

(a) *Reconsiderations of ASCQR Program decisions.* An ASC may request reconsideration of a decision by CMS that it has not met the requirements of the ASCQR Program for a particular payment determination year. An ASC must submit a reconsideration request to CMS by no later than the first business day on or after March 17 of the affected payment year.

(b) *Requirements for reconsideration requests.* A reconsideration request must contain the following information:

(1) The ASC CCN and related NPI(s);

(2) The name of the ASC;

(3) The CMS-identified reason for not meeting the requirements of the ASCQR Program for the affected payment determination year as provided in any CMS notification to the ASC;

(4) The ASC's basis for requesting reconsideration. The ASC must identify its specific reason(s) for believing it met the ASCQR Program requirements for the affected payment determination year and should not be subject to the reduced ASC annual payment update;

(5) The ASC-designated personnel contact information, including name, email address, telephone number, and mailing address (must include physical mailing address, not just a post office box); and

(6) A copy of all materials that the ASC submitted to comply with the requirements of the affected ASCQR Program payment determination year. With regard to information on claims, ASCs are not required to submit copies of all submitted claims, but instead may focus on the specific claims at issue. For these claims, ASCs should submit relevant information, which could include copies of the actual claims at issue.

(c) *Reconsideration process.* Upon receipt of a request for reconsideration, CMS will do the following:

(1) Provide an email acknowledgement, using the contact information provided in the reconsideration request, notifying the ASC that the request has been received; and

(2) Provide a formal response to the ASC contact using the information provided in the reconsideration request notifying the ASC of the outcome of the reconsideration process.

(d) *Final ASCQR Program payment determination.* For an ASC that submits a timely reconsideration request, the reconsideration determination is the final ASCQR Program payment determination. For an ASC that does not submit a timely reconsideration request, the CMS determination is the final payment determination. There is no appeal of any final ASCQR Program payment determination.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 27. The authority citation for Part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

■ 28. Section 419.2 is amended by revising paragraph (c)(8) to read as follows:

§ 419.2 Basis of payment.

* * * * *

(c) * * *

(8) Corneal tissue acquisition or procurement costs for corneal transplant procedures.

■ 29. Section 419.32 is amended by adding new paragraph (b)(1)(iv)(B)(7) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(7) For calendar year 2016, a multifactor productivity adjustment (as determined by CMS), and 0.2 percentage point.

* * * * *

■ 30. Section 419.44 is amended by revising paragraph (b) to read as follows:

§ 419.44 Payment reductions for procedures.

* * * * *

(b) *Interrupted procedures.* (1) Subject to the provisions of paragraph (b)(2) of this section, when a procedure is terminated prior to completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicare program payment amount and the beneficiary copayment amount are based on—

(i) The full program and beneficiary copayment amounts if the procedure for which anesthesia is planned is discontinued after the induction of anesthesia or after the procedure is started;

(ii) One-half the full program and the beneficiary copayment amounts if the procedure for which anesthesia is planned is discontinued after the patient is prepared and taken to the room where the procedure is to be performed but before anesthesia is induced; or

(iii) One-half of the full program and beneficiary copayment amounts if a procedure for which anesthesia is not planned is discontinued after the patient is prepared and taken to the room where the procedure is to be performed.

(2) Beginning CY 2016, if a procedure involves an implantable device assigned to a device-intensive APC, the full device portion of the device-intensive APC procedure payment is removed prior to determining the program and beneficiary copayment amounts identified in paragraph (b)(1)(ii) of this section.

■ 31. Section 419.46 is amended by revising paragraphs (b), (d), (e), and (f)(1) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(b) *Withdrawal from the Hospital OQR Program.* A participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital may withdraw any time up to and including August 31 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.43(h), and is required to submit a new participation form in order to participate in any future year of the Hospital OQR Program.

* * * * *

(d) *Exemption.* CMS may grant an extension or exemption of one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an extension or exemption as follows:

(1) Upon request by the hospital. Specific requirements for submission of a request for an extension or exemption are available on the QualityNet Web site.

(2) At the discretion of CMS. CMS may grant extensions or exemptions to hospitals that have not requested them when CMS determines that an extraordinary circumstance has occurred.

(e) *Validation of Hospital OQR Program data.* CMS may validate one or more measures selected under section 1833(t)(17)(C) of the Act by reviewing documentation of patient encounters submitted by selected participating hospitals.

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 45 days of the date identified on the written request, in the form and manner specified in the written request.

(2) A hospital meets the validation requirement with respect to a calendar year if it achieves at least a 75-percent reliability score, as determined by CMS.

(f) * * *

(1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program for a particular calendar year. Except as provided in paragraph (d) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet Web site, no later than the first business day on or after March 17 of the affected payment year as determined using the date the request was mailed or submitted to CMS.

* * * * *

■ 32. Section 419.66 is amended by revising paragraph (b)(1) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(b) * * *

(1) If required by the FDA, the device must have received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of this chapter), or meet another appropriate FDA exemption for premarket approval or clearance. Under this provision, the pass-through payment application for a medical device must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability.

* * * * *

Dated: October 23, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare and Medicaid Services.

Dated: October 26, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–27943 Filed 10–30–15; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 80 Friday,

No. 219 November 13, 2015

Part III

Nuclear Regulatory Commission

10 CFR Parts 50 and 52

Mitigation of Beyond-Design-Basis Events; Proposed Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

[Docket Nos. PRM–50–97 and PRM–50–98; NRC–2011–0189 and NRC–2014–0240]

RIN 3150–AJ49

Mitigation of Beyond-Design-Basis Events

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations that establish regulatory requirements for nuclear power reactor applicants and licensees to mitigate beyond-design-basis events. The NRC is proposing to make generically applicable requirements in Commission orders for mitigation of beyond-design-basis events and for reliable spent fuel pool instrumentation. This proposed rule would establish regulatory requirements for an integrated response capability, including supporting requirements for command and control, drills, training and change control. This proposed rule also would establish requirements for enhanced onsite emergency response capabilities. Finally, this proposed rule would address a number of petitions for rulemaking (PRMs) submitted to the NRC following the March 2011 Fukushima Dai-ichi event. This rulemaking is applicable to power reactor licensees, power reactor license applicants, and decommissioning power reactor licensees. This rulemaking combines two NRC activities for which documents have been published in the **Federal Register**—Onsite Emergency Response Capabilities (RIN 3150–AJ11; NRC–2012–0031) and Station Blackout Mitigation Strategies (RIN 3150–AJ08; NRC–2011–0299). The new identification numbers for this consolidated rulemaking are RIN 3150–AJ49 and NRC–2014–0240.

DATES: Submit comments by February 11, 2016. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date. A public meeting will be held during the public comment period; refer to the NRC's public meeting schedule on the NRC Web site at *http://meetings.nrc.gov/pmns/mtg.*

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

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0240. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

You may submit comments on the guidance documents and the information collections by the methods indicated in the ''Availability of Guidance'' and ''Paperwork Reduction Act'' sections of this document.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Timothy Reed, Office of Nuclear Reactor Regulation, telephone: 301–415–1462, email: *Timothy.Reed@nrc.gov;* or Eric Bowman, Office of Nuclear Reactor Regulation, telephone: 301–415–2963, email: *Eric.Bowman@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Executive Summary

A. Need for the Regulatory Action

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to establish regulatory requirements for nuclear power reactor applicants and licensees to mitigate beyond-design-basis events. This proposed rule would make Commission Order EA–12–049 and Order EA–12–051 generically applicable; establish regulatory requirements for an integrated response capability, including supporting requirements for command and control, drills, training and change control; include requirements for enhanced onsite emergency response capabilities; and address a number of petitions for rulemaking submitted to the NRC following the March 2011 Fukushima Dai-ichi event. This rulemaking would be applicable to operating power reactor licensees, power reactor license applicants, and decommissioning power reactor licensees. The NRC is conducting this rulemaking to amend the regulations to reflect requirements imposed on current licensees by order and to reflect the lessons learned from the Fukushima accident.

B. Major Provisions

Major provisions of this proposed rule include amendments or additions to parts 50 and 52 of title 10 of the *Code of Federal Regulations* (10 CFR) that would:

- Revise the 10 CFR parts 50 and 52 ''Content of application'' requirements to reflect the additional information that would be required for applications.
- Add proposed § 50.155, which contains beyond-design-basis mitigation requirements that would make Orders EA–12–049 and EA–12–051 generically applicable; requires an integrated response capability for beyond-design-basis events that includes the integration of two guideline sets with the existing emergency operating procedures; training requirements; drills or exercise requirements; and change control requirements.
- Revise 10 CFR part 50, appendix E, to include enhanced capabilities for assessing the impact and release of radioactive materials for multi-unit events; to remove references to specific technology for each licensee's emergency response data system; to include enhanced capabilities for onsite and offsite communications; and to add staffing analysis requirements to address multi-unit events.

C. Costs and Benefits

The NRC prepared a draft regulatory analysis to determine the expected costs and benefits of the proposed rule. The draft analysis demonstrates that the proposed rule is justified. The draft analysis examines the benefits and costs of the proposed rule requirements relative to the baseline (*i.e.,* no action alternative). Additionally, the draft analysis estimates the historical costs incurred as a result of implementation of Order EA–12–049, Order EA–12–051, and related industry initiatives. The proposed rule costs are associated with the proposed provisions that make generically-applicable Order EA–12–049 and Order EA–12–051, as well as related industry initiatives and the NRC's rulemaking-related costs. Because the NRC uses a no action baseline to estimate incremental costs, the total cost

of the proposed rule is estimated to be approximately $7.2 million for the industry ($111,000 per site) to review the rule against the previous implementation of Orders EA–12–049 and EA–12–051 and make any additional changes to plant programs and procedures. This small impact stems from the fact that the proposed requirements are expected to be implemented prior to the effective date of the rule. However, this regulatory analysis does not estimate the impacts that may occur as a result of licensees needing to make changes to mitigation strategies including potential plant modifications as a result of the need to address the seismic and flooding reevaluated hazards for reasonable protection of the FLEX equipment. As part of the proposed rule, the NRC is seeking external stakeholder feedback to enable these impacts to be estimated.

The proposed rule would result in a total one-time cost to the NRC of $880,000 to complete the rulemaking (*i.e.,* complete the proposed rule, analyze public comments, hold public meeting(s), and develop the final rule and regulatory guidance).

Based on the NRC's assessment of the costs and benefits of the proposed rule, the NRC has concluded that the proposed rule is justified. For more information, please see the draft regulatory analysis (Accession No. ML15265A610 in the NRC's Agencywide Documents Access and Management System).

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2014–0240 when contacting the U.S. Nuclear Regulatory Commission (NRC) about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0240.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2014–0240 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

A. Fukushima Dai-ichi

At 2:46 p.m. Japan standard time on March 11, 2011, the Great East Japan Earthquake, rated a magnitude 9.0, occurred at a depth of approximately 25 kilometers, 130 kilometers east of Sendai and 372 kilometers northeast of Tokyo off the coast of Honshu Island. This earthquake resulted in the automatic shutdown of 11 nuclear power plants (NPPs) at four sites along the northeast coast of Japan including three of six reactors at the Fukushima Dai-ichi NPP (the three remaining plants were in outages). The earthquake precipitated a large tsunami that is estimated to have exceeded 14 meters in height at the Fukushima Dai-ichi NPP. The earthquake and tsunami produced widespread devastation across northeastern Japan, resulting in approximately 25,000 people dead or missing, displacing many tens of thousands of people, and significantly impacting the infrastructure and industry in the northeastern coastal areas of Japan.

The earthquake and tsunami disabled the majority of the external and internal electrical power systems at the Fukushima Dai-ichi NPP, leaving it with only a few hours' worth of battery power. Since an NPP licensee typically relies on electrical power to keep its reactor core and spent fuel pool (SFP) cool, this loss of internal and external power was a significant challenge to operators at Fukushima Dai-ichi. In addition, the combination of severe events challenged the implementation of emergency plans and procedures.

B. NRC Near-Term Task Force

The NRC Chairman's tasking memorandum, COMGBJ–11–0002, ''NRC Actions Following the Events in Japan,'' established a senior-level task force referred to as the ''Near-Term Task Force'' (NTTF) to conduct a systematic and methodical review of NRC regulations and processes to determine if the agency should make safety improvements in light of the events in Japan. On July 12, 2011, the NRC staff provided the Commission with the report of the NTTF (NTTF Report) as an enclosure to SECY–11–0093, ''Near-Term Report and Recommendations for Agency Actions Following the Events in Japan.'' The NTTF concluded that continued U.S. plant operation and NRC licensing activities present no imminent risk to public health and safety. While

the NTTF also concluded that the current regulatory system has served the NRC and the public well, it found that enhancements to safety and emergency preparedness are warranted and made a dozen general recommendations for Commission consideration. In examining the Fukushima Dai-ichi accident for insights for reactors in the United States, the NTTF addressed protecting against accidents resulting from natural phenomena, mitigating the consequences of such accidents, and ensuring emergency preparedness. The NTTF found that the Commission's longstanding defense-in-depth philosophy, supported and modified as necessary by state-of-the-art probabilistic risk assessment techniques, should continue to serve as the primary organizing principle of its regulatory framework. The NTTF concluded that the application of the defense-in-depth philosophy could be strengthened by including explicit requirements for beyond-design-basis events.

In response to the NTTF Report, the Commission directed the NRC staff to engage with stakeholders to review and assess the NTTF recommendations in a comprehensive and holistic manner and to provide the Commission with fully-informed options and recommendations. The Commission's Staff Requirements Memorandum (SRM)–SECY–11–0093 provided that direction and specifically directed the NRC staff to pursue recommendation 1 of the NTTF Report independent of the activities associated with the review of the remaining recommendations. The NTTF's recommendation 1 was to establish a logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations. This recommendation included steps for the establishment of a Commission policy statement for a risk-informed defense-in-depth framework including extended design-basis requirements and the initiation of rulemaking to implement that framework. The results of the NRC staff work on NTTF recommendation 1 were provided to the Commission in SECY–13–0132, ''Plan for Updating the U.S. Nuclear Regulatory Commission's Cost Benefit Guidance,'' and dispositioned by the Commission in SRM–SECY–13–0132, which specifically disapproved the establishment of a design-basis extension category of events and associated regulatory requirements and changes to the NRC's approach to defense-in-depth, but allowed for reevaluation, as appropriate, in the context of the Commission direction on the proposed policy statement for a long-term Risk Management Regulatory Framework. That work is outside of the scope of this rulemaking. The Commission has closed NTTF recommendation 1.

C. Implementation of the NTTF Recommendations

Following the issuance of the NTTF Report, the NRC staff provided the Commission with recommendations for near-term action in SECY–11–0124, ''Recommended Actions to be Taken Without Delay from the Near-Term Task Force Report,'' dated September 9, 2011. The suggested near-term actions addressed several NTTF recommendations associated with this rulemaking, including NTTF recommendations 4, 8, and 9.3. In SRM–SECY–11–0124, dated October 18, 2011, the Commission directed the NRC staff to, among other things: initiate a rulemaking to address NTTF recommendation 4, Station Blackout (SBO) regulatory actions, as an Advance Notice of Proposed Rulemaking (ANPR); designate the SBO rulemaking associated with NTTF recommendation 4 as a high priority rulemaking; craft recommendations that continue to realize the strengths of a performance-based system as a guiding principle; and consider approaches that are flexible and able to accommodate a diverse range of circumstances and conditions. As discussed more fully in later portions of this proposed rule, the regulatory actions associated with NTTF recommendation 4 evolved substantially from this early Commission direction, and included issuance of Order EA–12–049 that, as implemented, ultimately addressed all of NTTF recommendation 4 as well as other recommendations.

In SECY–11–0137, ''Prioritization of Recommended Actions To Be Taken in Response to Fukushima Lessons Learned,'' dated October 3, 2011, the NRC staff, based on its assessment of the NTTF recommendations, proposed to the Commission a three-tiered prioritization for implementing regulatory actions stemming from the NTTF recommendations. The Tier 1 recommendations were those actions having the greatest safety benefit that could be implemented without unnecessary delay. The Tier 2 recommendations were those actions that needed further technical assessment or critical skill sets to implement, and the Tier 3 recommendations were longer-term actions that depended on the completion of a shorter-term action or needed additional study to support a regulatory action. On December 15, 2011, the Commission approved the staff's recommended prioritization in SRM–SECY–11–0137.

The NTTF recommendations that form the basis of this rulemaking activity are:

- NTTF recommendation 4: Strengthen SBO mitigation capability at all operating and new reactors for design-basis and beyond-design-basis external events;
- NTTF recommendation 7: Enhance spent fuel pool makeup capability and instrumentation for the spent fuel pool;
- NTTF recommendation 8: Strengthen and integrate onsite emergency response capabilities such as emergency operating procedures (EOPs), Severe Accident Management Guidelines (SAMGs), and extensive damage mitigation guidelines (EDMGs);
- NTTF recommendation 9: Require that facility emergency plans address staffing, dose assessment capability, communications, training and exercises, and equipment and facilities for prolonged station blackout, multi-unit events, or both;
- NTTF recommendation 10: Pursue additional emergency protection topics related to multi-unit events and prolonged station blackout, including command and control structure and the qualifications of decision makers; and
- NTTF recommendation 11: Pursue emergency management topics related to decision making, radiation monitoring, and public education, including the ability to deliver equipment to the site with degraded offsite infrastructure.

In response to input received from stakeholders, the NRC accelerated the schedule originally proposed in SECY–11–0137. On February 17, 2012, the NRC staff recommended in SECY–12–0025, ''Proposed Orders and Requests for Information in Response to Lessons Learned From Japan's March 11, 2011, Great Tōhoku Earthquake and Tsunami,'' that the Commission issue orders and requests for information.

To address Tier 1 NTTF recommendation 4, the NRC issued Order EA–12–049 on March 12, 2012, requiring all U.S. nuclear power plant licensees to implement strategies that would allow them to cope without their permanent electrical power sources for an indefinite period of time. These strategies would provide additional capability to maintain or restore reactor core and spent fuel cooling, as well as protect the reactor containment. This order also addressed: portions of NTTF recommendation 9 to require that facility emergency plans address prolonged station blackouts and multi-

unit events; portions of NTTF recommendation 10 to pursue additional emergency protection topics related to multi-unit events and prolonged station blackout; and portions of NTTF recommendation 11 to pursue emergency procedure topics related to decision-making, radiation monitoring, and public education.

To address Tier 1 NTTF recommendation 7, the NRC issued Order EA–12–051 on March 12, 2012, requiring all U.S. nuclear power plant licensees to have a reliable indication of the water level in associated spent fuel storage pools.

To address Tier 1 NTTF recommendation 8, the NRC issued an ANPR on April 18, 2012 (77 FR 23161), to engage stakeholders in rulemaking activities associated with the methodology for integration of onsite emergency response processes, procedures, training and exercises.

D. Consolidation of Regulatory Efforts

While developing the NTTF rulemakings, the NRC staff recognized that efficiencies could be gained by consolidating the rulemaking efforts due to the inter-relationships among the proposed changes. The NRC staff recommended to the Commission in COMSECY–13–0002, ''Consolidation of Japan Lessons Learned Near-Term Task Force Recommendations 4 and 7 Regulatory Activities,'' COMSECY–13–0010, ''Schedule and Plans for Tier 2 Order on Emergency Preparedness for Japan Lessons Learned,'' and SECY–14–0046, ''Fifth 6-Month Status Update on Response to Lessons Learned From Japan's March 11, 2011, Great Tohoku Earthquake and Subsequent Tsunami,'' the consolidation of rulemaking activities that address NTTF recommendations 4, 7, 8, portions of 9, 10.2, and 11.1. Section II.B of this document contains a more complete discussion of the scope of NTTF recommendations addressed by this proposed rule. The Commission approved these consolidations in the associated SRMs. These consolidations were intended to:

1. Align the proposed regulatory framework with ongoing industry implementation efforts to produce a more coherent and understandable regulatory framework. Given the complexity of these requirements and their associated implementation, the NRC concluded that this is an important objective for the regulatory framework.

2. Reduce the potential for inconsistencies and complexities between the related rulemaking actions that could occur if the efforts remained as separate rulemakings.

3. Facilitate better understanding of the proposed requirements for both internal and external stakeholders, and thereby lessen the impact on internal and external stakeholders who would otherwise need to review and comment on multiple rulemakings while cross-referencing both proposed rules and sets of guidance documents.

E. Public Involvement

This proposed rule consolidates two previous rulemaking efforts: The Station Blackout Mitigation Strategies rulemaking, directed by SRM–COMSECY–13–0002, and the Onsite Emergency Response Capabilities rulemaking, which implemented NTTF recommendation 8. Both regulatory efforts offered extensive external stakeholder involvement opportunities, including public meetings, ANPRs issued for public comment, and draft regulatory basis documents issued for public comment. The major opportunities for stakeholder involvement were:

1. Station Blackout ANPR (77 FR 16175; March 20, 2012);

2. Onsite Emergency Response Capabilities ANPR (77 FR 23161; April 18, 2012);

3. Station Blackout Mitigation Strategies draft regulatory basis and draft rule concepts (78 FR 21275; April 10, 2013). The final Station Blackout Mitigation Strategies regulatory basis was subsequently issued on July 23, 2013 (78 FR 44035); and

4. Onsite Emergency Response Capabilities draft regulatory basis (78 FR 1154; January 8, 2013). The final Onsite Emergency Response Capabilities regulatory basis, with preliminary proposed rule language, was subsequently issued on October 25, 2013 (78 FR 63901).

The NRC described in each final regulatory basis document how it considered stakeholder feedback in developing the respective final regulatory basis, including consideration of ANPR comments and draft regulatory basis document comments. Section 5 of the Station Blackout Mitigation Strategies regulatory basis document includes a discussion of stakeholder feedback used to develop the final regulatory basis. Appendix B to the Onsite Emergency Response Capabilities regulatory basis includes a discussion of stakeholder feedback used to develop that final regulatory basis.

The public has had multiple opportunities to engage in these regulatory efforts. Most noteworthy were the following:

1. Preliminary proposed rule language for Onsite Emergency Response Capabilities made available to the public on November 15, 2013 (78 FR 68774).

2. Consolidated rulemaking proof of concept language made available to the public on February 21, 2014.

3. Preliminary proposed rule language for Mitigation of Beyond-Design-Basis Events rulemaking made available to the public on August 15, 2014.

4. Preliminary proposed rule language for Mitigation of Beyond-Design-Basis Events rulemaking made available to the public on November 13, 2014, and December 8, 2014, to support public discussion with the Advisory Committee on Reactor Safeguards (ACRS).

The NRC staff has had numerous interactions with the ACRS, and in all cases these were public meetings, including the following:

1. The ACRS Plant Operations and Fire Protection subcommittee met on February 6, 2013, to discuss the Onsite Emergency Response Capabilities regulatory basis.

2. The ACRS Regulatory Policies and Practices subcommittee met on December 5, 2013, and April 23, 2013, to discuss the Station Blackout Mitigation Strategies regulatory basis.

3. The ACRS full committee met on June 5, 2013, to discuss the Station Blackout Mitigation Strategies regulatory basis.

4. The ACRS Fukushima subcommittee met on June 23, 2014, to discuss consolidation of Station Blackout Mitigation Strategies and Onsite Emergency Response Capabilities rulemakings.

5. The ACRS full committee met on July 10, 2014, to discuss consolidation of Station Blackout Mitigation Strategies and Onsite Emergency Response Capabilities rulemakings.

6. The ACRS Fukushima subcommittee met on November 21, 2014, to discuss preliminary proposed Mitigation of Beyond-Design-Basis Events rulemaking language.

7. The ACRS Fukushima full committee met on December 4, 2014, to discuss preliminary proposed Mitigation of Beyond-Design-Basis Events rulemaking language.

The NRC held many additional public meetings that have supported the development of this proposed rule. Notwithstanding these efforts to engage the public during the preparation of this proposed rule, the Commission is committed to the rigors of the notice-and-comment process enacted by the Administrative Procedures Act, and is providing members of the public a 90-

day comment period on the requirements NRC is proposing today.

III. Petitions for Rulemaking

During development of this proposed rule, the NRC gave consideration to the issues raised in six petitions for rulemaking (PRMs) submitted to the NRC, five from the Natural Resources Defense Council Inc. (NRDC) (PRM–50–97, PRM–50–98, PRM–50–100, PRM–50–101, and PRM–50–102), and one submitted by Mr. Thomas Popik (PRM–50–96). The petitions filed by the NRDC use the NTTF Report as the sole basis for the PRMs. The NTTF recommendations that the NRDC PRMs rely upon are: 4.1, 7.5, 8.4, 9.1, and 9.2. This proposed rule addresses each of these recommendations, and therefore it would resolve the issues raised by the NRDC PRMs. The NRDC petitions were dated July 26, 2011, and docketed by the NRC on July 28, 2011. The NRC published a notice of receipt in the **Federal Register** on September 20, 2011 (76 FR 58165), and did not ask for public comment at that time.

In PRM–50–97 (NRC–2011–0189), the NRDC requested emergency preparedness enhancements for prolonged station blackouts in the areas of communications ability, Emergency Response Data System (ERDS) capability, training and exercises and equipment and facilities (NTTF recommendation 9.2). The NRC determined that the issues raised in this PRM should be considered in the NRC's rulemaking process. The NRC's consideration of the issues raised in PRM–50–97 are reflected in the proposed provisions in § 50.155(d) and (e), and the proposed amendments to appendix E in both section VI and in new section VII, ''Communications and Staffing Requirements for the Mitigation of Beyond Design Basis Events.'' The NRC concludes that consideration of the PRM issues, as discussed herein, would address PRM–50–97. The NRC is closing the docket for this petition and intends to take final action on this petition in the **Federal Register** notice the NRC issues for the final Mitigation of Beyond-Design-Basis Events rule.

In PRM–50–98 (NRC–2011–0189), the NRDC requested emergency preparedness enhancements for multi-unit events in the areas of personnel staffing, dose assessment capability, training and exercises, and equipment and facilities (NTTF recommendation 9.1). The NRC determined that the issues raised in this PRM should be considered in the NRC's rulemaking process. The NRC's consideration of the issues raised in PRM–50–98 are reflected in the proposed provisions in § 50.155(b)(4), (d), and (e); and the proposed amendment to appendix E in section IV as well as the addition of a new section VII. The NRC concludes that consideration of the PRM issues, as discussed herein, would address PRM–50–98. The NRC is closing the docket for this petition and intends to take final action on this petition in the **Federal Register** notice the NRC issues for the final Mitigation of Beyond-Design-Basis Events rule.

In PRM–50–100, the NRDC requested enhancement of spent fuel pool makeup capability and instrumentation for the spent fuel pool (NTTF recommendation 7.5). The NRC determined that the issues raised in this PRM should be considered in the NRC's rulemaking process, and the NRC published a document in the **Federal Register** with this determination on July 23, 2013 (78 FR 44034). The NRC's consideration of the issues raised in PRM–50–100 are reflected in the proposed provisions in § 50.155(b)(1) and (c)(4). This proposed rule would make generically applicable NRC's Order EA–12–051, ''Spent Fuel Pool Instrumentation.'' The NRC concludes that consideration of the PRM issues, as discussed herein, would address PRM–50–100. The NRC has already closed the docket for this petition and intends to take final action on this petition in the **Federal Register** notice the NRC issues for the final Mitigation of Beyond-Design-Basis Events rule.

In PRM–50–101, the NRDC requested that § 50.63, ''Loss of all alternating current power,'' be revised to establish a minimum coping time of 8 hours for a loss of all alternating current (ac) power, establish the equipment, procedures, and training necessary to implement an extended loss of ac power (72 hours) for core and spent fuel pool cooling and for reactor coolant system and primary containment integrity as needed, and preplan/prestage offsite resources to support uninterrupted core and spent fuel pool cooling and reactor coolant system and containment integrity as needed (NTTF recommendation 4.1). The NRC determined that the issues raised in this PRM should be considered in the NRC's rulemaking process, and the NRC published a document in the **Federal Register** with this determination on March 21, 2012 (77 FR 16483). The NRC's consideration of the issues raised in PRM–50–101 is reflected in the proposed provisions in § 50.155(b)(1), (c), (d), (e), and (f). The NRC concludes that consideration of the PRM issues, as discussed herein, would address PRM–50–101. The NRC has already closed the docket for this petition and intends to take final action on this petition in the **Federal Register** notice the NRC issues for the final Mitigation of Beyond-Design-Basis Events rule.

In PRM–50–102, the NRDC requested more realistic, hands-on training and exercises on SAMGs and EDMGs for licensee staff expected to implement those guideline sets and make decisions during emergencies (NTTF recommendation 8.4). The NRC determined that the issues raised in this PRM should be considered in the NRC's rulemaking process, and the NRC published a document in the **Federal Register** with this determination on April 27, 2012 (77 FR 25104). The NRC's consideration of the issues raised in PRM–50–102 are reflected in the proposed provisions in § 50.155(d) and (e). The NRC concludes that consideration of the PRM issues, as discussed herein, would address PRM–50–102. The NRC has already closed the docket for this petition and intends to take final action on this petition in the **Federal Register** notice the NRC issues for the final Mitigation of Beyond-Design-Basis Events rule.

In PRM–50–96, Mr. Thomas Popik requested that the NRC amend its regulations to require facilities licensed by the NRC to assure long-term cooling and unattended water makeup of spent fuel pools in the event of geomagnetic storms caused by solar storms resulting in long-term losses of power. The NRC determined that the issues raised in this PRM should be considered in the NRC's rulemaking process and the NRC published a document in the **Federal Register** with this determination on December 18, 2012 (77 FR 74788). In that **Federal Register** document, the NRC also closed the docket for this petition. Specifically, the NRC indicated that it would monitor the progress of the mitigation strategies rulemaking to determine whether the requirements established would address, in whole or in part, the issues raised in the PRM. In this context, the proposed requirements in § 50.155(b)(1) and (c) and the associated draft regulatory guidance should address, in part, the issues raised because these actions would establish offsite assistance to support maintenance of the key functions (including both reactor and spent fuel pool cooling) following an extended loss of ac power that has been postulated for geomagnetic events. Additional consideration of these issues will result from NRC's participation in the interagency task force developing a National Space Weather Strategy and the associated action plan. Both the strategy and action plan are expected to be completed in 2015. When the

National plans are completed, the NRC will reevaluate the need for additional actions to address the impact of geomagnetic storms on nuclear power plants within the overall context of the National Space Weather Strategy and action plan.

IV. Discussion

A. Rulemaking Objectives

The regulatory objectives of this rulemaking are to: (1) Make the requirements in Order EA–12–049 and Order EA–12–051 generically applicable, giving consideration to lessons learned from implementation of the orders; (2) establish new requirements for an integrated response capability; (3) establish new requirements for actions that are related to onsite emergency response; and (4) address issues raised by PRMs that were submitted to the NRC following the March 2011 Fukushima Dai-ichi event.

1. Make the requirements in Order EA–12–049 and Order EA–12–051 generically applicable, giving consideration to lessons learned from implementation of the orders.

An objective of this rulemaking is to place the requirements in Order EA–12–049 and Order EA–12–051 into the NRC's regulations so that they apply to all current and future power reactor applicants, and to provide regulatory clarity and stability to power reactor licensees. In making the requirements of Order EA–12–049 generically-applicable, this proposed rule would also consider the reevaluated hazard information developed in response to the March 12, 2012, NRC letter issued under § 50.54(f) as part of providing reasonable protection for mitigation strategies equipment against external flooding or seismic hazards. Because these orders were issued to current licensees, the requirements of these orders would not apply to future licensees. In the absence of this proposed rule, these requirements would need to be implemented for new reactor applicants or licensees through additional orders or license conditions (as was done for the Vogtle Electric Generating Plant, Units 3 and 4, Virgil C. Summer Nuclear Station, Units 2 and 3, and Enrico Fermi Nuclear Plant, Unit 3, combined licenses (COLs), respectively). As part of the rulemaking, the NRC considered stakeholder feedback and lessons-learned from the implementation of the orders, including any challenges or unintended consequences associated with implementation. The NRC reflected this stakeholder input in the draft regulatory guidance for this proposed rule.

2. Establish new requirements for an integrated response capability.

An objective of this rulemaking is to establish requirements for an integrated response capability for beyond-design-basis events that would integrate existing strategies and guidelines (implemented through guideline sets) with the existing EOPs. This would include guideline sets that implement the requirements of current § 50.54(hh)(2) and Order EA–12–049. This proposed rule would require sufficient staffing, command and control, training, drills, and change control to support the integrated response capability.

3. Establish new requirements for actions that are related to onsite emergency response.

An objective of this rulemaking is to establish requirements for onsite emergency response capabilities being implemented in conjunction with the implementation of Order EA–12–049. This proposed rule contains new requirements for staffing and communications assessment, and clarifies requirements for multiple source term dose assessment.

4. Address a number of PRMs submitted to the NRC following the March 2011 Fukushima Dai-ichi event.

An objective of this rulemaking is to address the five PRMs filed by the NRDC that raise issues that pertain to the technical objectives of this rulemaking. The petitions rely solely on the NTTF Report, and request that the NRC undertake rulemaking in a number of areas that would be addressed by this proposed rule. This proposed rule would also address, in part, the PRM submitted by Mr. Thomas Popik.

B. Rulemaking Scope

The scope of this rulemaking, described in terms of the relationship to various NTTF recommendations that provided the regulatory impetus for this proposed rule, includes:

1. All the requirements that were within the scope of Station Blackout Mitigation Strategies rulemaking. These requirements address NTTF recommendations 4 and 7. This aspect of the proposed rule would also address NTTF recommendation 11.1 regarding onsite emergency resources to support multi-unit events with station blackout, including the need to deliver equipment to the site despite degraded offsite infrastructure. This provision currently is being implemented through Order EA–12–049.

2. All the requirements that were within the scope of the Onsite Emergency Response Capabilities rulemaking. These requirements address NTTF recommendation 8, as directed by SRM–SECY–11–0137. This aspect of this proposed rule also would address command and control issues in NTTF recommendation 10.2.

3. Numerous requirements regarding onsite emergency response actions being implemented by Order EA–12–049; in addition, NRC staff has developed draft guidance to support the emergency response aspect of this proposed rule. The specific regulatory actions related to emergency response in this proposed rule and the associated NTTF recommendations are:

a. Staffing and communications requirements: would address NTTF recommendation 9.3; also discussed in NTTF recommendations 9.1 and 9.2. These regulatory issues currently are being implemented through Order EA–12–049. The proposed requirements also address supporting facilities and equipment, as discussed in the same NTTF recommendations.

b. Multiple source term dose assessment requirements: would address NTTF recommendation 9.3; also discussed in NTTF recommendation 9.1. This regulatory issue is being implemented voluntarily by industry.

c. Training and exercise requirements: would address NTTF recommendation 9.3; also discussed in NTTF recommendations 9.1 and 9.2. These regulatory issues currently are being implemented through Order EA–12–049.

Accordingly, this rulemaking would address all the justifiable recommendations in NTTF recommendations 4, 7, 8, 9.1, 9.2, 9.3 (with one exception—ERDS modernization is addressed, but maintenance of ERDS capability throughout the accident is not addressed), 10.2, and 11.1.

This rulemaking also would address NTTF recommendation, 9.4: modernize ERDS. This action differs from the other regulatory actions because ERDS is not an essential component of a licensee's capability to mitigate a beyond-design-basis external event. However, ERDS is an important form of communication between the licensee and the NRC. Modernization of ERDS has been completed voluntarily by industry; therefore, NRC has included amendments to remove the technology-specific references in 10 CFR part 50, appendix E, section VI, ''Emergency Response Data System,'' in this proposed rule.

SAMG Implementation

Unlike the requirements for the mitigation of beyond-design-basis external events imposed by Order EA–

12–049, and requirements that address the loss of large areas of the plant due to explosions and fire in current § 50.54(hh)(2) (NRC is proposing in this rule to move these requirements to a new section), SAMGs are not an NRC requirement imposed on licensees. Nevertheless, SAMGs are well established guidance documents that have been developed by the nuclear power industry with substantial NRC involvement, have been implemented by every operating nuclear power reactor licensee for decades, and are the subject of a license condition for combined licenses. Following the Three Mile Island (TMI) accident in 1979, the nuclear power industry revised its emergency response procedures to be symptom-based, and as a result, developed EOPs. In the mid-to-late 1980s, the NRC and the nuclear power industry identified a need to consider plant conditions that could lead to a severe accident. These efforts led to the nuclear industry voluntarily initiating a coordinated program on severe accident management in 1990. Section 5 of Nuclear Energy Institute (NEI) 91–04 (formerly Nuclear Management and Resources Council (NUMARC) 91–04), Revision 1, ''Severe Accident Closure Guidelines,'' describes the elements of the industry's severe accident management closure actions. The program involves the development of: (1) A structured method by which utilities could systematically evaluate and enhance their ability to deal with potential severe accidents, (2) vendor-specific SAMGs for use by licensees in developing plant-specific SAMGs, and (3) guidance and material to support utility activities related to training for severe accidents. In 1992, the Electric Power Research Institute (EPRI) developed the SAMG Technical Basis Report (TBR). Volume one of this report covers general actions that could be taken to manage a severe accident (referred to as SAMG candidate high level actions) and their effects, and volume two is a detailed report on the physics of accident progression. By letter dated June 20, 1994, the NRC accepted the industry's approach for mitigating the consequences of severe accidents, including licensee regulatory commitments to implement plant-specific SAMGs, using the guidance developed in section 5 of NEI 91–04, Revision 1, by December 31, 1998.

The NRC assessed the ongoing implementation of SAMGs at a select number of plants during the 1997–1998 time frame as discussed in SECY–97–132, ''Status of the Integration Plan for Closure of Severe Accident Issues and the Status of Severe Accident Research,'' and SECY–98–131, ''Status of the Integration Plan for Closure of Severe Accident Issues and the Status of Severe Accident Research,'' and concluded that the results of the voluntary initiative achieved the NRC's overall objectives established for accident management in SECY–89–012, ''Staff Plans for Accident Management Regulatory and Research Programs.'' In 2012, EPRI revised the TBR to account for the initial lessons learned from the Fukushima Dai-ichi accidents, as well as enhanced understanding of severe accident behavior gained from additional research and analyses performed since the original report was published.

Following the events at Fukushima Dai-ichi, the NRC again inspected the implementation, ongoing training, and maintenance of licensee SAMGs at all power reactor sites, except those that had permanently ceased operation, through performance of Temporary Instruction (TI)-2515/184, ''Availability and Readiness Inspection of Severe Accident Management Guidelines (SAMGs).'' The NRC found that some licensees had not maintained the SAMGs in accordance with the latest revisions of the applicable industry generic technical guidelines nor conducted training in a consistent and systematic manner. The NRC inspectors attributed the inconsistent implementation and training on SAMGs to the voluntary nature of this initiative.

Based in part on the findings of the inspections previously described, the NTTF recommended that the NRC require licensees to integrate onsite emergency response capabilities, including SAMGs. Unlike the Mitigating Strategies Order requirements, which were justified as necessary for adequate protection under § 50.109, SAMGs do not involve adequate protection. Because the imposition of SAMGs also would not be necessary to bring licensees into compliance with an existing NRC requirement, a SAMGs requirement would have to be justified under § 50.109 as a cost-justified, substantial increase in protection of the public health and safety or common defense and security.

In the regulatory analysis where the NRC considered an option to require SAMGs (*i.e.,* option 2 of the regulatory analysis including the supporting proposed backfit justification), the NRC used available quantified risk information that might provide risk insights to inform the justification. In this regard, the NRC looked at its recent technical analysis [1] performed in support of the Containment Protection and Release Reduction (CPRR) rulemaking regulatory basis.[2] This analysis is relevant because it examined regulatory alternatives that would be implemented after core damage to determine whether any of the contemplated approaches can be justified under the NRC's backfitting provisions. In this respect, the risk insights stemming from this work might have relevance to NRC's consideration of SAMG requirements where the safety benefits would occur after core damage. The NRC also considered other post-Fukushima regulatory efforts (*e.g.,* the safety benefits due to implementation of Order EA–12–049 mitigation strategies, which result in a reduction in core damage frequency) within this technical analysis. The NRC acknowledges that the work to support the CPRR rulemaking was not conducted to provide a complete quantitative measure of the possible safety benefits of SAMG requirements, particularly with regard to how SAMGs might benefit maintenance of containment integrity or support more informed protective action recommendations by the emergency response organization following core damage. However, this technical analysis work does provide valuable risk insights that the NRC concluded were important to fully inform the decision on this matter, and that additionally influenced the NRC's development of the SAMG framework considered in the regulatory analysis.

The CPRR technical analysis includes a screening for a conservative high estimate of frequency-weighted individual latent cancer fatality risk. This screening analysis combined the highest ELAP frequency among all boiling water reactors (BWRs) with Mark I or Mark II containments, a success probability in the FLEX equipment [3] of 0.6 per demand following core melt, the highest conditional individual latent cancer fatality (ILCF) risk among all BWRs with Mark I or Mark II containments, and a worst case re-habitability assumption. This yields a conservative high estimate of frequency-weighted individual latent

[1] The technical risk insights were presented to the ACRS Reliability and PRA, and Fukushima subcommittees on August 22, 2014, and to the ACRS Reliability and PRA subcommittee on November 19, 2014. This footnote is informational only; it does not imply advisory committee endorsement of the technical analysis.

[2] Refer to the draft regulatory basis for Containment Protection and Release Reduction.

[3] Refer to NEI 12–06, Revision 0, ''Diverse and Flexible Coping Strategies (FLEX) Implementation Guide,'' for a description of industry-developed guidance on FLEX strategies and equipment.

cancer fatality risk of approximately 7×10^{-8} per reactor year. This combination of assumptions does not exist at any BWR with a Mark I or Mark II containment. This conservative estimate of the risk can be viewed as the maximum possible risk that could be removed or reduced through regulatory action (*i.e.,* the CPRR technical analysis examines a range of post-core damage regulatory actions for BWRs with Mark I or Mark II containments to identify whether any of these proposals might result in a safety benefit large enough to be justified under the Commission's backfitting requirements). This estimate is compared against the quantitative health objective, which is a quantitative measure that equates to 1/10 of 1 percent of the ILCF risk and relates to the Commission's Safety Goal Policy. This quantitative metric for the individual latent cancer fatality risk is approximately 2×10^{-6} per reactor year. This technical work shows that the risk is well below a level that equates to 1/10 of 1 percent of the surrounding population's latent cancer fatality risk. This result also means, that, from a quantitative standpoint, achieving risk reductions that might satisfy backfitting requirements is very unlikely. More refined risk estimates from the same work (*i.e.,* which remove the worst case assumptions and instead use assumptions specific to each power reactor), push this potential risk benefit significantly lower, by approximately two orders of magnitude. This result demonstrates the benefits of the NRC's regulations to both effectively keep the frequency of core damage very low at BWRs with Mark I and II containments, and to ensure through emergency preparedness requirements that the surrounding population is adequately protected. Those general attributes of the NRC's regulations that result in this risk insight (*i.e.,* requirements that resulted in reduced core damage frequencies and effective emergency preparedness requirements) apply to all power reactor designs. The NRC has not performed a comprehensive quantitative analysis of the potential safety benefits of SAMG requirements for all types of reactors. However, the general risk insights obtained from the CPRR work align well with NUREG–1935, ''State-of-the-Art Reactor Consequence Analyses (SOARCA) Report,'' (November 2012), which shows very low levels of risk (*e.g.,* individual early fatality risk is essentially zero, ILCF risk is thousands of times lower than the NRC Safety Goal, and millions of times lower than the general cancer fatality risk in the United States from all causes). As such, the available risk insights point to the likely outcome that a comprehensive quantitative analysis, where the proposed regulatory action is intended to provide its safety benefit in the post-core damage environment (as is the case for use of SAMGs), would not demonstrate a substantial safety benefit. In addition, for the specific case of the consideration of SAMG requirements in this proposed rule, the proposed regulatory action's benefit must also recognize that imposing SAMG requirements must be compared with the current regulatory state, (*i.e.,* SAMGs) exist and are voluntarily in use under an industry initiative.

Along with its quantitative analysis, the Commission considered a proposed SAMG backfit analysis that relied on qualitative factors, relating SAMGs to defense-in-depth. The Commission concluded that the imposition of SAMG requirements was not warranted as it did not meet the substantial additional protection criteria under 10 CFR 50.109(a)(3), and consequently SAMGs will continue to be implemented and maintained through a voluntary industry initiative. The Commission notes that the industry indicated it would strengthen its voluntary initiative for SAMGs in its letter dated May 11, 2015.

Scope of Procedure and Guideline Integration

This rulemaking limits the scope of the integrated response capability to two guideline sets. This proposed rule includes these new provisions:

1. § 50.155(b)(1), resulting from Order EA–12–049, and addressing beyond-design-basis external events; these requirements are those that the NRC termed in previous regulatory basis interactions as ''Station Blackout Mitigation Strategies.'' The nuclear industry refers to these as ''FLEX Support Guidelines'' (FSGs).

2. § 50.155(b)(2) (current § 50.54(hh)(2)). These requirements are defined in NEI 06–12, Revision 2, ''B.5.b Phase 2 & 3 Submittal Guideline,'' as a subset of the strategies and guidelines for addressing the loss of large areas of the plant due to explosions and fires and are termed ''Extensive Damage Mitigation Guidelines.'' The NRC proposes to expand the scope of the generic term ''EDMGs'' to include all of the strategies and guidelines used to implement § 50.54(hh)(2).

The NRC is proposing this integrated response capability structure to avoid unnecessarily revisiting the existing symptom-based EOPs that were developed following the TMI accident. The NRC has determined that current regulations addressing EOPs, which include the quality assurance requirements of criterion V, ''Instructions, Procedures, and Drawings,'' and criterion VI, ''Document Control,'' in appendix B to 10 CFR part 50, and the administrative controls section of the technical specifications for each plant as well as the guidance provided in regulatory guides and technical reports (*e.g.,* NUREG–0660, ''NRC Action Plan Developed as a Result of the TMI–2 Accident,'' issued May 1980; NUREG–0737, ''Clarification of TMI Action Plan Requirements,'' issued November 1980; and NUREG–0711, ''Human Factors Engineering Program Review Model,'' issued November 2012) provide sufficient regulation and control of the EOPs to provide reasonable assurance of adequate protection of public health and safety. In addition, the EOPs are the subject of a national consensus standard (American National Standards Institute/American Nuclear Society 3.2 1994, ''Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants''). In order to avoid the unnecessary regulatory burden that would result by restructuring the EOPs, proposed § 50.155(b)(3) would require that the FSGs, and EDMGs be integrated with the EOPs, rather than moving the requirements for EOPs to § 50.155.

Guideline Sets Excluded From This Proposed Rule

During the development of this proposed rule, other guideline sets were considered for inclusion within the integrated response capability. The guideline sets considered included fire response procedures, alarm response procedures (ARPs), and abnormal operating procedures (AOPs).

Similar to the EOPs, ARPs and AOPs are subject to existing NRC regulations (*e.g.,* 10 CFR part 50, appendix B, criteria V and VI) that adequately ensure integration with other procedure sets in use at power reactors. These procedures have been used by operating power reactor licensees in actual and simulated events for many years; any further integration effort to address potential issues would likely have already been identified and corrected by existing processes (or will be identified and corrected under the quality assurance program).

The issue of whether to include fire response procedures in the scope of proposed § 50.155(b) was initially raised as recommendation 1.g. by the ACRS in its letter to the then-Chairman Jaczko dated October 13, 2011, ''Initial ACRS Review of: (1) The NRC Near-Term Task

Force Report on Fukushima and (2) Staff's Recommended Actions to be Taken Without Delay.'' That letter expressed the ACRS view that:

> [The] efforts to integrate the onsite emergency response capabilities should be expanded to include the plant fire response procedures. These procedures provide operator guidance for coping with fires that are beyond a plant's original design basis. Some plant-specific fire response procedures instruct operators to manually de-energize major electrical buses and realign fluid systems in configurations that may not be consistent with the guidance or expectations in the EOPs. Experience from actual fire events has shown that parallel execution of fire procedures, Abnormal Operating Procedures (AOPs), and EOPs can be difficult and can introduce operational complexity. Therefore, these procedures should also be included in the comprehensive efforts to better coordinate and integrate operator responses during challenging plant conditions.

This recommendation was reiterated in the ACRS letter of November 8, 2011, ''ACRS Review of Staff's Prioritization of Recommended Actions to Be Taken in Response to Fukushima Lessons Learned (SECY–11–0137).''

In SECY–12–0025, enclosure 3, the NRC documented the formal process used in evaluating additional recommendations that were made by the ACRS as follows:

> The staff developed a process to disposition all additional issues, including recommendations by the ACRS. All issues are reviewed by a panel of senior-level advisors from different NRC program offices. The panel determines whether each issue represents a valid safety concern, and whether there is a clear nexus to the Fukushima Dai-ichi accident. If neither criterion is met, or only one criterion is met, the panel chooses to either disposition the issue with no action, or direct it to one of the NRC's existing regulatory processes (*e.g.,* generic issue process). If both criteria are met, the issue is forwarded for further consideration by the cognizant technical staff in the appropriate NRC line organization. Should the issue go forward, the cognizant technical staff is tasked with developing a proposal for Steering Committee (SC) disposition. The SC may elect to take no further action, disposition the issue using an existing NRC process, or prioritize the issue as a Tier 1, 2, or 3 item under the Japan Lessons–Learned Program.

By letter dated February 27, 2012, the NRC responded to the ACRS recommendations of October 13, 2011, and November 8, 2011, discussing the disposition of ACRS recommendation 1.g. as follows:

> The NRC staff evaluated how to appropriately integrate the fire response procedure into a licensee's onsite emergency response capabilities and determined that the fire response procedures would be best considered with the agency's Tier 3 actions associated with NTTF Recommendation 3.

This disposition of the ACRS recommendation also was documented in SECY–12–0025. In its letter of March 13, 2012, the ACRS acknowledged that the formal screening process used by the NRC for additional recommendations was acceptable, but nevertheless expressed the view that integration of the fire response procedures presents similar challenges to those associated with the integration of other guideline sets such as the EDMGs with the EOPs. Accordingly, the ACRS recommended that the integration effort should address fire response procedures as part of NTTF recommendation 8 rather than as a seismic-induced-fire issue under NTTF recommendation 3.

Recognizing the continued ACRS interest in the integration of fire response procedures with onsite emergency actions and the existence of an additional program of work to be taken up on the ACRS recommendation, the NRC has concluded that the reasoning underlying the initial prioritization of ACRS recommendation 1.g was sound and it would be inappropriate to include fire response procedure integration within this rulemaking effort. The NRC offers the following reasons for the exclusion of firefighting strategies and procedures from the scope of integration in this rulemaking:

1. The NRC-required fire protection program is designed to function autonomously from other ongoing activities and is implemented by a fire brigade that is manned in all modes of operation and is well-trained. Firefighting activities are led by personnel knowledgeable of overall plant operations, including the equipment necessary for safe shutdown of the plant. These personnel communicate with the main control room in order to prioritize and deconflict activities.

2. Comprehensive firefighting strategies and implementing procedures have been developed for each area of the plant and fire brigade qualified individuals participate in drills on a quarterly basis to demonstrate proficiency with the use of these strategies and procedures in the context of concurrent use of other, non-integrated procedures throughout the plant.

3. The EOPs, EDMGs, and FSGs account for equipment lost due to concurrent fires during events by providing alternate methods to accomplish the functions the equipment was to have performed.

C. Proposed Rule Organization

To accomplish the NRC's rulemaking objectives in a manner consistent with the described scope, this proposed rule has been based on these precepts:

1. The central requirement would be an integrated response capability that includes currently existing procedures and guideline sets. Additional requirements would support this integrated response capability.

The mitigation strategies under Order EA–12–049 established the basic framework for broader capability to mitigate beyond-design-basis external events that impact an entire reactor site. This framework includes: Supporting drills, training, change control, staffing, communications capability, multiple source term dose assessment capability, and command and control. As a result, the proposed new § 50.155 is structured to have:

1. Integrated response requirements in paragraph (b).

2. Supporting equipment requirements in paragraph (c) that include equipment required by both Order EA–12–049 and Order EA–12–051.

3. External hazard equipment protection requirements in paragraph (c) that reflect the hazard information developed under the § 50.54(f) letter of March 12, 2012.

4. Supporting training, drills, and change control requirements in paragraphs (d), (e), and (f).

5. Implementation requirements that establish compliance deadlines in paragraph (g).

In addition to proposed § 50.155, this proposed rulemaking is structured to have (1) supporting power reactor operating license application requirements (under either 10 CFR parts 50 or 52 processes) in the appropriate content of applications portions, and (2) requirements that relate to enhanced onsite emergency response capabilities located in appendix E to 10 CFR part 50, to include a new section VII.

The proposed requirements previously described would apply to both current licensees and new applicants (under either 10 CFR parts 50 or 52) as established by proposed paragraph § 50.155 (a). Finally, this proposed rule contains provisions to facilitate power reactor decommissioning.

D. Proposed Rule Regulatory Bases

Applicability

This proposed rule would apply, in whole or in part, to applicants for and holders of an operating license for a nuclear power reactor under 10 CFR

part 50, or combined license under 10 CFR part 52.

This proposed rule would not apply to applicants for, or holders of, an operating license for a non-power reactor under 10 CFR part 50. Non-power reactor licensees would not be subject to this proposed rule because non-power reactors pose lower radiological risks to the public from accidents than do power reactors because: (1) The core radionuclide inventories in non-power reactors are lower than in power reactors as a result of their lower power levels and often shorter operating cycle lengths; and (2) non-power reactors have lower decay heat associated with a lower risk of core melt and fission product release in a loss-of-coolant accident than power reactors.

A holder of a general or specific 10 CFR part 72 independent spent fuel storage installation (ISFSI) license for dry cask storage would not be subject to this proposed rule for the ISFSI, because the decay heat load of the irradiated fuel would be sufficiently low prior to movement to dry cask storage that it could be air-cooled. This would meet the proposed sunsetting criteria (discussed later in this section of this document).

The GE Morris facility in Illinois, which is the only spent fuel pool licensed under 10 CFR part 72 as an ISFSI would not need to comply with this proposed rule because it is excluded by the rule applicability described in proposed § 50.155(a). The NRC considered including the GE Morris facility within the scope of this proposed rule but found that the age (and corresponding low decay heat load) of the fuel in the facility made it unnecessary. The GE Morris facility also would meet this proposed rule's sunsetting criteria. While this proposed rule would leave in force the requirements of the current § 50.54(hh)(2), those requirements are not applicable to GE Morris due to its status as a non-10 CFR part 50 licensee. In the course of the development and implementation of the guidance and strategies required by the current § 50.54(hh)(2), the NRC evaluated whether additional mitigation strategies were warranted at GE Morris and concluded that no mitigating strategies were warranted beyond existing measures, due to the extended decay time since the last criticality of the fuel stored there, the resulting low decay heat levels, and the assessment that a gravity drain of the GE Morris SFP is not possible due to the low permeability of the surrounding rock and the high level of upper strata groundwater.

This proposed rule would establish a ''sunsetting'' or phased removal of requirements for licensees of decommissioning power reactors. Licensees would not need to meet requirements that relate to the reactor source term and associated fission product barriers once all fuel has been permanently removed from the reactor vessel and placed in the spent fuel pool. This proposed rule would require secondary containment for reactor designs that employ this feature as a fission product barrier for the spent fuel pool source term.

Once the NRC has docketed a licensee's § 50.82(a)(1) or § 52.110(a) certification of permanent removal of fuel from the reactor vessel and certification of permanent cessation of operations, that licensee would not be subject to requirements to have mitigation strategies and guidelines for maintaining or restoring core cooling and containment capabilities. As discussed previously, these proposed requirements are based on Order EA–12–049. The licensees for the Kewaunee Power Station, Crystal River Unit 3 Nuclear Generating Plant, San Onofre Nuclear Generating Station, Units 2 and 3, and Vermont Yankee Nuclear Power Station, submitted § 50.82(a)(1) certifications after issuance of Order EA–12–049; the NRC has rescinded Order EA–12–049 to this group of NPP licensees (Shutdown NPP Group). These rescissions were based on the NRC's conclusion that the lack of fuel in the licensee's reactor core and the absence of challenges to the containment rendered unnecessary the development of guidance and strategies to maintain or restore core cooling and containment capabilities. Consistent with these rescissions, the NRC proposes to relieve licensees in decommissioning from the requirement to comply with proposed requirements to have mitigation strategies and guidelines to maintain or restore core cooling and containment capabilities. Moreover, these licensees would not need to comply with any of the other requirements in this proposed rule that support compliance with the proposed requirement to have mitigation strategies and guidelines for maintaining or restoring core cooling and containment capabilities.

This proposed rule treats the EDMG requirements in a manner similar to the requirements for FSGs. For a licensee who has § 50.82(a)(1) or § 52.110(a) certifications docketed at the NRC, the lack of fuel in their reactor core and the absence of challenges to the containment would render unnecessary EDMGs for core cooling and containment capabilities. This licensee would not need to comply with any requirements in this proposed rule associated with core cooling or containment capabilities; rather, the licensee would be required to comply with the proposed requirement to have EDMGs as based on the presence of fuel in the spent fuel pool.

Once the NRC has docketed a licensee's § 50.82(a)(1) or § 52.110(a) certifications, that licensee would not need to comply with the requirement proposed by this rule that the equipment relied on for the mitigation strategies include reliable means to remotely monitor wide-range spent fuel pool levels to support effective prioritization of event mitigation and recovery actions. This proposed requirement is based on the requirements in Order EA–12–051. This order requires a reliable means of remotely monitoring wide-range SFP levels to support effective prioritization of event mitigation and recovery actions in the event of a beyond-design-basis external event with the potential to challenge both the reactor and SFP.

The NRC has also rescinded Order EA–12–051 for the Shutdown NPP Group mentioned previously. These rescissions were based, in part, on the NRC's conclusions that once a licensee certifies the permanent removal of the fuel from its reactor vessel, the safety of the fuel in the SFP becomes the primary safety function for site personnel. In the event of a challenge to the safety of fuel stored in the SFP, decision-makers would not have to prioritize actions and the focus of the staff would be the SFP condition. Therefore, once fuel is permanently removed from the reactor vessel, the basis for the Order EA–12–051 would no longer apply. Consistent with the NRC order rescissions, the NRC proposes to no longer require licensees in decommissioning to have a reliable means to remotely monitor wide-range spent fuel pool levels to support effective prioritization of event mitigation and recovery actions in the event of a beyond-design-basis external event with the potential to challenge both the reactor and SFP.

Once the NRC has docketed a licensee's § 50.82(a)(1) or § 52.110(a) certifications, that licensee would not need to comply with the requirements in proposed Section VII, ''Communications and Staffing Requirements for the Mitigation of Beyond Design Basis Events,'' in 10 CFR part 50, appendix E. These proposed requirements are based on the March 12, 2012, § 50.54(f) letters that requested operating power reactor licensees to perform, among other things, emergency preparedness communication and

staffing evaluations for prolonged loss of power events consistent with NTTF recommendation 9.3. Once the licensees for the Shutdown NPP Group were no longer operating power reactors, they informed the NRC that they would no longer proceed with implementing recommendation 9.3. In response to the filings, the NRC determined that, for beyond-design-basis external events challenging the safety of the spent fuel at the Shutdown NPP Group:

> recovery and mitigation actions could be completed over a long period of time due to the slow progression of any accident as a result of the very low decay heat levels present in the pool within a few months following permanent shutdown of the reactor. Thus, spent fuel pool beyond design basis accident scenarios at decommissioning reactor sites do not require the enhanced communication and staffing that may be necessary for the reactor-centered events the 50.54(f) letter addresses.[4]

Order EA–12–049 also required power reactor licensees to have certain spent fuel pool cooling capabilities. In the rescission letters to the licensees for the Shutdown NPP Group, the NRC determined that, due to the passage of time, the fuel's low decay heat and the long time to boil off the water inventory in the spent fuel pool obviated the need for the Shutdown NPP Group licensees to have guidance and strategies necessary for compliance with Order EA–12–049. The rescission of Order EA–12–049 for those licensees eliminated the requirement for them to comply with the Order's requirements concerning beyond-design-basis event strategies and guidelines for spent fuel pool cooling capabilities. Consistent with the basis for the Order rescissions, licensees in decommissioning could be relieved from the proposed requirements concerning beyond-design-basis event strategies and guidelines for spent fuel pool cooling capabilities and any related requirements. These licensees would have to perform and retain an analysis demonstrating that sufficient time has passed since the fuel within the spent fuel pool was last irradiated such that the fuel's low decay heat and boil-off period provide sufficient time for the licensee to obtain offsite resources to sustain the spent fuel pool cooling function indefinitely. Licensees could make use of the equipment in place for EDMGs should that equipment be available, recognizing that the protection for that equipment is against the hazards posed by events that result in losses of large areas of the plant due to fires or explosions rather than beyond-design-basis external events resulting from natural phenomena. If the EDMG equipment is not available, the offsite resources would be used by the licensee for only onsite emergency response (*i.e.,* spent fuel pool cooling). This proposed amendment would not impact any commitments licensees have made regarding exemptions from offsite emergency planning requirements, which consider a beyond-design-basis event that could result in a zirconium cladding fire due to a loss of SFP inventory and do not consider offsite resources in mitigation strategies.

The NRC proposes to maintain the EDMGs requirement, because an event for which EDMGs would be required is not based on the condition of the fuel, but may instead result from aircraft impact and a beyond-design-basis security event which could introduce kinetic energy into the spent fuel pool independent from the decay heat of the fuel. These types of events and their potential consequences were considered as a part of the rulemaking dated March 7, 2009, on Power Reactor Security Requirements (74 FR 13926). In the course of that rulemaking, the NRC took into account stakeholder input and determined that it would be inappropriate to apply the EDMG requirements to permanently shutdown and defueled reactors where the fuel was removed from the site or moved to an ISFSI. However the resulting rule was written to remove the EDMG requirements once the certifications of permanent cessation of operations and removal of fuel from the reactor vessel were submitted rather than upon removal of fuel from the SFP. The NRC proposes to correct this error from the 2009 final rule in this proposed rule as explained in the ''EDMGs'' portion of this section.

The NRC proposes to exclude from proposed § 50.155, the licensee for Millstone Power Station Unit 1, Dominion Nuclear Connecticut, Inc. Dominion Nuclear Connecticut, Inc. is also the licensee for Millstone Power Station Units 2 and 3, but this exclusion would apply to Dominion Nuclear Connecticut, Inc. in its capacity as licensee for only Unit 1, which is not operating but has irradiated fuel in its spent fuel pool and satisfies the proposed criteria for not having to comply with this proposed rule except for the EDMG requirements. In the course of the development and implementation of the guidance and strategies required by current § 50.54(hh)(2), the NRC evaluated whether additional mitigation strategies were warranted at Millstone Power Station Unit 1 and concluded that no mitigating strategies were warranted beyond existing measures, principally due to the extended decay time since the last criticality there on November 4, 1995, and the resulting low decay heat levels allowing sufficient time for the use of existing strategies augmented by mitigation strategies existing in 2005. The exclusion for Millstone Power Station Unit 1 in this proposed rule is based upon that conclusion, recognizing that additional mitigating capabilities will be present due to the implementation of the § 50.54(hh)(2) strategies at the collocated Millstone Power Station Units 2 and 3.

In contrast to Millstone Power Station Unit 1, the Shutdown NPP Group licensees were issued license conditions for the mitigating strategies corresponding to the § 50.54(hh)(2) strategies. These license conditions are condition 2.C.(10) to Renewed Operating License No. DPR–43 for Kewaunee Power Station, condition 2.C.(14) to Facility Operating License No. DPR–72 for Crystal River Unit 3 Nuclear Generating Plant, condition 2.C.(26) to Facility Operating License NPF–10 for San Onofre Nuclear Generating Station Unit 2, condition 2.C.(27) to Facility Operating License NPF–15 for San Onofre Nuclear Generating Station Unit 3, and condition 3.N to Renewed Operating License No. DPR–28 for Vermont Yankee Nuclear Power Station. Those licensees and future power reactor licensees that enter decommissioning would have the burden to show that operation in a decommissioning status with irradiated fuel in the spent fuel pool without the EDMG license condition or the proposed requirement to comply with the proposed EDMG requirement would provide adequate protection of public health and safety.

Integrated Response Capability

Each applicant or licensee subject to the proposed requirements would be required to develop, implement, and maintain an integrated response capability that includes FSGs, EDMGs, EOPs, sufficient staffing, and a supporting organizational structure with defined roles, responsibilities, and authorities for directing and performing these strategies, guidelines, and procedures.

As discussed in the NTTF Report, EOPs have long been part of the NRC's safety requirements. The NRC regulations address them through the quality assurance requirements of

[4] See the ''Availability of Documents'' section of this document for the NRC letters to the licensees for Kewaunee Power Station, Crystal River Unit 3 Nuclear Generating Plant, San Onofre Nuclear Generating Station, Units 2 and 3, and Vermont Yankee Nuclear Power Station.

criterion V and criterion VI in appendix B to 10 CFR part 50, and in the administrative controls section of the technical specifications for each plant. Following the accident at TMI Unit 2, EOPs were upgraded to address human factors considerations in order to improve human reliability including the operator's ability to mitigate the consequences of a broad range of initiating events and subsequent multiple failures without the need to diagnose specific events. In other words, EOPs were modified from their previous event-driven nature to be symptom-based. Numerous subsequent regulatory guides (RGs) and technical reports (*e.g.,* NUREG–0660, NUREG–0737, and NUREG–0711) also address EOPs. In addition, the EOPs are the subject of a national consensus standard (American National Standards Institute/American Nuclear Society 3.2–2012, ''Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants''). The subject matter for the initial and requalification training, written exam, and operating test for reactor operators and senior reactor operators also includes the EOPs. While implementing EOPs, the event command and control functions remain in the control room under the direction of the senior licensed operator on shift.

The nuclear industry developed EDMGs following the terrorist events of September 11, 2001, in response to security advisories, orders, and license conditions issued by the NRC that required licensees to develop and implement guidance and strategies intended to maintain or restore core cooling and containment and spent fuel pool cooling capabilities under the circumstances associated with the loss of large areas of the plant due to fire or explosion. The EDMGs further extend the range of initiating events and plant damage states for which strategies and guidelines are available for use by operators to include the loss of large areas of the plant and a subsequent impairment of the operability and functionality of structures, systems and components that are within that area. NEI 06–12, ''B.5.b Phase 2&3 Submittal Guideline,'' Revision 2, December 2006 (the NRC-endorsed guidance for the requirements associated with EDMGs) provides appropriate coordination of the EDMGs with the voluntarily maintained SAMGs through its guidance that the EDMGs ''must be interfaced with existing SAMGs so that potential competing considerations associated with implementing these and other strategies are appropriately addressed.''

Based upon these considerations, the NTTF recommended that the NRC require licensees to further integrate EOPs, SAMGs and EDMGs, including a clarification of transition points, command and control, decision making, and rigorous training that includes conditions that are as close to real accident conditions as feasible.

Subsequent to issuance of the NTTF Report, the range of initiating events and plant damage states for which strategies and guidelines are available for use by operators was further extended through the development of mitigating strategies for beyond-design-basis external events in response to Order EA–12–049. The development and implementation of this set of strategies and guidelines was accomplished with the knowledge of the existence of the other NTTF recommendations and took them into account to the extent practical. In order to provide better integration with the EOPs, the resulting strategies and guidelines (FSGs) leave the designation of command and control and decision-making functions within the EOPs or SAMGs, as maintained under the voluntary industry initiative, as appropriate. As recommended in the NTTF Report, this proposed rule would require that EDMGs and FSGs be integrated with EOPs, consistent with the expectation that EOPs remain the central element of a licensee's initial response capability.

In establishing a requirement for a response capability that encompasses the use of EOPs, EDMGs, and FSGs, the NRC considered the fact that these strategies, guidelines and procedures were, and are currently being, developed at separate times over a period of several decades and that the associated efforts have been focused on responding to different types of initiating events and plant damage states. As a result, these strategies, guidelines and procedures may not properly reflect consideration of the interfaces (*e.g.,* procedure transitions), dependencies (*e.g.,* reliance on common systems or resources) and interactions (*e.g.,* alignment of response strategies) among strategies, guidelines and procedures that may be used in combination, either consecutively or concurrently, to mitigate a design-basis or beyond-design-basis event.

Additionally, the NRC considered that these strategies, guidelines and procedures are not used by a single licensee organizational unit but will often require coordination and transfer of responsibilities amongst licensee organizational units. For example, the EDMGs may be implemented under conditions of loss of the main control room and therefore initiated and directed by knowledgeable and available site personnel until coordination and augmentation efforts enable transition to a more stable command and control structure. The mitigation strategies for extreme external events, though initiated by the main control room complement of licensed operators, may require coordination with and augmentation by offsite organizations. Further, and as noted previously, there are potential accident scenarios in which a licensee might employ strategies from more than one of these strategies, guidelines and procedures during its response to an accident. One plausible sequence is for an initial response to be under the EOPs, supplemented by actions under the FSGs, and ultimately transition to actions under the SAMGs, which are implemented under a voluntary initiative. Such an accident progression would engage and require the coordination of multiple licensee organizational units.

In light of the preceding considerations, this proposed rule would require that the mitigating strategies, guidelines and procedures, staffing, and supporting organizational structure be developed, implemented, and maintained such that they function as an ''integrated'' response capability. The intent is to ensure that applicants and licensees establish and maintain a functional capability to produce a coordinated and logical response under a wide range of accident conditions. The intent is not to require physical integration (*e.g.,* organizations need not be merged and strategies, guidelines and procedures need not be combined), but rather to require a functional integration of the elements of the response capability. To achieve this functional integration, the NRC expects that applicants and licensees would have addressed the interfaces, dependencies, and interactions among the elements of their response capability such that elements work together to support effective performance under the full range of accident conditions. For example, functional integration of the strategies, guidelines and procedures would ensure that transition points are explicitly identified and conflicts between strategies are eliminated to the extent practical. Functional integration of response organizations would ensure that organizations working together to use these strategies, guidelines, and procedures (*e.g.,* to coordinate actions or provide support) have clearly defined lines of communication between the

organizations, as well as clearly defined authorities and responsibilities relative to each other, such that there are no gaps or conflicts.

The proposed requirements for FSGs would make generically-applicable requirements previously imposed on licensees by Order EA–12–049, for Virgil C. Summer Nuclear Station Units 2 and 3 by license condition as described in Memorandum and Order CLI–12–09,[5] and for Enrico Fermi Nuclear Plant Unit 3, License No. NPF–95, by license condition 2.D.(12)(g). These proposed requirements would provide additional defense-in-depth measures that increase the capability of nuclear power plant licensees to mitigate consequences of beyond-design-basis external events. Consistent with Order EA–12–049 and associated license conditions, these proposed provisions would be made generically-applicable in recognition that beyond-design-basis events have an associated significant uncertainty, and that the NRC concluded additional measures were warranted in light of this uncertainty.

The proposed FSG strategies and guideline requirements are intended to mitigate consequences of beyond-design-basis external events from natural phenomenon that result in an ELAP concurrent with either a loss of normal access to the ultimate heat sink, or for passive reactor designs, a loss of normal access to the normal heat sink. Recognizing that beyond-design-basis external events are fundamentally unbounded, and that these events can result in a multitude of damage states and associated accident conditions, a significant regulatory challenge is developing bounded requirements that meaningfully address the regulatory issue. From a practical standpoint, development of mitigation strategies requires that there be some definition (or boundary conditions established) for an onsite damage state for which the strategies would then address and thereby provide an additional capability to mitigate beyond-design-basis external event conditions that might occur. The damage state should ideally be representative of a large number of potential damage states that might occur as a result of extreme external events, and it should present an immediate challenge to the key safety functions, so that the resultant strategies actually improve safety. The assumed damage state for this proposed rule is the same as that assumed to implement the requirements of EA–12–049, attachment 2 for currently operating power reactors: An ELAP condition concurrent with loss of normal access to the ultimate heat sink (LUHS). This assumed damage state is effective at immediately challenging the key safety functions following a beyond-design-basis external event (*i.e.,* core cooling, containment and spent fuel pool cooling). Requiring strategies to maintain or restore these key functions under such circumstances would result in an additional mitigation capability consistent with the Commission's objective when it issued Order EA–12–049.

This proposed rule would not be prescriptive in terms of the specific set of initial and boundary conditions assumed for the ELAP and LUHS condition, recognizing that the damage state for current operating reactors, defined in more detail in draft regulatory guidance for this proposed rule (DG)-1301, ''Flexible Mitigation Strategies for Beyond-Design-Basis Events,'' reflects current operating power reactor designs and the reliance of those designs on ac power, while the assumed damage state for a future design may be different depending upon the design features. Specifically, this damage state was implemented through the assumption of the ELAP to the onsite emergency ac buses, but did allow for ac power from the inverters to be assumed available in order to establish event sequence and the associated times for when mitigation actions would be assumed to be required. To address the Order EA–12–049 requirement for an actual loss of all ac power, including ac power from the batteries (through inverters), contingencies are included in the mitigation strategies to enable actions to be taken under those circumstances (*e.g.,* sending operators to immediately take manual control over a non ac-powered core cooling pump). As such, this proposed provision is meant to make generically-applicable the current implementation under EA–12–049 (*i.e.,* there is no intent to either relax or impose new requirements), and be performance-based to allow some flexibility for future designs. As an example, some reactor designs (*e.g.,* Westinghouse AP1000 and General Electric Economic Simplified Boiling Water Reactor (ESBWR)) use passive safety systems to meet NRC requirements for maintaining key safety functions. The inherent design of those passive safety systems makes certain assumptions, such as loss of access to the ultimate heat sink, not credible. Accordingly, the assumed condition for the FSG requirements for passive reactors is the loss of normal access to the normal heat sink, discussed further in this section. Nevertheless, in this proposed rule the NRC is requiring that the strategies and guidelines be capable of implementation during a loss of all ac power.

Regarding the assumed LUHS for combined licenses or applications referencing the AP1000 or the ESBWR designs, the assumption was modified to be a loss of normal access to the normal heat sink (see attachment 3 to Order EA–12–049, *Summer,* CLI–12–09, 75 NRC at 440, the V.C. Summer Unit 2 license, License No. NPF–93, Condition 2.D.(13), the V.C. Summer Unit 3 license, License No. NPF–94, Condition 2.D.(13) and Enrico Fermi Nuclear Plant Unit 3 License, License No. NPF–95, Condition 2.D.(12)(g)). This modified language reflects the passive design features of the AP1000 and the ESBWR that provide core cooling, containment, and spent fuel cooling capabilities for 72 hours without reliance on ac power. These features do not rely on access to any external water sources for the first 72 hours because the containment vessel and the passive containment cooling system serve as the safety-related ultimate heat sink for the AP1000 design and the isolation condenser system serves as the safety-related ultimate heat sink for the ESBWR design.

As discussed previously, the range of beyond-design-basis external events is unbounded. These proposed provisions are not intended, and should not be understood to mean, that the mitigation strategies can adequately address all postulated beyond-design-basis external events. It is always possible to postulate a more severe event that causes greater damage and for which the mitigation strategies may not be able to maintain or restore the functional capabilities (*e.g.,* meteorite impact). Instead, the proposed requirements provide additional mitigation capability in light of uncertainties associated with external events, consistent with the NRC's regulatory objective when it issued Order EA–12–049.

This proposed rule would require that the FSGs be capable of being implemented site-wide. This recognizes that severe external events are likely to impact the entire reactor site, and for multi-unit sites, damage all the power reactor units on the site. This requirement means that there needs to be sufficient equipment and supporting staff to enable the core cooling, containment, and spent fuel pool

[5] *Summer,* CLI–12–09, 75 NRC at 440, and the V.C. Summer Unit 2 license, License No. NPF–93, Condition 2.D.(13) and V.C. Summer Unit 3 license, License No. NPF–94, Condition 2.D.(13).

cooling functions to be maintained or restored for all the power reactor units on the site. This is a distinguishing characteristic of this set of mitigating strategies from those that currently exist for § 50.54(hh)(2), for which the damage state was a more limited, albeit large area of a single plant, reflecting the hazards for which that set of strategies was developed.

The NRC gave consideration to whether there should be changes made to § 50.63 to link those requirements with this proposed rule. This consideration stemmed from recommendation 4.1 of the NTTF Report to ''initiate rulemaking to revise 10 CFR 50.63'' and the understanding that this proposed rule could result in an increased station blackout coping capability, in addition to the regulatory objective of the proposed provisions, which is to provide additional beyond-design-basis external event mitigation. Because of the substantive differences between the requirements of § 50.63 for licensees to be able to withstand and recover from a station blackout and the proposed requirements, the NRC determined that such a linkage was not necessary and could lead to regulatory confusion.

The principal regulatory objective of § 50.63 was to establish station blackout coping durations for a specific scenario (*i.e.,* loss-of-offsite power coincident with a failure of both trains of emergency onsite ac power, typically, the failure of multiple emergency diesel generators). In meeting this regulatory objective, the NRC recognized that there would be safety benefits accrued through the provision of an alternate ac source diverse from the emergency diesel generators and therefore defined such a source in § 50.2. In furtherance of this alternative means to comply with § 50.63, the NRC also defined the event a licensee must withstand and recover from as a station blackout rather than a loss of all ac power. A station blackout allows for continued availability of ac power to buses fed by station batteries through inverters or by alternate ac sources. This proposed rule would provide an additional capability to mitigate beyond-design-basis external events. Because the condition assumed for the mitigation strategies to establish the additional mitigation capability includes an ELAP, which is more conservative than a station blackout as defined in § 50.2, there can be a direct relationship between the two different sets of requirements with regard to the actual implementation at the facility. Specifically, implementation of the proposed mitigation strategies links into the station blackout procedures (*e.g.,* the applicable strategies would be implemented to maintain or restore the key safety functions when the EOPs reach a ''response not obtained'' juncture).[6]

Step-by-step procedures are not necessary for many aspects of the proposed mitigating strategies and guidelines. Rather, the strategies and guidelines should be flexible, and therefore enable plant personnel to adapt them to the conditions that result from the beyond-design-basis external event. The proposed provisions typically would result in strategies and guidelines that use both installed and portable equipment, instead of only relying on installed ac power sources (with the exception of protected battery power) to maintain or restore core cooling, containment, and spent fuel pool cooling capabilities. By using equipment that is separate from the normal installed ac-powered equipment, the strategies and guidelines have a diverse attribute. By having available multiple sets of portable equipment that can be deployed and used in multiple ways depending on the circumstances of the event, operators are able to implement strategies and guidelines that are flexible and adaptable.

The proposed mitigation strategies requirements are both performance-based and functionally-based. The proposed performance-based requirements recognize that the new requirements would provide most benefit to future reactors whose designs could differ significantly from current power reactor designs and as such, use of more prescriptive requirements could be problematic and create unnecessary regulatory impact and need for exemptions. Use of functionally-based requirements results from the need to have requirements that can address a wide range of damage states that might exist following beyond-design-basis external events. Maintaining or restoring three key functions (core cooling, containment' and spent fuel pool cooling) supports maintenance of the fission product barriers (*i.e.,* fuel clad, reactor coolant pressure boundary, and containment) and results in an effective means to mitigate these events, while remaining flexible such that the strategies and guidelines can be adapted to the damage state that occurs. Functionally-based requirements also result in strategies that align well with the symptom-based procedures used by power reactors to respond to accidents. Accordingly, Order EA–12–049 contained requirements for a three-phased approach for current operating reactors. This proposed rule does not specify a number of phases; instead, the NRC is proposing higher level, performance-based requirements consistent with this discussion.

The NRC gave consideration to incorporating into this proposed rule a requirement that licensees be capable of implementing the strategies and guidelines ''whenever there is irradiated fuel in the reactor vessel or spent fuel pool.'' This provision would have been a means of making generically-applicable the requirement from Order EA–12–049 that licensees be capable of implementing the strategies and guidelines ''in all modes.'' The NRC considers the terminology ''whenever there is irradiated fuel in the reactor vessel or spent fuel pool'' would be a better means to address the Order requirement since the phrase does not use technical specification type language (*i.e.,* modes), which would not be in effect when a licensee completely offloads the fuel from the reactor vessel into the spent fuel pool during an outage. The NRC concluded that the use of the phrases ''whenever there is irradiated fuel in the reactor vessel or spent fuel pool'' or ''in all modes'' is not necessary because the proposed applicability provisions would ensure that licensees would be required to have mitigation strategies for beyond-design-basis external events for the various configurations that can exist for the reactor and spent fuel pools throughout the operational, refueling and decommissioning phases.

The mitigation strategies and guidelines implemented under NRC Order EA–12–049 assume a demanding condition that maximizes decay heat that would need to be removed from the reactor core and spent fuel pool source terms on site. This implementation results in a more restrictive timeline (*i.e.,* mitigation actions required earlier following the event to take action to maintain or restore cooling to these source terms) and a greater resulting additional capability. These assumed at-power conditions are 100 days at 100 percent power prior to the event for the reactor core as was used for § 50.63. This assumption establishes a conservative decay heat for the reactor source term. The assumed spent fuel

[6] One of the formats for symptom-based EOPs that are used in the operating power reactors has the operators take an action and verify that the system responds to the action in a manner that confirms that the action was effective. For example, a step in an EOP could be to open a valve in order to allow cooling water flow and the verification would be obtained by confirming there are indications that flow has commenced such as lowering temperature of the system being cooled. If those indications are not obtained, the procedure would provide instructions on the next step to accomplish in a separate column labeled ''response not obtained.''

pool conditions include the design basis heat load for the spent fuel pool, typically a full core offload following a refueling outage. This establishes a conservative heat load for the spent fuel pool. The NRC recognizes that, as a practical reality, these conditions would not exist simultaneously. The NRC considers the development of timelines for the proposed mitigating strategies using the maximum heat load for either the reactor core or the spent fuel pool to be appropriate. While establishing the capability to mitigate the maximum heat load for both simultaneously would be compliant with the proposed requirements, it would not be necessary.

The NRC recognizes the difficulty of developing engineered strategies for the extraordinarily large number of possible plant and equipment configurations that might exist under shutdown conditions (*i.e.,* at shutdown when equipment may be removed from service, when there is ongoing maintenance and repairs or refueling operations, or modifications are being implemented). The proposed requirements mean that licensees should be cognizant of such configurations, equipment availability, and decay heat states that could present greater challenges under these conditions, and design mitigation strategies that can be implemented under such circumstances.

The NRC considered requiring the strategies to be developed considering the need to plan for delays in the receipt of offsite resources as a result of damage to the transportation infrastructure. While severe events could damage local infrastructure, and could create challenges with regard to the delivery of offsite resources, the NRC concluded that having this level of specificity in the proposed provisions would not be necessary. Instead, this proposed rule contains provisions that are more performance-based, requiring continued maintenance or restoration of the functional capabilities until acquisition of offsite assistance and resources. Potential delays and other challenges presented by extreme events that affect acquisition and use of offsite resources would be addressed by licensee programs that implement the proposed provisions.

Order EA–12–049 included a requirement that licensees develop guidance and strategies to obtain ''sufficient offsite resources to sustain [the functions of core cooling, containment, and spent fuel pool cooling] indefinitely.'' The NRC considered using this language in this proposed rule, but concluded that this would be better phrased as ''indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies.'' The NRC concluded that this phrase better communicates the existence of a transition from the use of the mitigating strategies to recovery operations.

The NRC recognizes that the use of the proposed mitigating strategies would potentially require departure from a license condition or a technical specification (contained in a license issued under 10 CFR part 50 or 52) and could be considered a proceduralization of the allowance provided under § 50.54(x). Given that the initiation of the use of these strategies may be included in emergency operating procedures or other procedures, which might be considered procedures described in the final safety analysis report (as updated), there is an interaction with the provisions of § 50.59(c)(1) regarding the need to obtain a license amendment in order to make the necessary change to those procedures. The NRC considered including provisions in this proposed rule specifically to allow departures from license conditions or technical specifications in order to clarify this situation, but found these provisions unnecessary. For holders of operating licenses under 10 CFR part 50 and combined licenses under 10 CFR part 52 that were subject to Order EA–12–049, the provisions of that Order provided more specific criteria for making the necessary changes than § 50.59, making that section inapplicable as set forth in § 50.59(c)(4). Those criteria included the provision of submitting an overall integrated plan to the NRC for review. Similar criteria were included in license conditions for the combined licenses for Virgil C. Summer Nuclear Station, Units 2 and 3, and Enrico Fermi Nuclear Plant Unit 3.

EDMGs

The NRC proposes to move the EDMGs requirement currently in § 50.54(hh)(2) to a new mitigation of beyond-design-basis events section of 10 CFR part 50. In addition to moving the text, the NRC proposes to make a few editorial changes. The wording used to describe these requirements has evolved from ''guidance and strategies,'' in Interim Compensatory Measures Order EA–02–026, dated February 25, 2002, to ''strategies,'' in the corresponding license conditions, to ''guidance and strategies,'' in § 50.54(hh)(2), to its proposed form ''strategies and guidelines.'' The word ''guidelines'' was chosen rather than ''guidance'' to better reflect the nature of the instructions that could be developed as appropriate by a licensee and to avoid confusion with the term ''regulatory guidance.'' The word ''strategies'' is used in this proposed rule to reflect its meaning, ''plans of action.'' The resulting plans of action could include plant procedures, methods, or other guideline documents, as deemed appropriate by the licensee during the development of these strategies. These plans of action would also include the arrangements made with offsite responders for support during an actual event. No substantive change to the requirements is intended by this proposed change in the wording.

Applicability of the requirements of § 50.54(hh)(2) is currently governed by § 50.54(hh)(3), which makes these requirements inapplicable following the submittal of the certifications required under § 50.82(a) or § 52.110(a)(1). As discussed in the statement of considerations for the Power Reactor Security Rulemaking (74 FR 13926), the NRC believes that it would be inappropriate for the requirements for EDMGs to apply to a permanently shutdown, defueled reactor, where the fuel was removed from the site or moved to an ISFSI. The NRC proposes to require EDMGs for a licensee with permanently shutdown defueled reactors, but with irradiated fuel still in its spent fuel pool, because the licensee must be able to implement effective mitigation measures for large fires and explosions that could impact the spent fuel pool while it contains irradiated fuel. The difference between this proposed rule and § 50.54(hh)(3) would correct the wording of the latter provision to implement the sunsetting of the associated requirement as was intended by the Commission in 2009. This change would not constitute backfitting for currently operating reactors because the proposed change concerns decommissioning reactors. The proposed change would not constitute backfitting for currently decommissioning reactors because the EDMGs are also required by the licensees' license conditions that were made generically applicable through the Power Reactor Security Rulemaking and remain in effect.

Integration With EOPs

In developing a proposed requirement for the integration of FSGs and EDMGs with the EOPs, the NRC considered their differences in content and the standards for usage applied to them. The EOPs are a specific and prescribed set of instructions implemented in accordance with exacting standards for usage and adherence (*e.g.*, step-by-step sequential performance, concurrent execution of multiple sections) that

operators and plant staff are required to follow when performing a specific task or addressing plant conditions. When implementing procedures, each step is to be performed as prescribed, with rare exceptions. The strategies and guidelines that would be required differ from EOPs primarily in terms of the level of detail to which they are written and expectations regarding usage. These strategies and guidelines may be a less prescriptive set of instructions not subject to the same constraints imposed by standards of usage for procedure implementation (*e.g.*, may not be followed in a step-by-step manner). This is because of: (1) The large number of possible event initiators, plant configurations, and sequences; and (2) the high degree of uncertainties in event progression and consequences. The strategies and guidelines can take the form of high level plans that identify and describe potential, previously evaluated, success paths for addressing specific conditions such as loss of core cooling. As a result, strategies and guidelines provide operators and plant staff the information and latitude to respond as necessary to unpredictable and dynamic situations, allowing them to adapt to the actual conditions and damage states without the burden of detailed procedures and the challenge of determining which procedure may be applicable and effective under the uncertain conditions of a beyond design basis accident.

Given these differences in content and standards for usage, the intent of this proposed rule is not to require conformance of the strategies and guidelines to the level of detail and standards of usage for EOPs, or consolidation of the strategies, guidelines and procedures into a single set of instructions, but rather, as previously described, to require functional integration of strategies and guidelines with the EOPs. The objective is for the strategies, procedures, and guidelines to retain or employ the characteristics that support their effective use under the range of conditions to which they are each intended to apply while ensuring that the strategies and guidelines, in conjunction with the EOPs, constitute a useable and cohesive set of instructions for mitigating the consequences of a wide range of initiating events and plant damage states. To achieve this functional integration, the NRC expects that applicants and licensees would have addressed the interfaces, dependencies, and interactions among the strategies and guidelines that would be required under this proposed rule and the EOPs, such that they can be implemented in concert with each other, as necessary, to effectively use available plant resources and direct a logical and coordinated response to a wide range of accident conditions.

In keeping with the basis for a functional integration of the strategies and guidelines with EOPs, this proposed rule would require that the FSGs and EDMGs be integrated ''with the Emergency Operating Procedures (EOPs).'' This proposed language is intended to communicate the NRC's expectation that the EOPs retain their role as the primary means of directing emergency operations and that the strategies and guidelines that would be required under this proposed rule would be integrated with EOPs to support their implementation or augment them where their implementation is not successful in preventing significant fuel damage.

The NRC considered establishing specific criteria for the integration of the strategies and guidelines with EOPs but opted to specify only a high level requirement to allow applicants and licensees flexibility in the means by which they achieve the functional integration described previously. Approaches for achieving functional integration could include the following:

1. Strategies, guidelines, and procedures have clearly defined transitions (*e.g.*, entry and exit conditions with distinct pointers) from one strategy, guideline, or procedure to another.

2. Individuals are cued by the document or trained to know when transitions between the strategies, guidelines, and procedures result in corresponding changes in the associated standards for usage (*e.g.*, when transitioning from EOPs to the voluntarily maintained SAMGs, the operator is able to recognize the transition from a step-by-step procedure to a flexible guideline set where it is permissible to deviate from the order or method of accomplishing the steps).

3. Licensees establish expectations (*e.g.*, through standards for usage) pertaining to the parallel use of strategies, guidelines, and procedures. Plant personnel using different strategies, guidelines, and procedures concurrently understand which is the controlling procedure and therefore which actions take precedence.

4. Licensees identify and resolve conflicts between the strategies, guidelines and procedures.

5. Licensees identify competing considerations when using the strategies, guidelines and procedures and eliminate or address them in guidance.

6. Licensees control the development and maintenance of their content and format in accordance with human factors standards and guidelines (*e.g.*, writer's guides) that recognize and address the interfaces between them in order to achieve compatibility of the strategies, guidelines, and procedures.

Staffing

The NRC proposes to require licensees to provide the staffing necessary for having an integrated response capability to support implementation of the FSGs and EDMGs. To be effective, staffing for an expanded response capability should include the trained and qualified individuals who would be relied upon to analyze, recommend, authorize, and implement the mitigating strategies. The staffing must directly support the assessment and implementation of a range of mitigation strategies intended to maintain or restore the functions of core cooling, containment, and spent fuel pool cooling.

The staffing analyses required by proposed appendix E, section VII, should determine when personnel performing expanded response functions should report to the site, within a timeframe sufficient to support implementation of the strategies that are not assigned to the on-shift staff. This would ensure that the functions of core cooling, containment, and spent fuel pool cooling are continuously maintained or are promptly restored.

The NRC has endorsed the industry guidance for conducting staffing analyses, NEI 10–05, ''Assessment of On-Shift Emergency Response Organization Staffing and Capabilities,'' Revision 0, and NEI 12–01, ''Guideline for Assessing Beyond Design Basis Accident Response Staffing and Communications Capabilities,'' Revision 0, and the NRC has issued Interim Staff Guidance (ISG), NSIR/DPR–ISG–01, ''Emergency Planning for Nuclear Power Plants,'' that provides the requisite details for determining the staffing levels and for which positions, as well as which beyond design basis external events, the applicants and licensees should evaluate.

The recommended minimum positions and staffing levels for emergency plans were initially provided in NUREG–0654/FEMA–REP–1, Revision 1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants.'' Following the September 11, 2001, events, the NRC issued Enhancements

to Emergency Preparedness Regulations (EP final rule) (76 FR 72560) to amend 10 CFR part 50, appendix E, to address, in part, concerns about the assignment of tasks or responsibilities to on-shift emergency response organization (ERO) personnel that would potentially overburden them and prevent the timely performance of their functions under the emergency plan. Licensees must have enough on-shift staff to perform specified tasks in various functional areas of emergency response 24 hours a day, 7 days a week. This proposed rule would address the staffing requirements for the expanded response capabilities for on-shift response and the ERO.

This proposed rule would require adequate staffing to implement the FSGs and EDMGs with the EOPs without requiring further analysis to supplement analyses that were completed as a result of post-Fukushima orders or the EP final rule. Staffing levels should be established to ensure that if strategies are executed there would be no delays in completing them caused by the lack of qualified personnel. The NRC expects that the use of drills, existing training analyses and other methods would verify sufficient staffing levels.

Command and Control

The NRC proposes to require licensees to have a supporting organizational structure with defined roles, responsibilities, and authorities for directing and performing the FSGs and EDMGs. The objective is to ensure that licensees address the organizational implications of: (1) Implementing the FSGs; and (2) integrating the FSGs and EDMGs with the EOPs such that organizational units responsible for on-site accident mitigation (*e.g.*, main control room, emergency operations facility, and technical support center staff) can support a coordinated implementation of these procedures and guidelines under the challenging conditions presented by beyond-design-basis events.

Additional requirements currently exist in 10 CFR part 50, appendix E, section IV.A, for the inclusion within the emergency plan of a description of the organization for coping with radiological emergencies, including definition of authorities, responsibilities, and duties of individuals assigned to the licensee's emergency organization and the means for notification of such individuals in the event of an emergency. These requirements provide the command and control structure for use in the execution of the emergency plan. The current 10 CFR part 50, appendix E, sections IV.A.2.a. and IV.A.5., further require that the emergency plan include: (1) A detailed description of the authorities, responsibilities, and duties of the individual(s) who will take charge during an emergency; (2) plant staff emergency assignments, authorities, responsibilities, and duties of an onsite emergency coordinator who shall be in charge of the exchange of information with offsite authorities responsible for coordinating and implementing offsite emergency measures; and (3) the identification, by position and function to be performed, of other employees of the licensee with special qualifications for coping with emergency conditions that may arise.

The need for defined command and control structures and responsibilities for use in beyond-design-basis conditions was recognized in the course of the development of the guidance and strategies for the current § 50.54(hh)(2). As stated in the industry's guidance document for that set of requirements, NEI 06–12, ''B.5.b Phase 2 & 3 Submittal Guideline,'' Revision 2, ''Experience with large scale incidents has shown that command and control execution can be a key factor to mitigation success.'' The guidance and strategies developed for that effort include an EDMG for initial response to provide a bridge between normal operational command and control and the command and control that is provided by the ERO in the event that the normal command and control structure is disabled. The NRC considers that the actions taken in the development of the EDMG for initial response for the guidance and strategies for the current § 50.54(hh)(2) would continue to be adequate for compliance with this proposed rule for EDMGs following the proposed movement of those requirements.

The endorsed industry guidance in NEI 12–06, Revision 0, ''Diverse and Flexible Coping Strategies (FLEX) Implementation Guide,'' for the guidance and strategies required by Order EA–12–049, specifies that the existing command and control structure will be used for transition to the voluntarily maintained SAMGs

All previous requirements did not specify a command and control structure for a multi-unit event that includes the potential need for acquisition of offsite assistance to support onsite event mitigation. Additionally, these requirements were not understood to require such a response since they preceded the Fukushima event and the regulatory actions that stemmed from that event. As a practical matter, the current command and control structures, including any changes that resulted from the implementation of Order EA–12–049 requirements, are expected to be sufficient to ensure that the functional objectives of this proposed rule are achieved. Accordingly, the NRC recognizes that this new requirement may not be necessary and is requesting stakeholder feedback on this issue (refer to section VI of this notice).

Equipment

The NRC proposes to have requirements for licensee equipment, including instrumentation, that is relied upon for use in proposed mitigation strategies and guidelines. This rulemaking does not propose to modify the regulatory treatment of equipment relied upon for the EDMGs currently required by § 50.54(hh)(2). The regulatory treatment of that equipment will remain as it is described in the endorsed guidance document for those strategies and guidelines.

This proposed rule would make generically applicable requirement (2) of Order EA–12–049, attachments 2 and 3, which reads as follows: ''These strategies must . . . have adequate capacity to address challenges to core cooling, containment, and SFP cooling capabilities at all units on a site subject to this Order.''

The industry guidance of NEI 12–06, as endorsed by NRC interim staff guidance JLD–ISG–2012–01, ''Compliance with Order EA–12–049, Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events,'' included specifications for licensee provision of a spare capability in order to assure the reliability and availability of the equipment required to provide the capacity and capability requirements of the Order. This spare capability was also referred to within the guidance as an ''N+1'' capability, where ''N'' is the number of power reactor units on a site. The NRC considered including requirements similar to the spare capability specification of NEI 12–06 in this proposed rule but determined that such an inclusion would be too prescriptive and could result in the need to grant exemptions for alternate approaches that provide an effective and efficient means to provide the required capability of the Order. One example of this is in the area of flexible hoses, for which a strict application of the sparing guidance could necessitate provision of spare hose or cable lengths sufficient to replace the longest run of hoses when significant operating experience with similar hoses for fire protection does not show a failure rate that would support this as a need.

The development of the mitigating strategies in response to Order EA–12–049 relied upon a variety of initial and boundary conditions that were provided in the regulatory guidance of JLD–ISG–2012–01, Revision 0, and NEI 12–06, Revision 0. These initial and boundary conditions followed the philosophy of the basis for imposition of the requirements of Order EA–12–049, which was to require additional defense-in-depth measures to provide continued reasonable assurance of adequate protection of public health and safety. As a result, the industry response to Order EA–12–049 includes diverse and flexible means of accomplishing safety functions rather than providing an additional further hardened train of safety equipment. These requirements and conditions included the acknowledgement that, due to the fact that initiation of an event requiring use of the strategies would include multiple failures of safety-related structures, systems, and components (SSCs), it is inappropriate to postulate further failures that are not consequential to the initiating event. As a result, the NRC has determined that the conditions to which the instrumentation relied on for the mitigating strategies would be exposed do not include conditions stemming from fuel damage, but instead are limited as described previously. The NRC has determined that it should not be necessary for the instrumentation to be designed specifically for use in the mitigating strategies and guidelines, but instead it would be necessary that the design and associated functional performance be sufficient to meet the demands of those strategies.

The underlying proposed requirements are for events that are not included in the design basis events as that term is used in the § 50.2 definition of safety-related SSCs. Because of this, reliance on equipment for use in the related strategies would not result in the applicability of 10 CFR part 50, appendix A, General Design Criterion (GDC)–2, ''Design bases for protection against natural phenomena,'' or the principal design criterion (PDC) applicable to a plant's operating license if issued prior to GDC–2. This proposed rule would require reasonable protection for the equipment relied on for the mitigation strategies to a hazard level as severe as that originally determined for the facility under GDC–2 or the applicable PDC unless the reevaluated hazards stemming from the March 12, 2012, NRC letter issued under § 50.54(f), as assessed by the NRC show that increased protection is necessary. The March 12, 2012, NRC letter requested information on licensees' seismic and flooding hazards; licensees and the NRC are currently scheduled to complete most of the work on the flooding reevaluations prior to the anticipated effective date of this proposed rule. The NRC notes that there are some licensees whose licensing bases include requirements for protection from natural phenomena beyond those established at the original licensing (*e.g.*, North Anna Power Station for the seismic hazard), but anticipates that these different hazard levels would be captured in the reevaluation of external hazards under the March 12, 2012, NRC letter.

As discussed in COMSECY–14–0037, ''Integration of Mitigating Strategies for Beyond-Design-Basis External Events and The Reevaluation of Flooding Hazards,'' and its associated SRM, the requirements of Order EA–12–049 were imposed in parallel with the agency's March 12, 2012, requests for information on the reevaluation of external hazards. As a result, Order EA–12–049 included a requirement in both attachment 2 and 3 for licensees to provide reasonable protection for equipment associated with the required mitigating strategies from external events without specific reference to the necessary level of protection. The appropriate level of protection from external hazards, particularly flooding, was the subject of discussion in the course of NRC-held public meetings leading up to the issuance of JLD–ISG–2012–01 and its endorsement of the industry guidance for Order EA–12–049, NEI 12–06. Section 6.2.3.1 of NEI 12–06 specifies that the level of protection for flooding should be ''the flood elevation from the most recent site flood analysis. The evaluation to determine the elevation for storage should be informed by flood analysis applicable to the site from early site permits, combined license applications, and/or contiguous licensed sites.'' The choice of this hazard level was driven by the recognition that, while the flooding hazard reevaluations by holders of operating licenses and construction permits may not be complete in advance of the development and implementation of the mitigating strategies, information available from flood analyses for nearby sites could be taken into account in choosing the appropriate level in order to avoid the need for rework or modification of the strategies. Many licensees took the former approach, using their best estimates of potential hazard levels and providing additional margin to the current licensing basis. (See, *e.g.*, the description of the flooding strategies for Fort Calhoun Station on page B–43 *et seq.*, of Omaha Public Power District's Overall Integrated Plan (Redacted) in Response to March 12, 2012, Order EA–12–049.)

In COMSECY–14–0037, the NRC staff requested that the Commission affirm that: (1) Licensees for operating nuclear power plants need to address the reevaluated flooding hazards within their mitigating strategies for beyond-design-basis external events; (2) licensees for operating nuclear power plants may need to address some specific flooding scenarios that could significantly damage the power plant site by developing targeted or scenario-specific mitigating strategies, possibly including unconventional measures, to prevent fuel damage in reactor cores or spent fuel pools; and (3) the NRC staff should revise the flooding assessments and integrate the decision-making into the development and implementation of mitigating strategies in accordance with Order EA–12–049 and this rulemaking. These principles reflect the NEI 12–06 reference to the ''most recent flood analysis'' previously discussed and the documentation by licensees in their overall integrated plans for the mitigating strategies that, at the time of their submittals, ''flood and seismic reevaluations pursuant to the § 50.54(f) letter of March 12, 2012, are not completed and therefore not assumed in this submittal. As the reevaluations are completed, appropriate issues would be entered into the corrective action system and addressed on a schedule commensurate with other licensing bases changes.'' In SRM–COMSECY–14–0037, the Commission approved the first two items recommended by the NRC staff, regarding the need for operating nuclear power plant licensees to address the reevaluated flood hazards within the mitigating strategies and the potential for using targeted or scenario specific mitigating strategies. The Commission did not approve the third recommendation, but that recommendation is outside the scope of this rulemaking effort. The NRC drafted the proposed rule to reflect this direction and in recognition of the fact that the wording of Order EA–12–049 and its associated guidance did not make clear that the mitigating strategies equipment would require protection to the reevaluated hazard levels resulting from the § 50.54(f) request for information of March 12, 2012.

Because the events for which the proposed mitigating strategies are to be used are outside the scope of the design basis events considered in establishing the basis for the design of the facility, equipment that is relied upon for those

mitigating strategies may not fall within the scope of § 50.65, ''Requirements for monitoring the effectiveness of maintenance at nuclear power plants.'' Nevertheless, the NRC proposes that such equipment should receive adequate maintenance in order to assure that it is capable of fulfilling its intended function when called upon.

The NRC proposes to require licensees to have a means to remotely monitor wide-range SFP level as a part of the equipment relied upon to support the FSGs. This provision would make generically-applicable the requirements imposed by Order EA–12–051. The NRC considered including the detailed requirements from Order EA–12–051 within this proposed rule, but determined that the more performance-based approach taken with this proposed rule would better enable an applicant for a new reactor license or design certification to provide innovative solutions to address the need to effectively prioritize event mitigation and recovery actions between the source term contained in the reactor vessel and that contained within the spent fuel pool.

Training

The NRC anticipates that mitigation of the effects of beyond-design-basis events using the proposed strategies and guidelines would be principally accomplished through manual actions rather than automated plant responses. Additionally, the instructions provided for event mitigation may be largely provided as high level strategies and guidelines rather than step-by-step procedures. The use of strategies and guidelines supports the ability to adapt the mitigation measures to the specific plant damage and operational conditions presented by the event. However, effective use of this flexibility would depend upon the knowledge and abilities of personnel to select appropriate strategies or guidelines from a range of options and implement mitigation measures using equipment or methods that may differ from those employed for normal operation or design-basis event response. As a result, the NRC considers personnel training and qualification necessary to ensure that individuals would be capable of effectively performing their roles and responsibilities in accordance with the strategies and guidelines that would be required by this proposed rule.

The NRC acknowledges that licensee training programs, such as those required for licensed operators under 10 CFR part 55, ''Operators' Licenses,'' the programs for plant personnel specified under § 50.120, ''Training and Qualification of Nuclear Power Plant Personnel,'' and the training for emergency response personnel required by 10 CFR part 50, appendix E, section IV.F, ''Training,'' would likely provide for many of the knowledge and abilities required for performing activities in accordance with the strategies and guidelines that would be required by this proposed rule. Nevertheless, as noted previously, the NRC anticipates that these strategies and guidelines may use new methods or equipment that require knowledge and abilities not currently addressed under existing training programs and, as a result, there may be gaps in these training programs that must be addressed to support effective use of the strategies and guidelines. Accordingly, this proposed rule would further require that licensees provide for the training of personnel using a systems approach to training as defined in § 55.4 (the Systems Approach to Training (SAT) process), except for elements already covered under other NRC regulations.[7] The SAT process, which is acceptable for meeting training requirements under 10 CFR part 55 and § 50.120, would also be appropriate for licensee identification and resolution of any current gaps or future modifications to personnel training that may be necessary to provide for the training of personnel performing activities in accordance with the mitigating strategies and guidelines that would be required by this proposed rule. The NRC recognizes that there are other training programs that are currently acceptable for meeting other regulatory required training (*e.g.*, 10 CFR part 50, appendix E, section IV.F) that do not use the SAT process. In light of the existence of these training programs, which have been found acceptable for more frequently occurring design-basis events, the NRC has determined that these training programs can meet the needs for common elements with beyond-design-basis event mitigation. Therefore, the NRC would not require licensees to revise these training programs to use the SAT process to meet the proposed requirements. Licensees would be required to use the SAT process for newly identified training requirements supporting the effective use of the strategies and guidelines that would be required by this proposed rule.

By using the SAT process, licensees would identify and train on any additional tasks that would be necessary to implement the strategies and guidelines for the mitigation of beyond-design-basis events as defined in this proposed rule. The additional tasks identified would be incorporated into the training program to ensure appropriate training would be administered for each qualified individual designated to implement the strategies and guidelines required by this proposed rule.

Change Control

The proposed requirements address beyond-design-basis events, and as such, currently existing change control processes do not address all aspects of a contemplated change, including most notably § 50.59. As such, the proposed change control provision is intended to supplement the existing change control processes and focus on the beyond-design-basis aspects of the proposed change.

This proposed rule would not contain criteria typically included in other change control processes that are used as a threshold for determining when a licensee needs to seek NRC review and approval prior to implementing the proposed change. Instead, the proposed provisions would require that the evaluations of the proposed change reach a conclusion that all new requirements continue to be met and that this evaluation is documented and maintained to support NRC inspection.

Proposed changes that remain consistent with regulatory guidance would be acceptable, since such changes would ensure continued compliance with the proposed provisions in this rulemaking. The NRC recognizes that the proposed change control provisions may result in licensees seeking NRC review and approval of proposed changes that do not follow current regulatory guidance for this proposed rulemaking potentially through a license amendment or through NRC review of new or revised regulatory guidance. Accordingly, the NRC is requesting stakeholder feedback on this issue to determine whether there is a better regulatory approach for change control (refer to the ''Specific Requests for Comments'' section of this document).

During public discussions before issuance of this proposed rule, there was a suggestion that the NRC should consider a provision to allow a licensee to request NRC review of a proposed change, and that if the NRC did not act

[7] This definition of a systems approach to training (SAT), is a training program that includes the following five elements: (1) Systematic analysis of the jobs to be performed; (2) learning objectives derived from the analysis which describe desired performance after training; (3) training design and implementation based on the learning objectives; (4) evaluation of trainee mastery of the objectives during training; and (5) evaluation and revision of the training based on the performance of trained personnel in the job setting.

upon the request for a suggested time period (*e.g.*, 180 days) that the request be considered ''acceptable.'' The NRC did not include this ''negative consent'' type of approval process in this proposed rule and instead the proposed change control process places the responsibility on the licensees to ensure that proposed changes result in continued compliance with the proposed rule provisions, or are otherwise submitted to the NRC following the § 50.12 exemption process. The NRC expects to obtain stakeholder feedback on this issue and will consider that feedback when developing the final rule provisions.

A licensee may intend to change its facility, procedures, or guideline sets to revise some aspect of beyond-design-basis mitigation (*i.e.*, governed by the proposed provisions of this rulemaking), and the same change can impact multiple aspects of the facility (*i.e.*, impact ''design basis'' aspects of the facility and be subject to other regulations and change control processes). As previously discussed, the NRC anticipates that a licensee would ensure that a proposed change is consistent with endorsed guidance to ensure continued compliance with the proposed provisions. This same change could also impact safety-related structures, systems, and components, either directly (*e.g.*, a proposed change that impacts a physical connection of mitigation strategies equipment to a safety-related component or system) or indirectly (*e.g.*, a proposed change that involves the physical location of mitigation equipment in the vicinity of safety-related equipment that presents a potential for adverse physical/spatial interactions with safety-related components). As such, § 50.59 would need to be applied to evaluate the proposed change for any potential impacts to safety-related SSCs.

Additionally, proposed changes can impact numerous aspects of the facility beyond the safety-related impacts, including implementation of fire protection requirements, security requirements, emergency preparedness requirements, or safety/security interface requirements. Accordingly, it would be necessary for a licensee to ensure that all applicable change control provisions are used to judge the acceptability of facility changes including, for example, change control requirements for fire protection, security, and emergency preparedness. Additionally, recognizing the nature of mitigation strategies and the reliance on human actions, it is also necessary to ensure that the proposed changes satisfy the safety/security interface requirements of § 73.58. It is the obligation of the licensee to comply with all applicable requirements, and as such, the proposed change control provisions could be viewed as unnecessary. However recognizing the potential complexity of proposed facility changes and the complexity of existing regulatory requirements that govern change control, the NRC concluded that adding the proposed change control provision, for the purposes of regulatory clarity, was warranted.

Implementation

The NRC proposes a compliance schedule of 2 years following the effective date of the rule. This proposed rule does not include any special provision for a holder of a COL as of the effective date of the rule for which the Commission has not made the finding required under § 52.103(g) (*i.e.*, a COL holder still in the construction phase). The NRC considers the duration of 2 years prior to compliance with the requirements of this proposed rule to be acceptable because the majority of these requirements have been previously implemented under Orders EA–12–049 and Order EA–12–051 or § 50.54(hh)(2), or are in response to the § 50.54(f) requests for information issued March 12, 2012.

Regulatory Basis for New Emergency Response Capability Requirements

A significant objective of this rulemaking is to make the requirements that were previously imposed under Order EA–12–049 generically applicable. As an implicit part of the implementation of Order EA–12–049, additional emergency response capabilities were included to address a beyond-design-basis external event that impacts multiple power reactor units, and potentially multiple source terms, on the site. In all cases, these additional proposed revisions are considered to be necessary to effectively mitigate such an event, consistent with the NRC's intent in issuing Order EA–12–049. These proposed requirements were not explicitly addressed in the previous regulatory basis documents issued for the two rulemakings that were consolidated into this rulemaking. This section discusses the basis for these proposed emergency response capability provisions.

The March 12, 2012, § 50.54(f) letters (*i.e.*, Request for Information Pursuant to title 10 of the *Code of Federal Regulations* 50.54(f)) requested information from the licensees that, in part, was intended to verify the adequacy of emergency planning to address what was then termed prolonged SBO [8] and multi-unit events. The accident at Fukushima highlighted the need to determine and implement the required staff to fill all necessary positions responding to multi-unit events. Additionally, NRC recognizes that the communication equipment relied upon to coordinate the event response during an ELAP should be powered and maintained.

1. Onsite and Offsite Communications Capability

This proposed rule would require additional communications capabilities for events that result in extended loss of ac power onsite, or potential destruction of offsite communications infrastructure. Because of the destruction to communications capability that occurred at Fukushima, the NRC would propose requirements for licensees to provide a greater capability to communicate with onsite staff to support mitigation of the event, and to support offsite communications to gain any additional support or to perform emergency preparedness functions. The proposed requirements would support effective implementation of the FSGs and were included as part of the implementation of Order EA–12–049.

2. Staffing Assessment

This proposed rule would require an assessment that is considered essential for effective implementation of the FSGs. This assessment matches the one that was conducted under the March 12, 2012, request for information that was developed to align with the requirements included in Order EA–12–049 (*i.e.*, the staffing analysis specifically considered the staffing needs for implementing Order EA–12–049); licensees would not be required to repeat the staffing analysis. A lesson-learned from the Fukushima event is that there are increased staffing demands following a beyond-design-basis external event, and this coupled with the subsequent NRC requirements issued in Order EA–12–049 required the staffing analysis to provide a level of assurance that the FSGs can be implemented. This provision would then support the proposed requirements of the rule to have sufficient staffing to implement the FSGs and EDMGs in conjunction with the EOPs.

[8] While the letter made use of the term ''prolonged SBO,'' the request for information was for a loss of all alternating current power, which was subsequently termed an ELAP. The phrase ''prolonged SBO'' is retained here to accurately reflect the wording used in the letter.

3. Change Control

The NRC would not require a power reactor applicant or licensee to address or implement the proposed communications and staffing analysis requirements through the licensee's or applicant's emergency plan or maintain the capabilities as a part of the emergency preparedness program. This approach would allow for site-specific flexibility in implementation. Therefore, the requirements of maintaining the communications and staffing analysis in an effective emergency plan and controlling changes to it under § 50.54(q) would not apply when implementation of the requirements is not in the emergency plan, but in all cases, the change control process of this proposed rule would apply. However, if an applicant or a licensee incorporates the communications and staffing analysis into the emergency preparedness program through the emergency plan or emergency plan implementing procedures, the requirements of § 50.54(q) would apply.

4. Multiple Source Dose Assessment Capability

This proposed rule would require licensees to have a means for determining the magnitude of, and for continually assessing the impact of, the release of radioactive materials, including from all reactor core and spent fuel pool sources. A lesson learned from the Fukushima Dai-ichi event is that there is a potential for a beyond-design-basis external event to result in multiple source terms from multiple release points, and under such a situation, additional capabilities are necessary to support development of appropriate protective action recommendations. In COMSECY–13–0010, ''Schedule and Plans for Tier 2 Order on Emergency Preparedness for Japan Lessons Learned,'' dated March 27, 2013, the NRC staff informed the Commission that licensees would provide information about their current multiple source term dose assessment capability, or a schedule for implementing such a capability, and that associated implementation would occur by the end of calendar year 2014. Licensee implementation of the multiple source term dose assessment capability would be verified by inspection under TI–2515/191, ''Inspection of the Licensee's Responses to Mitigation Strategies Order EA–12–049, Spent Fuel Pool Instrumentation Order EA–12–051 and Emergency Preparedness Information Requested in NRC March 12, 2012.'' The NRC has been working with the industry and stakeholders through public meetings to review and provide feedback on NEI 13–06, ''Enhancements to Emergency Response Capabilities for Beyond Design Basis Accidents and Events,'' Revision 0, which, in part, would provide licensees with guidance on implementing a multiple source term dose assessment capability.

The capability should be available to support responses during events both within and beyond the plant design basis. Also, the licensee should discuss the site's multi-unit and multiple source term dose assessment capability with the offsite response organizations, particularly, with the agencies that are responsible for making decisions on public protective action recommendations. Agreement on the methods and results would avoid unnecessary delays during the event in making the public protective action decisions, public notification, and the implementation of protective actions.

5. Technology-Neutral Emergency Response Data System

The proposed requirements of 10 CFR part 50, appendix E, section VI, for the Emergency Response Data System (ERDS) would reflect the use of up-to-date technologies and remain technology-neutral so that the equipment supplied by NRC would continue to be replaced as needed, without the need for future rulemaking because equipment becomes obsolete. In 2005, the NRC initiated a comprehensive, multi-year effort to modernize all aspects of the ERDS, including the hardware and software that constitute the ERDS infrastructure at NRC headquarters, as well as the technology used to transmit data from licensed power reactor facilities. As described in NRC Regulatory Issue Summary 2009–13, ''Emergency Response Data System Upgrade From Modem to Virtual Private Network Appliance,'' the NRC engaged licensees in a program that replaced the existing modems used to transmit ERDS data with Virtual Private Network (VPN) devices. The licensees now have less burdensome testing requirements, faster data transmission rates, and increased system security.

V. Section-by-Section Analysis

Proposed § 50.8 Information Collection Requirements: OMB Approval

This section, which lists all information collections in 10 CFR part 50 that have been approved by the Office of Management and Budget (OMB), is revised by adding a reference to § 50.155, the mitigation of beyond-design-basis events rule. As discussed in the ''Paperwork Reduction Act Statement'' section of this document, the OMB has approved the information collection and reporting requirements in the final mitigation of beyond-design-basis events rule. No specific requirement or prohibition is imposed on applicants or licensees in this section.

Proposed § 50.34 Contents of Applications; Technical Information

Section 50.34 identifies the technical information that must be provided in applications for construction permits and operating licenses. Paragraphs (a) and (b) of this section identify the information to be submitted as part of the preliminary or final safety analysis report, respectively. New paragraph (i) of this section would identify information to be submitted as part of an operating license application, but not necessarily included in the final safety analysis report.

The NRC is proposing an administrative change to § 50.34(a)(13) and (b)(12) to remove the word ''stationary'' from the requirement for power reactor applicants who apply for a construction permit or operating license, respectively. Section 50.34(a)(13) and 50.34(b)(12) were added to the regulations in 2009 to reflect the requirements of § 50.150(b) regarding the inclusion of information within the preliminary or final safety analysis reports for applicants subject to § 50.150. Section 50.34(a)(13) and (b)(12) were inadvertently limited to ''stationary power reactors,'' matching the wording of § 50.34(a)(1), (a)(12), (b)(10), and (b)(11), which pertain to seismic risk hazards for stationary power reactors. The NRC does not intend to change the meaning of this requirement by removing the word ''stationary'' from these requirements. This change is intended to ensure consistency in describing the types of applications to which the requirements apply.

Proposed § 50.34(i) would require each application for an operating license to include the applicant's plans for implementing the requirements of proposed § 50.155 and 10 CFR part 50, appendix E, section VII, including a schedule for achieving full compliance with these requirements. This paragraph would also require the application to include a description of: (1) The integrated response capability that would be required by proposed § 50.155(b); (2) the equipment upon which the strategies and guidelines that would be required by proposed § 50.155(b)(1) rely, including the

planned locations of the equipment and how the equipment and SSCs would meet the design requirements of proposed § 50.155(c); and (3) the strategies and guidelines that would be required by proposed § 50.155(b)(2).

Proposed § 50.54 Conditions of Licenses

Applicability of the requirements of § 50.54(hh) is currently governed by § 50.54(hh)(3), which makes these requirements inapplicable to a nuclear power plant for which the certifications required under § 50.82(a) or § 52.110(a)(1) have been submitted. This rulemaking proposes to renumber § 50.54(hh)(3) to reflect the proposed movement of the requirements currently within § 50.54(hh)(2) to proposed § 50.155(b)(2). The proposed § 50.54(hh)(2) includes editorial changes to reflect that the applicability is to the licensee rather than the facility and to correct the section numbers for the required certifications. Additionally, proposed § 50.54(hh)(2) clarifies that the inapplicability is dependent upon the NRC docketing of the certifications rather than licensee submittal because § 50.82(a)(2) and § 52.110(b) set the docketing of the certifications as the point at which operation of the reactor is no longer authorized and fuel cannot be placed in the reactor vessel.

Proposed § 50.155(a), ''Applicability''

Proposed § 50.155(a) would describe which entities would be subject to this proposed rule. Proposed § 50.155(a)(1) would provide that each holder of an operating license for a nuclear power reactor under part 50 and each holder of a combined license under part 52 after the Commission has made the finding under § 52.103(g) that the acceptance criteria have been met, would be required to comply with the requirements of this proposed rule until the time when the NRC has docketed the certifications described in § 50.82(a)(1) or § 52.110(a). These certifications inform the NRC that the licensee has permanently ceased to operate the reactor and permanently removed all fuel from the reactor vessel. Upon the docketing of the certifications, by operation of law under § 50.82(a)(2) or § 52.110(b), the licensee's part 50 or 52 license, respectively, no longer authorizes operation of the reactor or emplacement or retention of fuel in the reactor vessel. At this point, many portions of this proposed rule would not apply to the licensee because the removal of fuel from the reactor vessel would eliminate the risk of a reactor-based beyond-design-basis event and the need to prepare to mitigate those events. Proposed § 50.155(a)(3) would set forth the requirements that would apply to the licensee with § 50.82(a)(2) or § 52.110(b) certification.

Proposed § 50.155(a)(2) would provide that each applicant for an operating license for a nuclear power reactor under part 50 and each holder of a combined license before the Commission makes the finding under § 52.103(g) would be required to comply with the requirements of this proposed rule no later than the date on which the Commission issues the operating license under § 50.57 or makes the finding under § 52.103(g), respectively. Under this regulation, operating license applicants and COL holders would be in compliance with this proposed rule before they begin operating their reactors, thereby providing additional defense-in-depth capabilities at the inception of power operations.

Proposed § 50.155(a)(3) would address power reactor licensees that permanently stop operating and defuel their reactors and begin decommissioning the reactors. The proposed paragraph would provide that when an entity subject to the requirements of proposed § 50.155 submits to the NRC the certifications described in § 50.82(a)(1) or § 52.110(a), and the NRC dockets those certifications, then that licensee would be required to comply with the requirements of proposed § 50.155(b) through (e) associated with maintaining or restoring secondary containment, if applicable, and spent fuel pool cooling capabilities for the reactor described in the § 50.82(a)(1) or § 52.110(a) certifications, except for the requirements in proposed § 50.155(c)(4) and proposed in 10 CFR part 50, appendix E, section VII. In other words, the licensee could discontinue compliance with the requirements in proposed § 50.155 associated with maintaining or restoring core cooling or the primary reactor containment functional capability for the reactor described in the § 50.82(a)(1) or § 52.110(a) certifications. Compliance with the requirements of proposed § 50.155(b) through (e) associated with maintaining or restoring secondary containment, if applicable, and spent fuel pool cooling capabilities would continue as long as spent fuel remains in the spent fuel pool(s) associated with the reactor described in the § 50.82(a)(1) or § 52.110(a) certifications.

Proposed § 50.155(a)(3)(i) would discontinue the requirement to comply with proposed § 50.155(b)(1) requirements concerning beyond-design-basis event strategies and guidelines for spent fuel pool cooling capabilities, and any requirements based on compliance with proposed § 50.155(b)(1), for certain licensees in decommissioning. These licensees would have to perform and retain an analysis demonstrating that sufficient time has passed since the fuel within the spent fuel pool was last irradiated such that the fuel's low decay heat and boil-off period provide sufficient time in an emergency for the licensee to obtain off-site resources to sustain the spent fuel pool cooling function indefinitely and therefore obviate the need to comply with proposed § 50.155(b)(1) using installed or on-site portable equipment.

Proposed § 50.155(a)(3)(i) also would discontinue the requirement to comply with the remaining provisions of proposed § 50.155 except proposed § 50.155(b)(2) when the fuel in the spent fuel pool reaches the point where beyond-design-basis event strategies and guidelines for spent fuel cooling capabilities would no longer be needed.

Proposed § 50.155(a)(3)(ii) would exempt the licensee for Millstone Power Station Unit 1, Dominion Nuclear Connecticut, Inc. from the requirements of proposed § 50.155.

Under proposed § 50.155(a)(3), once a power reactor licensee has permanently stopped operating and defueled its reactor and has removed all irradiated fuel from the spent fuel pool(s) associated with the reactor described in the § 50.82(a)(1) or § 52.110(a) certifications, the licensee could cease compliance with all requirements in proposed § 50.155 for the unit(s) described in the § 50.82(a)(1) or § 52.110(a) certifications.

Proposed § 50.155(b), ''Integrated Response Capability''

Proposed paragraph (b) would require that each applicant or licensee develop, implement, and maintain an integrated response capability that includes: (1) Mitigation strategies for beyond-design-basis external events, (2) extensive damage mitigation guidelines, (3) integration of these strategies and guidelines with emergency operating procedures, (4) sufficient staffing to support implementation of the guidelines in conjunction with the EOPs, and (5) a supporting organizational structure with defined roles, responsibilities, and authorities for directing and performing these strategies, guidelines, and procedures. The intent is to require that the operating and combined license holders described in § 50.155(a) be able to mitigate the consequences of a wide range of initiating events and plant

damage states that can challenge public health and safety.

The specification of strategies, guidelines and procedures for the response capability not only defines the required scope of the capability but sets forth the expectation that the response capability must include planned methods for responding that are documented in some form of written instruction. To serve their function, these strategies, guidelines and procedures must be acted upon by individuals capable of understanding their appropriate application and implementing them. Accordingly, proposed § 50.155(b)(4), in conjunction with proposed § 50.155(d), would require that the response capability include an adequate number of personnel with the knowledge and skills to implement the strategies, guidelines and procedures and that the mitigation activities of these individuals be coordinated in accordance with a defined command and control structure as would be required by proposed § 50.155(b)(5).

Proposed § 50.155(b) would specify that the integrated response capability be ''developed, implemented, and maintained.'' This language reflects NRC consideration that whereas certain elements of the integrated response capability have been developed and are currently in place (*e.g.*, the EDMGs), other elements (*e.g.*, guidelines to mitigate beyond-design-basis external events) may require additional efforts to complete and integrate. The term ''implement'' is used in proposed § 50.155(b) to mean that the integrated response capability is established and available to respond, if needed (*e.g.*, the licensee has approved the strategies, guidelines, and procedures for use). The term ''maintain'' as used in proposed § 50.155(b) reflects the NRC's intent that licensees ensure that the integrated response capability, once established, be preserved consistent with the change control provisions of proposed § 50.155(g).

Proposed § 50.155(b)(1) would establish requirements for applicants and licensees to develop, implement and maintain strategies and guidelines to mitigate beyond-design-basis external events from natural phenomenon that result in an extended loss of ac power concurrent with either a loss of normal access to the ultimate heat sink or, for passive reactor designs, a loss of normal access to the normal heat sink. These provisions would require that the strategies and guidelines be capable of being implemented site-wide and include:

i. Maintaining or restoring core cooling, containment, and spent fuel pool cooling capabilities; and

ii. Enabling the use and receipt of offsite assistance and resources to support the continued maintenance of the functional capabilities for core cooling, containment, and spent fuel pool cooling indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies.

New reactors may establish different approaches from operating reactors in developing strategies to mitigate beyond-design-basis events. For example, new reactors may use installed plant equipment for both the initial and long-term response to an ELAP with less reliance on portable equipment and offsite resources than currently operating nuclear power plants. The NRC would consider the specific plant approach when evaluating the SSCs relied on as part of the mitigating strategies for beyond-design-basis events. Additional information on these strategies is provided in DG–1301, which would endorse an updated version of the industry guidance, for use by applicants and licensees, that incorporates lessons learned and feedback stemming from the implementation of Order EA–12–049, consistent with Commission direction.

The proposed § 50.155(b)(1) would limit the requirements for mitigation strategies to addressing ''external events from natural phenomena.'' This proposed language is meant to differentiate these requirements from those that currently exist within § 50.54(hh)(2), which address beyond-design-basis external events leading to loss of large areas of the plant due to explosions and fire. This proposed provision also results in the need to have mitigation equipment be reasonably protected from the effects of external natural phenomena as discussed in later portions of this proposed notice.

The proposed requirements to enable ''the acquisition and use of offsite assistance and resources to support the functions required by (b)(1)(i) of this section indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies'' means that licensees would need to plan for obtaining sufficient resources (*e.g.*, fuel for generators and pumps, cooling and makeup water) to continue removing decay heat from the irradiated fuel in the reactor vessel and spent fuel pool as well as to remove heat from containment as necessary until an alternate means of removing heat is established. The alternate means of removing heat could be achieved through repairs to existing SSCs, commissioning of new SSCs, or reduction of decay heat levels through the passage of time sufficient to allow heat removal through losses to the ambient environment. More detailed planning for offsite assistance and resources would be necessary for the initial period following the event; less detailed planning would be necessary as the event progresses and the licensee can mobilize additional support for recovery.

Proposed § 50.155(b)(2) would move requirements for EDMGs that currently exist in § 50.54(hh)(2) to proposed § 50.155(b)(2). This move would consolidate the requirements for beyond-design-basis strategies and guidance into a single section to promote efficiency in their consideration and allow for better integration. Although the wording of proposed § 50.155(b)(2) differs from that of § 50.54(hh)(2), no substantive change in the requirements is intended.

The preamble to § 50.155(b)(2) that is contained in § 50.155(b) is worded so that it would require that licensees ''develop, implement, and maintain'' the strategies and guidance required in § 50.155(b)(2) rather than using the wording of § 50.54(hh)(2) to require that licensees ''develop and implement'' the described guidance and strategies. The addition of the word ''maintain'' was proposed in order to correct an inconsistency with the wording of § 50.54(hh)(1), which was promulgated along with § 50.54(hh)(2) in the Power Reactor Security Rulemaking, issued on March 27, 2009 (74 FR 13926), and to clarify that the NRC considers the plain language meaning of the transitive verb ''to implement,'' ''to put into effect,'' as it was used in the context of § 50.54(hh)(2) as including maintenance of the resulting guidance and strategies. The requirement as it was originally issued in the Interim Compensatory Measures Order, EA–02–026, dated February 25, 2002, was worded to require licensees to ''develop'' specific guidance, while the corresponding license conditions imposed by the conforming license amendment was worded to require each affected licensee to ''develop and maintain'' strategies. The NRC believes that the phrase ''develop, implement, and maintain'' would provide better clarity of what is necessary for compliance with the requirements without substantively changing the requirements.

Proposed § 50.155(b)(3) would establish requirements for licensees to integrate the strategies and guidelines in

(b)(1) and (2) with EOPs. The Commission's intent regarding integration of strategies, guidelines, and procedures was introduced in the section-by-section analysis of the proposed § 50.155(b) requirement for an integrated response capability and is described further under ''Integration with EOPs'' of Section IV.D, Proposed Rule Regulatory Bases.

Proposed § 50.155(b)(4) would establish requirements for licensees to provide the staffing necessary for having an integrated response capability to support implementation of the strategies and guidelines in proposed (b)(1) and (2). The number and composition of the response staff should be sufficient to implement mitigation strategies intended to maintain or restore the functions of core cooling, containment, and spent fuel pool cooling for all affected units. The word ''sufficient'' is used in the proposed paragraph to reflect its meaning ''adequate.''

Proposed § 50.155(b)(5) would establish requirements for licensees to have a supporting organizational structure with defined roles, responsibilities, and authorities for directing and performing the guidelines in (b)(1) and (2).

Proposed § 50.155(c) Equipment Requirements

Proposed § 50.155(c)(1) would require that equipment relied on for the mitigation strategies of proposed paragraph (b)(1) have sufficient capacity and capability to simultaneously maintain or restore core cooling, containment, and spent fuel pool capabilities for all the power reactor units and spent fuel pools within the licensee's site boundary.

The phrase sufficient ''capacity and capability'' in proposed § 50.155(c)(1) means that the equipment, and the instrumentation relied on to support the decision making necessary to accomplish the associated mitigating strategies of § 50.155(b)(1), should have the design specifications necessary to assure that it would function and provide the requisite plant information when subjected to the conditions it is expected to be exposed to in the course of the execution of those mitigating strategies. These design specifications would include appropriate consideration of environmental conditions that are predicted in the thermal-hydraulic and room heat up analyses used in the development of the mitigating strategies responsive to § 50.155(b)(1).

Proposed § 50.155(c)(2) would require reasonable protection of the § 50.155(b)(1) equipment rather than the treatment of SSCs important to safety under GDC–2, which requires that those SSCs be designed to withstand the effects of natural phenomena without loss of capability to perform their safety functions. The phrase ''reasonable protection'' was initially proposed in recommendation 4.2 of the NTTF Report in the context of a proposed NRC Order to licensees to require ''reasonable protection'' of equipment required by § 50.54(hh)(2) from the effects of design-basis external events along with providing additional sets of equipment as an interim measure during a subsequent rulemaking on prolonged SBO. The NTTF based this recommendation on the potential usefulness of the EDMGs in circumstances that do not involve loss of a large area of the plant and explained that reasonable protection from external events as used in the NTTF Report meant that the equipment must ''be stored in existing locations that are reasonably protected from significant floods and involve robust structures with enhanced protection from seismic and wind-related events.''

The NRC carried forward the use of the phrase ''reasonable protection'' in Order EA–12–049 with regard to the protection required for equipment associated with the mitigation strategies. That Order did not, however, define ''reasonable protection.'' The NRC guidance in JLD–ISG–2012–01 discussed ''reasonable protection'' as follows:

> Storage locations chosen for the equipment must provide protection from external events as necessary to allow the equipment to perform its function without loss of capability. In addition, the licensee must provide a means to bring the equipment to the connection point under those conditions in time to initiate the strategy prior to expiration of the estimated capability to maintain core and spent fuel pool cooling and containment functions in the initial response phase.

In JLD–ISG–2012–01, the NRC endorsed NEI 12–06, Revision 0, as providing an acceptable method to provide reasonable protection, storage, and deployment of the equipment associated with Order EA–12–049. The NEI 12–06, Revision 0, also omitted a definition for the phrase ''reasonable protection,'' but did provide guidelines for use by licensees for protecting the equipment from the hazards that would be commonly applicable: (1) Seismic hazards; (2) flooding hazards; (3) severe storms with high winds; (4) snow, ice and extreme cold; and(5) high temperatures. These guidelines included the use of structures designed to or evaluated equivalent to American Society for Civil Engineers (ASCE) Standard 7–10, ''Minimum Design Loads for Buildings and Other Structures,'' for the seismic and high winds hazards, rather than requiring the use of a structure that meets the plant's design basis for the Safe Shutdown Earthquake or high winds hazards including missiles. The NEI 12–06 guidelines also allow storage of the equipment above the flood elevation from the most recent site flood analysis, storage within a structure designed to protect the equipment from the flood, or storage below the flood level if sufficient time would be available and plant procedures would address the need to relocate the equipment above the flood level based on the timing of the limiting flood scenario(s). The NEI 12–06 guidelines further provide that multiple sets of equipment may be stored in diverse locations in order to provide assurance that sufficient equipment would remain deployable to assure the success of the strategies following an initiating event. The NRC-endorsed guidelines in NEI 12–06 do not consider concurrent, unrelated beyond-design-basis external events to be within the scope of the initiating events for the mitigating strategies. There is an assumption of a beyond-design-basis external event that establishes the event conditions for reasonable protection, and then it is assumed that the event leads to an ELAP and LUHS. But, for example, there is not an assumption of multiple beyond-design-basis external events occurring at the same time. As a result, reasonable protection for the purposes of compliance with Order EA–12–049 would allow the provision of specific sets of equipment for specific hazards with the required protection for those sets of equipment being against the hazard for which the equipment is intended to be used.

The NRC proposes to continue the use of the phrase ''reasonable protection'' in proposed § 50.155(c)(2) in order to distinguish the character of the required protection of GDC–2, which requires that SSCs important to safety be designed to withstand the effects of natural phenomena, from that of proposed § 50.155(c)(2), which would allow damage to or loss of specific pieces of equipment so long as the capability to use some of the equipment to accomplish its intended purpose is retained. ''Reasonable protection'' would also allow for protection of the equipment using structures that could deform as a result of natural phenomena so long as the equipment could be

deployed from the structure to its place of use.

The remaining portion of proposed § 50.155(c)(2) would set the hazard level for which ''reasonable protection'' of the equipment must be provided. The hazard level would be the level determined for the design basis for the facility for protection of safety-related SSCs from the effects of natural phenomena, or, for the seismic or flooding hazards, the greater of the hazard level determined for the design basis for the facility and the licensee's reevaluated hazards, stemming from the March 12, 2012, NRC letter issued under § 50.54(f). The timing for the proposed requirement for reasonable protection against the reevaluated hazards is set by § 50.155(g) at 2 years following the effective date of this proposed rule. Operating power reactor licensees that were requested to reevaluate their seismic and flooding hazard levels by the NRC by letter dated March 12, 2012, under 10 CFR 50.54(f) are currently on a submittal and NRC review schedule to have confirmation of the reevaluated hazard levels by December 2015. Given that the rulemaking schedule for this proposed rule is to provide the final rule to the Commission in December 2016, the anticipated effective date of the final rule would be mid-to-late 2017. Requiring compliance within 2 years following the effective date of the final rule would allow licensees with a new hazard level the opportunity to take measurements to support any necessary plant modifications during the first refueling outage following NRC confirmation of those levels and the opportunity to implement those modifications in a subsequent refueling outage after the effective date of the rule. The NRC is requesting feedback on this proposed implementation schedule in section VI of this notice.

Proposed paragraph (c)(3) would require that licensees perform adequate maintenance on the equipment relied on for the mitigation strategies responsive to proposed paragraph (b)(1) to assure that the equipment is capable of fulfilling its intended function following a beyond-design-basis external event. The phrase ''adequate maintenance'' means sufficient routine maintenance and testing are performed, reflecting the storage and readiness conditions of the equipment, for a licensee to conclude that the equipment is capable of performing its function to a degree that would support the successful execution of the mitigation strategies of paragraph (b)(1). Provision of ''adequate maintenance'' also entails the establishment of a system of programmatic controls for the equipment to limit the quantity of equipment taken out of service for maintenance and testing in order to limit the unavailability of that equipment appropriately and to provide assurance that sufficient equipment would remain available to satisfy proposed paragraph (c)(1).

Proposed paragraph (c)(4) would make generically applicable the requirements of Order EA–12–051 by requiring that licensees include a reliable means to remotely monitor wide-range spent fuel pool levels to support effective prioritization of event mitigation and recovery actions.

Proposed § 50.155(d) Training Requirements

Proposed § 50.155(d) would require that each licensee specified in § 50.155(a) provide for the training and qualification of personnel that perform activities in accordance with the strategies and guidelines identified in § 50.155(b)(1) and (2).

Proposed § 50.155(e) Drills and Exercises

Proposed § 50.155(e) would require that each licensee and applicant specified in § 50.155(a) conduct drills and exercises for personnel that would perform activities in accordance with the strategies and guidelines identified in § 50.155(b)(1) and (2). The use of drills and exercises allows demonstration and evaluation of the licensee's capability to execute the integrated response capability required by § 50.155(b) mitigation strategies and guidelines in light of the specific plant damage and operational conditions presented by an initiating event. ''Integrated'' is used to describe the licensee's or applicant's approach to using all tools, spaces, qualified personnel and resources during a performance enhancing experience to the furthest extent practical given a set of initiating conditions and within the bounds of a drill or exercise scenario. When two or more strategies or guidelines in § 50.155(b)(1) and (2) are potentially useful, ''integrated'' is meant that transitions to and from one set of strategies or guidelines in § 50.155(b)(1) and (2) to another are coordinated.

This proposed rule uses the words ''drill'' and ''exercise'' as they are defined in NUREG–0654/FEMA–REP–1, Revision 1,[9] meaning an evaluated performance-enhancing experience that reasonably simulates the interactions between appropriate centers, work groups, strike teams, or individuals that would be expected to occur during the event. For the initial drill or exercise, the licensee would be required to demonstrate its capability to transition to and use one or more of the strategies that would be required by § 50.155(b)(1) and (2) from the AOPs or EOPs, whichever would govern for the initiating event and plant degraded conditions, using the equipment and communication systems used for the EOPs and guidelines.

Proposed § 50.155(e)(1) would require the initial drill or exercise to be conducted within 12 months prior to the issuance of the first operating license (OL) for the unit described in the application. This would allow the license applicant to implement any improvements or corrective actions identified during the drill or exercise, and allow the Commission to consider the results of any drill or exercise actions in the decision on whether to authorize the OL. Because § 50.155(e)(1) applies only to applicants for operating licenses, it would not apply to holders of operating licenses under 10 CFR part 50, who are subject to proposed § 50.155(e)(4), or holders of combined licenses under 10 CFR part 52, who are subject to proposed § 50.155(e)(2) through (4). Following issuance of the operating license, the applicant, as a licensee, would be subject to proposed § 50.155(e)(3).

Proposed § 50.155(e)(2) would require the licensee to conduct an initial drill or exercise that demonstrates the capability to transition from the AOPs or EOPs, use one or more of the strategies and guidelines in paragraphs (b)(1) and (2) of this section, and use communications equipment required in 10 CFR part 50, appendix E, section VII, no more than 12 months before the date specified for completion of the last inspections, tests, and analyses in the inspections, tests, analyses, and acceptance criteria (ITAAC) completion schedule as required by § 52.99(a) for the unit described in the combined license.

This proposed rule would set the completion date for the initial drill or exercise at ''no more than 12 months before the date specified for completion of the last inspections, tests, and analyses in the ITAAC completion schedule required by § 52.99(a) for the unit described in the combined license'' in order to allow the licensee to implement any improvements or corrective actions identified during the drill or exercise, and allow the Commission to consider the results of any drill or exercise actions.

The proposed § 50.155(e)(2) requirement for initial drills or exercises is limited to holders of combined

[9] Planning Standards N.1 Exercise and N.2 Drills.

licenses under 10 CFR part 52 before the Commission has made the finding under § 52.103(g). A combined license holder for whom the Commission has already made the finding under § 52.103(g) as of the effective date of the rule would not be subject to proposed § 50.155(e)(2), but would instead be subject to § 50.155(e)(4) for the proposed initial drill requirements.

Proposed § 50.155(e)(3) would require holders of operating power reactor licenses issued under 10 CFR part 50 subsequent to the effective date of this rule, and holders of combine licenses issued under 10 CFR part 52 for whom the Commission has made the finding under § 52.103(g) subsequent to the effective date of this rule, to conduct subsequent drills, exercises, or both that collectively demonstrate a capability to use at least one of the strategies and guidelines in each of proposed § 50.155(b)(1) and (2) in succeeding 8-year intervals. This would require that the drills and exercises performed to demonstrate this capability include transitions from other procedures and guidelines, as applicable, and the use of communications equipment that would be required by proposed 10 CFR part 50, appendix E, section VII. This proposed requirement differs from the proposed § 50.155(e)(1) and (2) initial demonstration requirement, in that it would require licensees to demonstrate a continuing capability, and as such, it is structured to require licensees to demonstrate at least one of the strategies and guidelines from each of the guidelines during the 8-year interval.

Proposed § 50.155(e)(4) would require holders of operating licenses or combined licenses for which the Commission has made the finding under § 52.103(g) to conduct an initial drill or exercise that demonstrates the capability to transition to and use one or more of the strategies and guidelines in proposed § 50.155(b)(1) and (2) and use communications equipment required in 10 CFR part 50, appendix E, section VII. Proposed § 50.155(e)(4) would be equivalent to proposed § 50.155(e)(1) and (2) for initial drills or exercises, but would apply to current licensees. Following this initial drill or exercise, the licensee would be required to conduct subsequent drills, exercises, or both that collectively demonstrate a capability to use at least one of the strategies and guidelines in each of proposed § 50.155(b)(1) and (2) in succeeding 8-year intervals. Proposed § 50.155(e)(4) would be equivalent to proposed § 50.155(e)(3) for subsequent drills or exercises, but would apply to current licensees under 10 CFR part 50 and those under 10 CFR part 52 for whom the Commission has made the finding under § 52.103(g) as of the effective date of the rule.

Proposed § 50.155(f) Change Control

Proposed § 50.155(f) would establish requirements that govern changes in the implementation of the requirements of proposed § 50.155 and 10 CFR part 50, appendix E, section VII. Prior to implementing a proposed change, proposed § 50.155(f)(1) would require the licensee to perform an evaluation to ensure that the provisions of proposed § 50.155 and 10 CFR part 50, appendix E, section VII, continue to be met. Proposed § 50.155(f)(2) would require that licensees maintain documentation of the paragraph (f)(1) evaluations until the requirements of this proposed § 50.155 and 10 CFR part 50, appendix E, section VII, no longer apply. Finally, proposed § 50.155(f)(3) would inform licensees that proposed changes must continue to be subject to all other applicable change control processes.

Proposed § 50.155(g) Implementation

Proposed § 50.155(g) would set schedules for compliance for different classes of licensees depending on the circumstances unique to each class. Paragraphs (g)(1) and (2) would require licensees of operating reactors to comply with all requirements within 2 years of the effective date of the rule.

Proposed 10 CFR Part 50, Appendix E, Section I, Introduction

The NRC proposes adding the sentence, ''Section VII of this appendix also provides for 'Communications and Staffing Requirements for the Mitigation of Beyond-Design-Basis Events' that do not need to be contained within a licensee's emergency plan'' to the end of paragraph I.2. The NRC is not proposing to require an applicant or licensee to address or implement the proposed requirements in Section VII of Appendix E through the applicant's or licensee's emergency plan or to maintain the capabilities as a part of the emergency preparedness program. This would allow for site-specific flexibility in implementation.

Proposed 10 CFR Part 50, Appendix E, Section IV.B, Assessment Actions

The NRC proposes adding the phrase, ''including from all reactor core and spent fuel pool sources,'' into paragraph B.1 following ''determining the magnitude of, and for continually assessing the impact of, the releases of radioactive materials.'' This proposed rule would require all licensees to establish the capability to perform offsite dose assessments during an event involving concurrent radiological releases from all on-site units and spent fuel pools, and for multiple release points. The capability would quantify the total releases from the site and estimate the offsite dose consequences.

Proposed 10 CFR Part 50, Appendix E, Section IV.E, Emergency Facilities and Equipment

The NRC proposes adding the phrase, ''including from all reactor core and spent fuel pool sources,'' into paragraph E.2 following ''equipment for determining the magnitude of, and for continuously assessing the impact of, the release of radioactive materials to the environment.'' This proposed rule would require that equipment used for multi-unit dose assessment be maintained in a ready state.

Proposed 10 CFR Part 50, Appendix E, Section IV, Training

This proposed rule would move the § 50.54(hh)(2) exercise requirement from 10 CFR part 50, appendix E, section IV.F.2.j, to § 50.155(e). This move would change the exercise requirement to a drill requirement, aligning the requirement with the mitigation strategies drill requirements described in § 50.155(e).

This proposed rule would also require that periodic opportunities for a performance-enhancing experience should be provided to personnel responsible for performing multiple source term dose assessment and assessing the results in accordance with the site's emergency plan and implementing procedures.

Proposed 10 CFR Part 50, Appendix E, Section VI, Emergency Response Data Systems

The NRC proposes to change its Emergency Response Data Systems regulations to require the use of technology-neutral equipment. The NRC proposes to restate the requirements in paragraph 3.c to replace the phrase ''onsite modem'' with ''equipment'' and removing references to a specific ''unit'' or equipment use.

Proposed 10 CFR Part 50, Appendix E, Section VII, Communications and Staffing Requirements for the Mitigation of Beyond-Design-Basis Events

Proposed section VII would require power reactor applicants and licensees to conduct a detailed analysis to provide the basis for the staffing necessary for responding to a beyond-design-basis external event as described in § 50.155(b)(1) during an extended loss of ac power (ELAP), and while access to the plant and normal access to the

ultimate or normal heat sink are lost. Additionally, the proposed section VII would require power reactor applicants and licensees to maintain at least one onsite and one offsite communications system functional during an ELAP and a loss of the local communication infrastructure.

The current rule in 10 CFR part 50, appendix E, section IV.E.9, requires, ''At least one onsite and one offsite communication system; each system shall have a backup power source.'' However, the current rule doesn't address an interruption in the offsite communication services. This proposed rule would require the power reactor applicants and licensees to maintain the communication capabilities of communication amongst onsite staff and between onsite staff and offsite personnel in light of the lessons learned at Fukushima Dai-ichi. Furthermore, this proposed rule would require the power reactor applicants and licensees to submit the staffing analysis, results and implementation plans to meet the requirements, and the submissions would afford the NRC the opportunity to identify any common industry implementation problems and address them in guidance.

This proposed rule would require an applicant for an operating license to complete a detailed staffing analysis at least 2 years before the issuance of the first operating license for full power (one authorizing operation above 5 percent of rated thermal power). The time frame allows the applicant to implement any improvements or corrective actions identified during the analysis, and the results of any analysis to inform the Commission's decision in authorizing the operating license.

This proposed rule would require that an applicant for a combined license conduct a detailed staffing analysis and submit the analysis and results to the NRC 2 years before the date specified for completion of the last inspections, tests, and analyses in the ITAAC completion schedule required by § 52.99(a) for the unit described in the combined license. The time frame allows the applicant to implement any staffing and communications system improvements and corrective actions identified during the analysis.

This proposed rule would provide that when the NRC has docketed the certifications described in § 50.82(a)(1) or § 52.110(a) for a power reactor licensee, then that licensee would no longer be subject to section VII of appendix E to 10 CFR part 50 for the unit described in the § 50.82(a)(1) or § 52.110(a) certifications.

Proposed § 52.80 Contents of Applications; Additional Technical Information

Section 52.80 identifies the required additional technical information to be included in an application for a combined license. Proposed paragraph (d) would be amended to require a combined license applicant to include the applicant's plans for implementing the requirements of proposed § 50.155 and 10 CFR part 50, appendix E, section VII, including a schedule for achieving full compliance with these requirements. This paragraph would also require the application to include a description of: (1) The integrated response capability that would be required by proposed § 50.155(b); (2) the equipment upon which the strategies and guidelines that would be required by proposed § 50.155(b)(1) rely, including the planned locations of the equipment and how the equipment and SSCs would meet the design requirements of proposed § 50.155(c); and (3) the strategies and guidelines that would be required by proposed § 50.155(b)(2).

VI. Specific Requests for Comments

The NRC is seeking advice and recommendations from the public on this proposed rule. We are particularly interested in comments and supporting rationale from the public on the following:

1. *Change Control.* The provisions governing change control in proposed § 50.155(f) do not contain a criterion or a set of criteria that would establish a threshold beyond which prior NRC review and approval would be necessary to support a proposed change to the facility impacting the beyond-design-basis aspects of this proposed rulemaking and its supporting implementation guidance. For example, a set of criteria that asks whether a proposed facility change adversely impacts the capability to maintain and restore core cooling, containment, and spent fuel pool cooling capabilities, in conjunction with a criterion that asks whether the proposed facility change adversely impacts the supporting equipment requirements in proposed paragraph (c) might be sufficient for judging whether changes to the facility that impact the implementation of the mitigation strategies of proposed (b)(1) require prior NRC review and approval. What are stakeholders' views on this proposed change control structure, and what do stakeholders suggest for revising the change control process to contain criteria for determining the need for prior NRC review and approval?

2. *Application of Other Change Control Processes.* Proposed § 50.155(f)(3) contains a requirement for licensees to use all applicable change control processes for facility changes, and not simply apply proposed paragraph (f) (*i.e.,* the proposed change control process of paragraph (f) is only applicable to facility changes with respect to their beyond-design-basis aspects and to the extent that such changes impact implementation of the requirements of proposed § 50.155 or the proposed 10 CFR part 50, appendix E, section VII) to the exclusion of other change control processes. This recognizes that facility changes can impact multiple aspects of the plant having different applicable requirements, and being subject to different change control requirements. For example, a licensee may want to make a facility change (*e.g.,* a physical connection device) to support implementation of the beyond-design-basis external event mitigation strategies, and this change might impact safety-related SSCs. In addition to applying the new change control provision to ensure beyond-design-basis aspects of the proposed change result in continued compliance with the new requirements of this proposed rule, the licensee would also need to apply 10 CFR 50.59 to ensure that the facility change does not, due to its impact on safety-related SSCs, require prior NRC approval. The NRC requests feedback on the need for this proposed provision, or suggestions on how it might be improved.

3. *Reasonable Protection.* This proposed rule contains a requirement in proposed § 50.155(c)(2) that equipment supporting the proposed mitigation requirements of paragraph (b)(1) be ''reasonably protected'' from the effects of natural phenomenon including both those in the current plant design basis as well as the reevaluated hazards under the March 12, 2012, § 50.54(f) request concerning flooding and seismic hazards. As a practical matter, implementation of Order EA–12–049 began before the reevaluated hazard information was available. The NRC recognizes that licensees were mindful of the hazard information, and attempted to address it during implementation. The NRC requests feedback concerning any costs and impacts that licensees would expect to occur as a result of this proposed requirement to include such things as rework or changes to previously implemented mitigation strategies.

4. *Mitigation of Beyond-Design-Basis Events Staffing Analysis.* Proposed 10 CFR part 50, appendix E, section VII,

would require an analysis for the staffing necessary to support mitigation of a beyond-design-basis external event. This requirement would supplement the separate staffing analysis requirement that already exists in 10 CFR part 50, appendix E, section IV.A.9. The reason for the two separate staffing analysis requirements is related to the historical imposition of the requirements for the staffing analyses in the emergency preparedness rulemaking of 2011 and the March 12, 2012, Request for Information under 10 CFR 50.54(f). The NRC is seeking feedback on whether it would be more efficient in practice for the two staffing analyses and their corresponding requirements to be combined, particularly for future reactor applicants. Would there be any unintended consequences to keeping the analyses separate or combining them? Is there a better way of achieving the underlying purpose of this requirement?

5. *Training Requirements.* Section 50.155(d) of this proposed rule would require licensees to provide for the training and qualification of personnel that perform activities in accordance with the strategies and guidelines identified in paragraphs (b)(1) and (2) (*i.e.,* mitigation strategies for beyond-design-basis external events and extensive damage mitigation guidelines) using the SAT process as defined in § 55.4. The NRC notes that whereas many individuals at licensee facilities that would be subject to this proposed rule are trained under the SAT process (*e.g.,* individuals specified under § 50.120), some individuals (*e.g.,* firefighting and emergency preparedness personnel) may be currently trained under programs that are not required by NRC regulation to use the SAT process (*e.g.,* National Fire Protection Association standards for training and 10 CFR part 50, appendix E). It is not the NRC's intent to extend the requirement for SAT-based training to the entirety of such programs. Rather, the intent of the proposed requirement would be to ensure that any training that is not currently part of existing programs but would be needed for performing activities in accordance with the strategies and guidelines identified in paragraphs proposed § 50.155(b)(1) and (2) be identified and provided for in accordance with the SAT process. The NRC requests comment on potential unintended consequences of the proposed rule language for programs not currently required to be SAT-based and if unintended consequences are identified, proposed alternative language for requiring the necessary amendments to such programs.

6. *Drill or Exercise Frequency.* Proposed § 50.155(e)(3) and (4) would require that following an initial drill or exercise, licensees would be required to conduct subsequent drills, exercises, or both, that collectively demonstrate a capability to use at least one of the strategies and guidelines in each of proposed § 50.155(b)(1) and (2) in succeeding 8-year intervals. This would require that the drills or exercises performed to demonstrate this capability include transitions from other procedures and guidelines as applicable, and the use of communications equipment that would be required by proposed 10 CFR part 50, appendix E, section VII, and that licensees shall not exceed 8 years between any consecutive drills or exercises. These requirements would be separate from the 8-year emergency preparedness exercise cycle requirements in 10 CFR part 50, appendix E, section IV.F. The NRC is seeking feedback on whether the drill or exercise frequency proposed by § 50.155(e)(3) and (4) is appropriate.

7. *Equipment Requirements.* Proposed § 50.155(c)(1) would require the capacity and capability of the equipment relied on for the mitigation strategies required by proposed § 50.155 (b)(1) to be sufficient to simultaneously maintain or restore core cooling, containment, and spent fuel pool cooling capabilities for all the power reactor units within the site boundary. Additionally, proposed § 50.155(c)(3) would require the equipment relied on for the mitigation strategies in proposed § 50.155(b)(1) to receive adequate maintenance such that the equipment is capable of fulfilling its intended function. The intent of these two proposed provisions is to make elements of Order EA–12–049 generically-applicable. Order EA–12–049 did not contain a specific maintenance requirement, but instead contained a performance-based requirement ''to develop, implement and maintain strategies,'' and failure to perform adequate maintenance would likely lead to a failure to meet this more general requirement, which is also contained in proposed § 50.155(b)(1). Additionally, the supporting guidance for this proposed rule for proposed § 50.155(b)(1) carries forward the same approach that was used for implementation of Order EA–12–049, and contains a number of programmatic controls that in an analogous fashion to the maintenance provision in proposed § 50.155(c)(3), if not followed, would likely lead to a loss of equipment capacity and capability and result in a failure to comply with the proposed § 50.155(b)(1). Therefore, the NRC would like stakeholder views on the need for a separate maintenance provision.

8. *Equipment Protection Implementation Deadline.* The NRC is proposing to require licensees to reasonably protect the equipment relied upon to implement the mitigation strategies required by proposed § 50.155(b)(1). That equipment would need to be reasonably protected from the effects of natural phenomena that are, at a minimum, equivalent to the design basis of the facility. This proposed rule would require each licensee that received the March 12, 2012, NRC letter issued under § 50.54(f) to provide reasonable protection against that reevaluated seismic or flooding hazard(s) by 2 years following the effective date of the final rule, if the reevaluated hazard exceeds the design basis of its facility. This is based on the anticipated completion dates for the licensees' hazard reevaluations and their confirmation by the NRC and the potential need for planning and implementing modifications during refueling outages. The NRC recognizes that certain licensees may need input into their analyses of reevaluated hazards from other government agencies, without any certainty of when that input would be provided. This reliance on information from other entities could remove from the licensee's control the ability to comply with the rule by a specific date. The NRC requests comments on the proposed implementation schedule, including suggestions for the criteria that licensees would need to satisfy to extend the schedule.

9. *Methodology for addressing reevaluated hazards.* In SRM–COMSECY–14–0037, the Commission affirmed that: (1) Licensees for operating nuclear power plants need to address the reevaluated flooding hazards within their mitigating strategies for beyond-design-basis external events; and (2) licensees for operating nuclear power plants may need to address some specific flooding scenarios that could significantly damage the power plant site by developing targeted or scenario-specific mitigating strategies, possibly including unconventional measures, to prevent fuel damage in reactor cores or spent fuel pools. The NRC is proposing to require licensees for operating nuclear power plants to address the reevaluated flooding hazard levels by reasonably protecting the mitigating strategies equipment to those levels if they exceed the design-basis flood level

for the facility. Alternatively, the NRC could: (1) Place this requirement within § 50.155(b)(1) as a condition the associated strategies and guidelines must be capable of addressing; or (2) include a separate requirement for targeted or scenario-specific mitigating strategies as an option to address the reevaluated flooding hazards. The NRC seeks comment on whether the first of these options would be a better means to communicate the need for a licensee's strategies and guidelines to be capable of execution in the context of the new flooding hazard levels than including the requirement in § 50.155(c)(2). The NRC seeks additional comment on whether it would be appropriate to allow further flexibility in the licensee's strategies and guidelines by establishing an alternative means of compliance that does not include the surrogate condition of a loss of all alternating current power for specific beyond-design-basis conditions such as the reevaluated flooding hazards. For example, if a licensee could protect their internal power distribution system and emergency diesel generators from the reevaluated flooding hazard, it may not be necessary for the licensee to assume the loss of all alternating current power.

10. *Command and Control.* Requirements for command and control and organizational structures currently exist in numerous locations, including 10 CFR part 50, appendix E, section IV.A, as well as within the typical administrative controls portions of technical specifications for power reactor licensees. These requirements do not plainly limit the scope of the roles, responsibilities and authorities to events within the design or licensing basis of the facility, although past NRC practice has been to treat these requirements in that manner. This proposed rule includes a further requirement on the subject in order to clarify the scope of what is required for organizational structures at power reactor licensees. Alternatively, the NRC is considering whether the expansion of scope of regulatory oversight of the organizational structures would require imposition of a new requirement or the expansion of scope would be better accomplished by communicating the understanding that the scope of the existing requirements covers the full spectrum of events that would be included in this rulemaking. The latter method of accomplishing this would have the potential advantage of leaving the requirements for command and control and organizational structures in a single regulation (*i.e.,* 10 CFR part 50, appendix E, section IV.A). The NRC seeks stakeholder input on this subject.

VII. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or established in 10 CFR 2.810, ''NRC size standards.''

VIII. Availability of Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analyses examine the costs and benefits of the alternatives considered by the NRC. The NRC requests public comment on the draft regulatory analysis. The draft regulatory analysis is available as indicated in the ''Availability of Documents'' section of this document. Comments on the draft analysis may be submitted to the NRC as indicated in the **ADDRESSES** section of this document.

IX. Availability of Guidance

The NRC is issuing for comment draft regulatory guidance (DG) to support the implementation of the proposed requirements in this rulemaking. You may access information and comment submissions related to the DGs by searching on *http://www.regulations.gov* under Docket ID NRC–2014–0240.

The DG–1301, ''Flexible Mitigation Strategies for Beyond-Design-Basis Events,'' provides licensees and applicants with an acceptable method of responding to an ELAP and demonstrating compliance with the proposed regulations requiring additional defense-in-depth measures for the mitigation of beyond-design-basis external events.

The DG–1317, ''Wide-Range Spent Fuel Pool Level Instrumentation,'' describes one method of providing safety enhancements in the form of reliable spent fuel pool instrumentation for beyond-design-basis external events.

The DG–1319, ''Integrated Response Capabilities for Beyond-Design-Basis Events,'' describes one method the NRC endorses to enhance a site's ability to implement the on-site emergency preparedness programs and guidelines and better cope with conditions resulting from a beyond-design-basis external event.

You may submit comments on the draft regulatory guidance by the following methods:

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0240. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.*
- Mail comments to: Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

X. Backfitting and Issue Finality

Proposed Rule

As required by §§ 50.109, 52.63, 52.83, and 52.98, the Commission has completed a backfit and issue finality analysis for this proposed rule. The Commission finds that the backfit contained in this proposed rule, (*i.e.,* multiple source term dose assessment), is considered, as part of the set of emergency preparedness (EP) requirements, to provide continued reasonable assurance of adequate protection of public health and safety under 10 CFR 50.109(a)(4)(ii), consistent with the regulatory basis for EP that has existed for more than three decades. Availability of the backfit and issue finality analysis is indicated in the ''Availability of Documents'' section of this document.

Draft Regulatory Guidance

The NRC is issuing, for public comment, three DGs that would support implementation of this proposed rule: DG–1301, ''Flexible Mitigation Strategies for Beyond-Design-Basis Events''; DG–1317, ''Wide-Range Spent Fuel Pool Level Instrumentation''; and DG–1319, ''Integrated Response Capabilities for Beyond-Design-Basis Events.'' These DGs would provide guidance on the methods acceptable to the NRC for complying with this proposed rule. The DGs would apply to all current holders of, and applicants for operating licenses under 10 CFR part 50 and combined licenses under 10 CFR part 52.

Issuance of the DGs in final form would not constitute backfitting under § 50.109 and would not otherwise be inconsistent with the issue finality provisions in 10 CFR part 52. As discussed in the ''Implementation'' section of each DG, the NRC has no current intention to impose the DGs, if finalized, on current holders of an operating license or combined license.

Applying the DGs, if finalized, to applications for operating licenses or combined licenses would not constitute

backfitting as defined in § 50.109 or be otherwise inconsistent with the applicable issue finality provisions in 10 CFR part 52, because such applicants are not within the scope of entities protected by § 50.109 or the applicable issue finality provisions in 10 CFR part 52. Neither § 50.109 nor the issue finality provisions under 10 CFR part 52—with certain exceptions—were intended to apply to every NRC action that substantially changes the expectations of current and future applicants.

XI. Cumulative Effects of Regulation

The NRC engaged extensively with external stakeholders throughout this rulemaking and related regulatory activities. Public involvement has included: (1) Issuance of two ANPRs and two draft regulatory basis documents that requested stakeholder feedback; (2) issuance of conceptual and preliminary proposed rule language in support of public meetings; (3) numerous public meetings with the ACRS; and (4) many more public meetings that supported both the development of the draft regulatory basis documents as well as development of the implementing guidance for the two orders that this rulemaking would make generically applicable (*i.e.,* Orders EA–12–049 and EA–12–051). Section II.E of this notice provides a more detailed discussion of public involvement.

The NRC is following its CER process with regard to the issuance of draft guidance with this proposed rule to support more informed external stakeholder feedback. The ''Availability of Guidance'' section of this document describes how the public can access the draft guidance for which the NRC seeks external stakeholder feedback.

Finally, the NRC is requesting CER feedback on the following questions:

1. In light of the current or projected CER challenges, does this proposed rule's compliance dates provide sufficient time to implement the new proposed requirements, including changes to programs, procedures, and the facility? Specifically, the current proposed rule would require each holder of an operating license or holder of a combined license for which the Commission made the finding specified in § 52.103(g) to comply with all provisions of this proposed rule no later than 2 years following the effective date of the rule, unless otherwise specified in proposed 10 CFR part 50, appendix E, section VII. The NRC requests feedback on what this time period should be.

2. If current or projected CER challenges exist, what should be done to address this situation? For example if more time is required for implementation of the new requirements, what period of time would be sufficient?

3. Do other NRC regulatory actions, including the post-Fukushima actions and any other actions (*e.g.,* generic communications, license amendment requests, inspection findings of a generic nature), influence the implementation of this proposed rule's requirements?

4. Are there unintended consequences associated with implementation of these requirements, including implementing the requirements as a priority over other facility modifications that are currently being prioritized and scheduled?

5. Please provide feedback on the NRC's supporting regulatory analysis for this rulemaking. Of note, the regulatory analysis estimates the cost of implementing both Order EA–12–049 and Order EA–12–051. The NRC would appreciate feedback regarding those estimates.

XII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31883). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XIII. Environmental Assessment and Proposed Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this proposed rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and an environmental impact statement is not required. The basis of this determination reads as follows: The proposed action would not result in any radiological effluent impact as it would not change any design basis structures, systems, or components that function to limit the release of radiological effluents during or after an accident. This proposed rule does not change the standards and requirements for radiological releases and effluents. None of the revisions or additions in this proposed rule would affect current occupational or public radiation exposure. The proposed rule would not cause any significant non-radiological impacts, as it would not affect any historic sites or any non-radiological plant effluents. The NRC concludes that this proposed rule would not cause any significant radiological or non-radiological impacts on the human environment.

The determination of this environmental assessment is that there would be no significant effect on the quality of the human environment from this action. Public stakeholders should note, however, that comments on any aspect of this environmental assessment may be submitted to the NRC as indicated in the **ADDRESSES** section of this document. The environmental assessment is available as indicated under the ''Availability of Documents'' section.

The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and has requested comments.

XIV. Paperwork Reduction Act

This proposed rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This proposed rule has been submitted to the OMB for approval of the information collection requirements.

Type of submission, new or revision: Revision.

The title of the information collection: Mitigation of Beyond-Design-Basis Events Proposed Rule.

The form number if applicable: Not applicable.

How often the collection is required: Once.

Who will be required or asked to report: Operating nuclear power reactor sites (comprised of 65 operating sites).

An estimate of the number of annual responses: 65 (65 recordkeepers).

The estimated number of annual respondents: 65.

An estimate of the total number of hours needed to complete the requirement or request: 6500.

Abstract: In response to the Great East Japan Earthquake of March 11, 2011, the NRC is seeking to: (1) Make the requirements in Order EA–12–049 and Order EA–12–051 generically-applicable giving consideration to lessons learned from implementation of the orders; (2) establish new requirements for an integrated response capability; (3) establish new requirements for actions that are related to onsite emergency response; and (4) address a number of PRMs submitted following the March 2011 Fukushima Dai-ichi event.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

A copy of the OMB clearance package and proposed rule is available in ADAMS under Accession No. ML15274A031 or may be viewed free of charge at the NRC's PDR, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, MD 20852. You may obtain information and comment submissions related to the OMB clearance package by searching on *http://www.regulations.gov* under Docket ID NRC–2014–0240.

You may submit comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the previously stated issues, by the following methods:

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0059.
- Mail comments to: FOIA, Privacy, and Information Collections Branch, Office of Information Services, Mail Stop: T–5 F53, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 or to Vlad Dorjets, Desk Officer, Office of Information and Regulatory Affairs (3150–0011 and 3150–0151), NEOB–10202, Office of Management and Budget, Washington, DC 20503; telephone: 202–395–7315, email: *oira_submission@omb.eop.gov.*

Submit comments by December 14, 2015. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XV. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the NRC is issuing this proposed rule that would amend 10 CFR parts 50 and 52 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement. Criminal penalties as they apply to regulations in 10 CFR parts 50 and 52 are discussed in §§ 50.111 and 52.303.

XVI. Coordination with NRC Agreement States

The Agreement States are receiving notification of the publication of this proposed rule.

XVII. Compatibility of Agreement State Regulations

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs,'' approved by the Commission on June 20, 1997, and published in the **Federal Register** (62 FR 46517; September 3, 1997), this proposed rule is classified as compatibility category ''NRC.'' Compatibility is not required for Category ''NRC'' regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of title 10 of the *Code of Federal Regulations,* and although an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with a particular State's administrative procedure laws, but does not confer regulatory authority on the State.

XVIII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would add requirements for the mitigation of beyond-design-basis events. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XIX. Public Meeting

The NRC will conduct a public meeting on this proposed rule for the purpose of describing the proposed rule to the public and answering questions from the public on the proposed rule.

The NRC will publish a notice of the location, time, and agenda for the meeting on the NRC's public meeting Web site within at least 10 calendar days before the meeting. Stakeholders should monitor the NRC's public meeting Web site for information about the public meeting at: *http://www.nrc.gov/public-involve/public-meetings/index.cfm.* The meeting notice will also be added to the Federal rulemaking Web site at *http://www.regulations.gov* under Docket ID NRC–2014–0240. See the ''Availability of Documents'' section of this document for instructions on how to subscribe to a docket on the Federal rulemaking Web site.

XX. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No./web link/Federal Register citation
Primary Rulemaking Documents	
Draft Regulatory Analysis and Backfit and Issue Finality Analysis	ML15265A610
Environmental Assessment	ML15260B014
Draft Regulatory Guides	
DG–1301, Flexible Mitigation Strategies for Beyond-Design-Basis Events	ML13168A031
DG–1317, Wide-Range Spent Fuel Pool Level Instrumentation	ML14245A454
DG–1319, Integrated Response Capabilities for Beyond-Design-Basis Events	ML14265A070

Document	ADAMS accession No./web link/Federal Register citation
Other References	
ACRS Transcript—Full Committee, Discuss Preliminary Mitigation of Beyond-Design-Basis Events Rulemaking Language, December 4, 2014.	ML14345A387
ACRS Transcript—Fukushima Subcommittee, Discuss Preliminary Mitigation of Beyond-Design-Basis Events Rulemaking Language, November 21, 2014.	ML14337A671
ACRS Transcript—Full Committee, Discuss Consolidation of Station Blackout Mitigation Strategies and Onsite Emergency Response Capabilities Rulemakings, July 10, 2014.	ML14223A631
ACRS Transcript—Full Committee, Discuss the Station Blackout Mitigation Strategies Regulatory Basis, June 5, 2013.	ML13175A344
ACRS Transcript—Joint Fukushima and PRA Subcommittees, Discuss CPRR Technical Analysis, August 22, 2014.	ML14265A059
ACRS Transcript—Plant Operations and Fire Protection Subcommittee, Discuss the Onsite Emergency Response Capabilities Regulatory Basis, February 6, 2013.	ML13063A403
ACRS Transcript—Reactor Safeguards Reliability and PRA Subcommittee, Discuss CPRR Technical Analysis, November 19, 2014.	ML14337A651
ACRS Transcript—Regulatory Policies and Practices Subcommittee, Discuss the Station Blackout Mitigation Strategies Regulatory Basis, December 5, 2013, and April 23, 2013.	ML13148A404
American National Standards Institute/American Nuclear Society 3.2–2012, ''Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants''.	*http://www.ans.org/store/*
CLI–12–09, South Carolina Electric & Gas Co. and South Carolina Public Service Authority (Also Referred to as Santee Cooper).	ML12090A531
COMGBJ–11–0002, ''NRC Actions Following the Events in Japan,'' March, 21, 2011	ML110800456
COMSECY–13–0002, ''Consolidation of Japan Lessons Learned Near-Term Task Force Recommendations 4 and 7 Regulatory Activities,'' January 25, 2013.	ML13011A037
COMSECY–13–0010, ''Schedule and Plans for Tier 2 Order on Emergency Preparedness for Japan Lessons Learned,'' dated March 27, 2013.	ML12339A262
COMSECY–14–0037, ''Integration of Mitigating Strategies for Beyond-Design-Basis External Events and The Reevaluation of Flooding Hazards,'' November 21, 2014.	ML14309A256
Conceptual Consolidated Preliminary Proposed Rule Language for NTTF Recommendations 4, 7, 8 and 9, February 21, 2014.	ML14052A057
Containment Performance and Release Reduction Draft Regulatory Basis	ML15022A214
Crystal River Unit 3, ''NRC Response to Duke Energy's Final Response to The March 2012 Request for Information Letter,'' January 22, 2014.	ML13325A847
Crystal River Unit 3, ''Rescission of Order EA–12–049, 'Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond Design Basis External Events','' August 27, 2013.	ML13212A366
Crystal River Unit 3, Final Response to March 12, 2012 Information Request Regarding Recommendations 2.1, 2.3 and 9.3, September 25, 2013.	ML13274A341
Crystal River Unit 3, ''Rescission Of Order EA–12–051, 'Order Modifying Licenses With Regard To Reliable Spent Fuel Pool Instrumentation','' August 27, 2013.	ML13203A161
Federal Register Notice—Enhancements to Emergency Preparedness Regulations, Final Rule, November 23, 2011.	76 FR 72560
Federal Register Notice—Onsite Emergency Response Capabilities, Regulatory Basis, October 25, 2013	78 FR 63901
Federal Register Notice—Onsite Emergency Response	77FR 23161
Capabilities, Advance Notice of Proposed Rulemaking, April 18, 2012	
Federal Register Notice—Onsite Emergency ResponseCapabilities, Draft Regulatory Basis, January 8, 2013	78 FR 1154
Federal Register Notice—Onsite Emergency Response	78 FR 68774
Capabilities, Preliminary Proposed Rule Language, November 15, 2013	
Federal Register Notice—Power Reactor Security Requirements, Final Rule, March 27, 2009	74 FR 13926
Federal Register Notice—PRM–50–100, Petition for Rulemaking Submitted by the Natural Resources Defense Council, Inc., July 23, 2013.	78 FR 44034
Federal Register Notice—PRM–50–101, Petition for Rulemaking Submitted by the Natural Resources Defense Council, Inc., March 21, 2012.	77 FR 16483
Federal Register Notice—PRM–50–102, Petition for Rulemaking; Submitted by the Natural Resources Defense Council, Inc., April 27, 2012.	77 FR 25104
Federal Register Notice—PRM–50–96, Long-Term Cooling and Unattended Water Makeup of Spent Fuel Pools, Consideration in the Rulemaking Process, December 18, 2012.	77 FR 74788
Federal Register Notice—PRM–50–97, PRM–50–98,	76 FR 58165
PRM–50–99, PRM–50–100, PRM–50–101, PRM–50–102, Petitions for Rulemaking Submitted by the Natural Resources Defense Council, Inc., Notice of Receipt, September 20, 2011.	
Federal Register Notice—Statement of Principles and Policy for the Agreement State Program; Policy Statement on Adequacy and Compatibility of Agreement State Programs, Final Policy Statements, September 3, 1997.	62 FR 46517
Federal Register Notice—Station Blackout Mitigation Strategies, Draft Regulatory Basis and Draft Rule Concepts, April 10, 2013.	78 FR 21275
Federal Register Notice—Station Blackout Mitigation Strategies, Regulatory Basis, July 23, 2013	78 FR 44035
Federal Register Notice—Station Blackout, Advance Notice of Proposed Rulemaking, March 20, 2012	77 FR 16175
Interim Staff Guidance, NSIR/DPR–ISG–01, ''Emergency Planning for Nuclear Power Plants,'' November 2011	ML113010523
JLD–ISG–2012–01, ''Compliance with Order EA–12–049, Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events,'' Revision 0, August 29, 2012.	ML12229A166
Inspection Manual Chapter (IMC) 0308, ''Reactor Oversight Process Basis Document,'' Attachment 2, ''Technical Basis for Inspection Program,'' October, 16, 2006.	ML062890421
Kewaunee Power Station, 60-Day Response to March 12, 2012, Information Request Regarding Recommendation 2.1. Seismic Reevaluations, April 29, 2013.	ML13123A004

Document	ADAMS accession No./web link/Federal Register citation
Kewaunee Power Station, Rescission of Order EA–12–049, ''Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond Design Basis External Events,'' June 10, 2014.	ML14059A411
Kewaunee Power Station, Response to Request for Relief from Responding Further to the March 2012 Request for Information Letter for Recommendation 9.3, January 22, 2014.	ML13322B255
Letter from ACRS to Chairman Jaczko, ''Initial ACRS Review of: (1) The NRC Near-Term Task Force Report on Fukushima and (2) Staff's Recommended Actions to be Taken Without Delay,'' October 13, 2011.	ML11284A136
Letter from ACRS to Mr. R. W. Borchardt, ''Response To February 27, 2012 Letter Regarding Final Disposition Of Fukushima-Related ACRS Recommendations In Letters Dated October 13, 2011, And November 8, 2011,'' March 13, 2012.	ML12072A197
Letter from R.W. Borchardt to J. Sam Amijo, Chairman ACRS, ''Final Disposition Of The Advisory Committee On Reactor Safeguards' Review Of (1) The U.S. Nuclear Regulatory Commission Near–Term Task Force Report On Fukushima, (2) Staff's Recommended Actions To Be Taken Without Delay (SECY–11–0124), And (3) Staff's Prioritization Of Recommended Actions To Be Taken In Response To Fukushima Lessons–Learned,'' February 27, 2012.	ML12030A198
Letter from ACRS to Chairman Stephen G. Burns, ''Draft SECY Paper Proposed Rulemaking: Mitigation of Beyond-Design-Basis Events (RIN 3150–AJ49),'' April 22, 2015.	ML15111A271
Letter from Mark Satorius to John Stetkar, ''Draft SECY Paper Proposed Rulemaking: Mitigation of Beyond-Design-Basis Events (RIN 3150–AJ49),'' May 15, 2015.	ML15125A485
Letter from NEI to Mark Satorious, ''Use of Qualitative Factors in Regulatory Decision Making,'' May 11, 2015	ML15217A314
NEI 06–12, ''B.5.b Phase 2&3 Submittal Guideline,'' Revision 2, December 2006	ML070090060
NEI 10–05, ''Assessment of On-Shift Emergency Response Organization Staffing and Capabilities,'' Revision 0, June 2011.	ML111751698
NEI 12–01, ''Guideline for Assessing Beyond Design Basis Accident Response Staffing and Communications Capabilities,'' Revision 0, May 2012.	ML12125A412
NEI 12–06, ''Diverse and Flexible Coping Strategies (FLEX) Implementation Guide,'' Revision 1a, October 2015 ...	ML15279A426
NEI 13–06, ''Enhancements to Emergency Response Capabilities for Beyond Design Basis Accidents and Events,'' Revision 0, September 2014.	ML14269A230
NEI 14–01, ''Emergency Response Procedures and Guidelines for Beyond Design Basis Events and Severe Accidents,'' Revision 0, September 2014.	ML14269A236
NEI 91–04 (formerly NUMARC 91–04), Severe Accident Issue Closure Guidelines, Revision 1, December 1994	ML072850981
Non-concurrence NCP–2015–003	ML15091A646
NUREG–0654/FEMA–REP–1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' Revision 1, November 1980.	ML040420012
NUREG–0660, Volume1 and 2, ''NRC Action Plan Developed as a Result of the TMI–2 Accident,'' May 1980	ML072470526 and ML072470524
NUREG–0711, ''Human Factors Engineering Program Review Model,'' Revision 3, November 2012	ML12324A013
NUREG–0737, ''Clarification of TMI Action Plan Requirements,'' November 1980	ML102560051
NUREG–0737, ''Clarification of TMI Action Plan Requirements,'' Supplement 1, November 1980	ML102560009
NUREG–1935, ''State-of-the-Art Reactor Consequence Analyses (SOARCA) Report,'' November 2012	ML12332A057
Omaha Public Power District's Overall Integrated Plan (Redacted) in Response to March 12, 2012, Order EA–12–049, February 28, 2013.	ML13116A208
Order EA–02–026, ''Order for Interim Safeguards and Security Compensatory Measures,'' February 25, 2002	ML020510635
Order EA–12–049, ''Issuance of Order to Modify Licenses With Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events,'' (Mitigating Strategies Order), March 12, 2012.	ML12054A735
Order EA–12–051, ''Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation''	ML12056A044
Preliminary Proposed Rule Language for Mitigation of Beyond-Design-Basis Events Rulemaking made available to the public on November 13, 2014, and December 8, 2014, to support public discussion with the ACRS.	ML14336A641
Preliminary Proposed Rule Language for Mitigation of Beyond-Design-Basis Events Rulemaking, August 15, 2014	ML14218A253
PRM 50–102, ''NRDC's Petition For Rulemaking to Require More Realistic Training on Severe Accident Mitigation Guidelines,'' July 26, 2011.	ML11216A242
PRM 50–97, ''NRDC's Petition For Rulemaking to Require Emergency Preparedness Enhancements for Prolonged Station Blackouts,'' July 26, 2011.	ML11216A237
PRM–50–100, ''NRDC's Petition For Rulemaking to Require Licensees to Improve Spent Nuclear Fuel Pool Safety,'' July 26, 2014.	ML11216A240
PRM–50–101, ''NRDC's Petition For Rulemaking to Revise 10 CFR § 50.63,'' July 26, 2011	ML11216A241
PRM–50–96, ''Petition for Rulemaking Submitted by Thomas Popik on Behalf of the Foundation for Resilient Societies to adopt regulations that would require facilities licensed by the NRC under 10 CFR Part 50 to assure long-term cooling and unattended water makeup of spent fuel pools,'' March 14, 2011.	ML110750145
PRM–50–98, ''NRDC's Petition For Rulemaking to Require Emergency Preparedness Enhancements for Multiunit Events,'' July 26, 2011.	ML11216A238
Regulatory Issue Summary 2009–13, ''Emergency Response Data System Upgrade from Modem to Virtual Private Network Appliance,'' September 28, 2009.	ML092670124
Request for Information Pursuant to Title 10 of the *Code of Federal Regulations* 50.54(f) Regarding Recommendations 2.1, 2.3, and 9.3, of the Near-Term Task Force Review of Insights from the Fukushima Dai-Ichi Accident, March 12, 2012.	ML12053A340
Severe Accident Management Guidance Technical Basis Report, Volume 1: Candidate High-Level Actions and Their Effects. EPRI, Palo Alto, CA: 2012. 1025295.	*http://www.epri.com/abstracts/Pages/ProductAbstract.aspx?ProductId=1025295*
Severe Accident Management Guidance Technical Basis Report, Volume 2: The Physics of Accident Progression. EPRI, Palo Alto, CA: 2012. 1025295.	
San Onofre Nuclear Generating Station Units 2 and 3, ''Rescission of Order EA–12–049, 'Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond Design Basis External Events','' June 30, 2014.	ML14113A572

Document	ADAMS accession No./web link/Federal Register citation
San Onofre Nuclear Generating Station Units 2 and 3, ''NRC Response To Southern California Edison's Final Response to the March 2012 Request for Information Letter,'' January 22, 2014.	ML13329A826
San Onofre Nuclear Generating Station Units 2 and 3, Final Response to the March 12, 2012 Information Request Regarding Near-Term Task Force Recommendations 2.1, 2.3, and 9.3 and Corresponding Commitments San Onofre Nuclear Generating Station (SONGS) Units 2 and 3, September 30, 2013.	ML13276A020
San Onofre Nuclear Generating Station Units 2 and 3, ''Rescission of Order EA–12–051, 'Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation','' June 30, 2014.	ML14111A069
SECY–11–0093, ''Near-Term Report and Recommendations for Agency Actions Following the Events in Japan,'' July 12, 2011.	ML11186A950
SECY–11–0124, ''Recommended Actions to be Taken Without Delay from the Near-Term Task Force Report,'' September 9, 2011.	ML11245A127
SECY–11–0137, ''Prioritization of Recommended Actions to Be Taken in Response to Fukushima Lessons Learned,'' October 3, 2011.	ML11272A111
SECY–12–0025, ''Proposed Orders and Requests for Information in Response to Lessons Learned From Japan's March 11, 2011, Great Tōhoku Earthquake and Tsunami,'' February 17, 2012.	ML12039A103
SECY–13–0132, ''Plan for Updating the U.S. Nuclear Regulatory Commission's Cost Benefit Guidance,'' January 2, 2014.	ML13274A495
SECY–14–0046, ''Fifth 6-Month Status Update on Response to Lessons Learned From Japan's March 11, 2011, Great Tohoku Earthquake and Subsequent Tsunami,'' April 17, 2014.	ML14064A523
SECY–15–0065, ''Proposed Rulemaking: Mitigation of Beyond-Design-Basis Events (RIN 3150–AJ49),'' April 30, 2015.	ML15049A201
SECY–89–012, ''Staff Plans for Accident Management Regulatory and Research Programs,'' January 18, 1989	ML12251A414
SECY–97–132, ''Status of the Integration Plan for Closure of Severe Accident Issues and the Status of Severe Accident Research,'' June 23, 1997.	ML992930144
SECY–98–131, ''Status of the Integration Plan for Closure of Severe Accident Issues and the Status of Severe Accident Research,'' June 8, 1998.	ML992880008
SRM–SECY–15–0065, ''Proposed Rulemaking: Mitigation of Beyond-Design-Basis Events (RIN 3150–AJ49)''	ML15239A767
SRM–COMSECY–14–0037, ''Integration of Mitigating Strategies for Beyond-Design-Basis External Events and The Reevaluation of Flooding Hazards''.	ML15089A236
SRM–COMSECY–13–0002, ''Consolidation of Japan Lessons Learned Near-Term Task Force Recommendations 4 and 7 Regulatory Activities''.	ML13063A548
SRM–SECY–11–0093, ''Near-Term Report and Recommendations for Agency Actions Following the Events in Japan,'' August 19, 2011.	ML112310021
SRM–SECY–11–0137, ''Prioritization of Recommended Actions to Be Taken in Response to Fukushima Lessons Learned,'' December 15, 2011.	ML113490055
SRM–SECY–13–0132, ''U.S. Nuclear Regulatory Commission Staff Recommendation for the Disposition of Recommendation 1 of the Near-Term Task Force Report,'' May 19, 2014.	ML14139A104
SRM–SECY–2011–0124, ''Recommended Actions to be Taken Without Delay From the Near-Term Task Force Report,'' October 18, 2011.	ML112911571
Temporary Instruction 2515/191, ''Inspection of the Licensee's Responses to Mitigation Strategies Order EA–12–049, Spent Fuel Pool Instrumentation Order EA–12–051 and Emergency Preparedness Information Requested in NRC March 12, 2012,'' March 12, 2012.	ML14273A444
Temporary Instruction 2515/184, ''Availability and Readiness Inspection of Severe Accident Management Guidelines (SAMGs),'' April 29, 2011.	ML11115A053
Vermont Yankee Nuclear Power Station, ''Rescission of Order EA–12–049, 'Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond Design Basis External Events','' March 2, 2015.	ML14321A685
Vermont Yankee Nuclear Power Station, ''Rescission of Order EA–12–051, 'Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation','' March 2, 2015.	ML14321A696

Throughout the development of this rulemaking, the NRC may post documents related to this rulemaking, including public comments, on the Federal rulemaking Web site at *http://www.regulations.gov* under Docket ID NRC–2014–0240. The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC–2014–0240); (2) click the ''Sign up for Email Alerts'' link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

List of Subjects

10 CFR Part 50

Administrative practice and procedure, Antitrust, Classified information, Criminal penalties, Education, Fire prevention, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 52

Administrative practice and procedure, Antitrust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Incorporation by reference, Inspection, Limited work authorization, Nuclear power plants and reactors, Penalties, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and recordkeeping requirements, Standard design, Standard design certification.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is proposing to adopt the following amendments to 10 CFR parts 50 and 52.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

■ 1. The authority citation for 10 CFR part 50 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Sec. 109, Pub. L. 96–295, 94 Stat. 783.

■ 2. In § 50.8, paragraph (b) is revised to read as follows:

§ 50.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 50.30, 50.33, 50.34, 50.34a, 50.35, 50.36, 50.36a, 50.36b, 50.44, 50.46, 50.47, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.60, 50.61, 50.61a, 50.62, 50.63, 50.64, 50.65, 50.66, 50.68, 50.69, 50.70, 50.71, 50.72, 50.74, 50.75, 50.80, 50.82, 50.90, 50.91, 50.120, 50.150, 50.155, and appendices A, B, E, G, H, I, J, K, M, N, O, Q, R, and S to this part.

* * * * *

■ 3. In § 50.34, paragraphs (a)(13), (b)(12), and (i) are revised to read as follows:

§ 50.34 Contents of applications; technical information.

(a) * * *

(13) On or after July 13, 2009, power reactor applicants who apply for a construction permit shall submit the information required by 10 CFR 50.150(b) as a part of their preliminary safety analysis report.

(b) * * *

(12) On or after July 13, 2009, power reactor applicants who apply for an operating license which is subject to 10 CFR 50.150(a) shall submit the information required by 10 CFR 50.150(b) as a part of their final safety analysis report.

* * * * *

(i) *Mitigation of beyond-design-basis events.* Each application for a power reactor operating license under this part must include the applicant's plans for implementing the requirements of § 50.155 and 10 CFR part 50, appendix E, section VII, including a schedule for achieving full compliance with these requirements. The application must also include a description of:

(1) The integrated response capability required by § 50.155(b);

(2) The equipment upon which the strategies and guidelines required by § 50.155(b)(1) rely, including the planned locations of the equipment and how the equipment and SSCs meet the design requirements of § 50.155(c); and

(3) The strategies and guidelines required by § 50.155(b)(2).

■ 4. In § 50.54 remove paragraph (hh)(2), redesignate paragraph (hh)(3) as (hh)(2) and revise it to read as follows:

§ 50.54 Conditions of licenses.

* * * * *

(hh) * * *

(2) This section does not apply to a licensee that has submitted the certifications required under § 50.82(a)(1) or § 52.110(a) of this chapter once the NRC has docketed those certifications.

* * * * *

■ 5. Add § 50.155 under the undesignated center heading Additional Standards for Lisences, Certifications, and Regulatory Approvals to read as follows:

§ 50.155 Mitigation of Beyond-Design-Basis Events.

(a) *Applicability.* (1) Each holder of an operating license for a nuclear power reactor under this part and each holder of a combined license under part 52 of this chapter after the Commission has made the finding under § 52.103(g), before the NRC's docketing of the license holder's certifications described in § 50.82(a)(1) or § 52.110(a) of this chapter, shall comply with the requirements of this section and section VII of appendix E to 10 CFR part 50.

(2) Each applicant for an operating license for a nuclear power reactor under this part and each holder of a combined license under part 52 of this chapter before the Commission has made the finding under § 52.103(g) shall comply with the requirements of this section and section VII of appendix E to 10 CFR part 50 no later than the date on which the Commission issues the operating license under § 50.57 or makes the finding under § 52.103(g), respectively.

(3) When the NRC has docketed the certifications described in § 50.82(a)(1) or § 52.110(a) of this chapter, submitted by a licensee subject to the requirements of this section and section VII of appendix E to 10 CFR part 50, then that licensee shall comply with the requirements of § 50.155(b) through (e) associated with maintaining or restoring secondary containment capabilities, if applicable, and spent fuel pool cooling capabilities, but need not comply with § 50.155(c)(4) and section VII of appendix E to 10 CFR part 50, for the unit described in the § 50.82(a)(1) or § 52.110(a) certifications until the spent fuel pool(s) is empty of all irradiated fuel.

(i) Holders of operating licenses or combined licenses for which the NRC has docketed the certifications described in § 50.82(a)(1) or § 52.110(a) of this chapter need not meet the requirements of this section except for paragraph (b)(2) of this section once the decay heat of the fuel in the spent fuel pool can be removed solely by heating and boiling of water within the spent fuel pool and the boil-off period provides sufficient time for the licensee to obtain off-site resources to sustain the spent fuel pool cooling function indefinitely, as demonstrated by an analysis performed and retained by the licensee.

(ii) Dominion Nuclear Connecticut, Inc. (Millstone Power Station Unit 1) is not subject to the requirements of this section.

(b) *Integrated response capability.* Each applicant or licensee shall develop, implement, and maintain an integrated response capability that includes:

(1) *Mitigation Strategies for Beyond-Design-Basis External Events.* Strategies and guidelines to mitigate beyond-design-basis external events from natural phenomena that result in an extended loss of all ac power concurrent with either a loss of normal access to the ultimate heat sink or, for passive reactor designs, a loss of normal access to the normal heat sink. These strategies and guidelines must be capable of being implemented site-wide and must include:

(i) Maintaining or restoring core cooling, containment, and spent fuel pool cooling capabilities; and

(ii) The acquisition and use of offsite assistance and resources to support the functions required by paragraph (b)(1)(i) of this section indefinitely, or until sufficient site functional capabilities can be maintained without the need for the mitigation strategies.

(2) *Extensive Damage Mitigation Guidelines (EDMGs).* Strategies and guidelines to maintain or restore core cooling, containment, and spent fuel pool cooling capabilities under the circumstances associated with loss of large areas of the plant due to explosions or fire, to include strategies and guidelines in the following areas:

(i) Firefighting;

(ii) Operations to mitigate fuel damage; and

(iii) Actions to minimize radiological release.

(3) Integration of strategies and guidelines in paragraphs (b)(1) and (2) of this section with the Emergency Operating Procedures (EOPs).

(4) Sufficient staffing to support implementation of the strategies and guidelines in paragraphs (b)(1) and (2) of this section in conjunction with the EOPs to respond to events.

(5) A supporting organizational structure with defined roles, responsibilities, and authorities for directing and performing the strategies and guidelines in paragraphs (b)(1) and (2) of this section.

(c) *Equipment.* (1) The capacity and capability of the equipment relied on for the mitigation strategies required by paragraph (b)(1) of this section must be sufficient to simultaneously maintain or restore core cooling, containment, and spent fuel pool cooling capabilities for all the power reactor units within the site boundary.

(2) The equipment relied on for the mitigation strategies required by paragraph (b)(1) of this section must be reasonably protected from the effects of natural phenomena that are equivalent to the design basis of the facility.

(i) Each licensee that received the March 12, 2012, NRC letter issued under § 50.54(f) concerning reevaluations of seismic and flooding hazard levels, shall provide reasonable protection against that reevaluated seismic or flooding hazard(s) if it exceeds the design basis of its facility.

(3) The equipment relied on for the mitigation strategies in paragraph (b)(1) of this section must receive adequate maintenance such that the equipment is capable of fulfilling its intended function.

(4) The equipment relied on for the mitigation strategies in paragraph (b)(1) of this section must include reliable means to remotely monitor wide-range spent fuel pool levels to support effective prioritization of event mitigation and recovery actions.

(d) *Training requirements.* Each licensee shall provide for the training and qualification of personnel that perform activities in accordance with the strategies and guidelines identified in paragraphs (b)(1) and (2) of this section. The training and qualification on these activities must be developed using the systems approach to training as defined in § 55.4 of this chapter except for elements already covered under other NRC regulations.

(e) *Drills and Exercises.* (1) An applicant for an operating license issued under this part shall conduct an initial drill or exercise that demonstrates the capability to transition to and use one or more of the strategies and guidelines in paragraphs (b)(1) and (2) of this section and use the communications equipment required in 10 CFR part 50, appendix E, section VII, no more than 12 months before issuance of an operating license for the unit described in the license application.

(2) A holder of a combined license issued under 10 CFR part 52 before the Commission has made the finding under § 52.103(g), shall conduct an initial drill or exercise that demonstrates the capability to transition to and use one or more of the strategies and guidelines in paragraphs (b)(1) and (2) of this section and use the communications equipment required in 10 CFR part 50, appendix E, section VII, no more than 12 months before the date specified for completion of the last inspections, tests, and analyses in the inspections, tests, analyses, and acceptance criteria (ITAAC) completion schedule required by § 52.99(a) for the unit described in the combined license.

(3) Once the Commission issues an operating license to an entity described in paragraph (e)(1) of this section or makes the finding under § 52.103(g) of this chapter for an entity described in paragraph (e)(2) of this section, the licensee shall conduct subsequent drills, exercises, or both that collectively demonstrate a capability to use at least one of the strategies and guidelines in each of paragraphs (b)(1) and (2) of this section in succeeding 8-year intervals. The drills and exercises performed to demonstrate this capability must include transitions from other procedures and guidelines as applicable, and the use of communications equipment required in 10 CFR part 50, appendix E, section VII. Each licensee shall not exceed 8 years between any consecutive drills or exercises.

(4) A holder of an operating license issued under this part or a combined license under 10 CFR part 52 for which the Commission has made the finding specified in § 52.103(g) as of [EFFECTIVE DATE OF THE FINAL RULE], shall conduct an initial drill or exercise that demonstrates the capability to transition to and use one or more of the strategies and guidelines in paragraphs (b)(1) and (2) of this section and use communications equipment required in 10 CFR part 50, appendix E, section VII, by [DATE 4 YEARS AFTER EFFECTIVE DATE OF THE FINAL RULE]. Following this initial drill or exercise, the licensee shall conduct subsequent drills, exercises, or both that collectively demonstrate a capability to use at least one of the strategies and guidelines in each of paragraphs (b)(1) and (2) of this section in succeeding 8-year intervals. The drills and exercises performed to demonstrate this capability must include transitions from other procedures and guidelines as applicable, and the use of communications equipment required in 10 CFR part 50, appendix E, section VII. Each licensee shall not exceed 8 years between any consecutive drills or exercises.

(f) *Change Control.* (1) A licensee may make changes in the implementation of the requirements in this section and 10 CFR part 50, appendix E, section VII, without NRC approval, *provided* that before implementing each such change, the licensee performs an evaluation demonstrating that the provisions of this section and 10 CFR part 50, appendix E, section VII, continue to be met.

(2) Documentation of all changes, including the evaluation required by paragraph (f)(1) of this section, shall be maintained until the requirements of this section and section VII of appendix E to 10 CFR part 50 no longer apply.

(3) Changes in the implementation of requirements in this chapter subject to change control processes other than paragraph (f) of this section and resulting from changes in the implementation of the requirements in this section and 10 CFR part 50, appendix E, section VII, must be processed via their respective change control processes.

(g) *Implementation.* Unless otherwise specified in this section or 10 CFR part 50, appendix E, section VII:

(1) Each holder of an operating license under this part on [EFFECTIVE DATE OF THE FINAL RULE] shall comply with all the provisions of this section no later than 2 years following [EFFECTIVE DATE OF THE FINAL RULE].

(2) Each holder of a combined license under 10 CFR part 52 for which the Commission made the finding specified in § 52.103(g) as of [EFFECTIVE DATE OF THE FINAL RULE] shall comply with all the provisions of this section no later than 2 years following [EFFECTIVE DATE OF THE FINAL RULE].

■ 6. In appendix E to part 50 revise paragraphs I.2, IV.B.1, IV.E.2, IV.F.2.j, and VI.3.c and add section VII to read as follows:

Appendix E to Part 50—Emergency Planning and Preparedness for Production and Utilization Facilities

* * * * *

I. * * *

2. This appendix establishes minimum requirements for emergency plans for use in attaining an acceptable state of emergency

preparedness. These plans shall be described generally in the preliminary safety analysis report for a construction permit and submitted as part of the final safety analysis report for an operating license. These plans, or major features thereof, may be submitted as part of the site safety analysis report for an early site permit. Section VII of this appendix also provides for ''Communications and Staffing Requirements for the Mitigation of Beyond-Design-Basis Events'' that do not need to be contained within a licensee's emergency plan.

* * * * *

IV. * * *

B. * * *

1. The means to be used for determining the magnitude of, and for continually assessing the impact of, the release of radioactive materials, including from all reactor core and spent fuel pool sources, shall be described, including emergency action levels that are to be used as criteria for determining the need for notification and participation of local and State agencies, the Commission, and other Federal agencies, and the emergency action levels that are to be used for determining when and what type of protective measures should be considered within and outside the site boundary to protect health and safety. The emergency action levels shall be based on in-plant conditions and instrumentation in addition to onsite and offsite monitoring. By June 20, 2012, for nuclear power reactor licensees, these action levels must include hostile action that may adversely affect the nuclear power plant. The initial emergency action levels shall be discussed and agreed on by the applicant or licensee and state and local governmental authorities, and approved by the NRC. Thereafter, emergency action levels shall be reviewed with the State and local governmental authorities on an annual basis.

* * * * *

E. * * *

2. Equipment for determining the magnitude of and for continuously assessing the impact of the release of radioactive materials, including from all reactor core and spent fuel pool sources, to the environment;

* * * * *

F. * * *

2. * * *

j. The exercises conducted under paragraph 2 of this section by nuclear power reactor licensees must provide the opportunity for the ERO to demonstrate proficiency in the key skills necessary to implement the principal functional areas of emergency response identified in paragraph 2.b of this section. Each exercise must provide the opportunity for the ERO to demonstrate key skills specific to emergency response duties in the control room, TSC, OSC, EOF, and joint information center. Additionally, in each eight calendar year exercise cycle, nuclear power reactor licensees shall vary the content of scenarios during exercises conducted under paragraph 2 of this section to provide the opportunity for the ERO to demonstrate proficiency in the key skills necessary to respond to the following scenario elements: hostile action directed at the plant site, no radiological release or an unplanned minimal radiological release that does not require public protective actions, an initial classification of or rapid escalation to a Site Area Emergency or General Emergency, and integration of offsite resources with onsite response. The licensee shall maintain a record of exercises conducted during each eight year exercise cycle that documents the content of scenarios used to comply with the requirements of this paragraph. Each licensee shall conduct a hostile action exercise for each of its sites no later than December 31, 2015. The first 8-year exercise cycle for a site will begin in the calendar year in which the first hostile action exercise is conducted. For a site licensed under 10 CFR part 52, the first 8-year exercise cycle begins in the calendar year of the initial exercise required by section IV.F.2.a of this appendix.

* * * * *

VI. * * *

3. * * *

c. In the event of a failure of NRC-supplied equipment, a replacement will be furnished by the NRC for licensee installation.

* * * * *

VII. Communications and Staffing Requirements for the Mitigation of Beyond Design Basis Events

All changes associated with implementation of the requirements in this section are subject to § 50.155(f). The change control provisions of § 50.54(q) do not apply to proposed changes associated with implementation of the requirements in this section, unless the requirements in this section are implemented within the licensee's emergency plan.

1. Each nuclear power reactor applicant or licensee shall perform a detailed analysis demonstrating that sufficient staff is available to implement the guidelines and strategies to respond to a beyond design basis external event resulting in impeded access to the nuclear power plant, an extended loss of ac power sources concurrent with either a loss of normal access to the ultimate heat sink or, for passive reactor designs, a loss of normal access to the normal heat sink, and affecting all units on-site.

a. An applicant for a power reactor operating license under this part shall perform this analysis and submit it to the NRC under § 50.4 at least 2 years before the issuance of the first operating license for full power (one authorizing operation above 5 percent of rated thermal power).

b. A holder of a combined license issued under 10 CFR part 52 before the Commission has made the finding under § 52.103(g) of this chapter shall perform this analysis and submit it to the NRC under § 52.3 of this chapter at least 2 years before the date specified for completion of the last inspections, tests, and analyses in the inspections, tests, analyses, and acceptance criteria (ITAAC) completion schedule required by § 52.99(a) of this chapter for the plant.

c. Each holder of a power reactor operating license or combined license for which the Commission has made the finding specified in § 52.103(g) of this chapter as of [EFFECTIVE DATE OF THE FINAL RULE], before the NRC's docketing of the license holder's certifications described in § 50.82(a)(1) or § 52.110(a) of this chapter, shall perform this analysis and submit it to the NRC under § 50.4 no later than [DATE 365 DAYS AFTER EFFECTIVE DATE OF THE FINAL RULE].

2. Each nuclear power reactor applicant or licensee shall make and describe adequate provisions for at least one onsite and one offsite communications system capable of remaining functional during an extended loss of alternating current power including the effects of the loss of the local communications infrastructure.

a. An applicant for a power reactor operating license under this part shall make these provisions no later than the issuance of the first operating license for full power (one authorizing operation above 5 percent of rated thermal power).

b. A holder of a combined license issued under 10 CFR part 52 before the Commission has made the finding under § 52.103(g) of this chapter shall make these provisions no later than the date specified for completion of the last inspections, tests, and analyses in the ITAAC completion schedule required by § 52.99(a) of this chapter for the plant.

c. Each holder of a power reactor operating license under this part or a combined license issued under 10 CFR part 52 for which the Commission has made the finding specified in § 52.103(g) of this chapter as of [EFFECTIVE DATE OF THE FINAL RULE], before the NRC's docketing of the license holder's certifications described in § 50.82(a)(1) or § 52.110(a) of this chapter, shall make these provisions no later than [DATE 365 DAYS AFTER EFFECTIVE DATE OF THE FINAL RULE].

PART 52—LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS

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

Authority: Atomic Energy Act of 1954, secs. 103, 104, 147, 149, 161, 181, 182, 183, 185, 186, 189, 223, 234 (42 U.S.C. 2133, 2134, 2167, 2169, 2201, 2231, 2232, 2233, 2235, 2236, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

■ 8. In § 52.80, revise paragraph (d) to read as follows:

§ 52.80 Contents of applications; additional technical information.

* * * * *

(d) The applicant's plans for implementing the requirements of § 50.155 of this chapter and 10 CFR part 50, appendix E, section VII, including a schedule for achieving full compliance with these requirements, and a description of:

(1) The integrated response capability required by § 50.155(b) of this chapter;

(2) The equipment upon which the strategies and guidelines required by § 50.155(b)(1) of this chapter rely, including the planned locations of the equipment and how the equipment and SSCs meet the design requirements of § 50.155(c) of this chapter; and

(3) The strategies and guidelines required by § 50.155(b)(2) of this chapter.

Dated at Rockville, Maryland, this 2nd day of November, 2015.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2015–28589 Filed 11–12–15; 8:45 am]

BILLING CODE 7590–01–P

FEDERAL REGISTER

Vol. 80 Friday,

No. 219 November 13, 2015

Part IV

Department of Justice

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances: Placement of Three Synthetic Phenethylamines Into Schedule I; Proposed Rule

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–423]

Schedules of Controlled Substances: Placement of Three Synthetic Phenethylamines Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing three synthetic phenethylamines: 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5), 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82) and 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36) into schedule I of the Controlled Substances Act. This proposed scheduling action is pursuant to the Controlled Substance Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe.

DATES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before December 14, 2015. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),'' may file a request for hearing, notice of appearance, or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45, 1316.47, and/or 1316.48, as applicable. Requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before December 14, 2015.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–423'' on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152.
- *Hearing requests:* All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing, Notice of Appearance at Hearing, Waiver of an Opportunity for a Hearing or To Participate in a Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. In accordance with 21 CFR 1308.44(a)–(c), requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those ''adversely affected or aggrieved by any rule or proposed rule

issuable pursuant to section 201 of the Act (21 U.S.C. 811).'' 21 CFR 1300.01. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and may include a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of a hearing is restricted to: ''(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed. . . .'' All requests for hearing and waivers of participation must be sent to the DEA using the address information provided above.

Legal Authority

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, and are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for the purposes of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed. . . .'' The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS),[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Assistant Secretary of the HHS and an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles, or proposes to handle, 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe.

Background

On November 15, 2013, the DEA published a final order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe), 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe), and 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe) into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 78 FR 68716. That final order, which became effective on the date of publication, was based on findings by the Deputy Administrator of the DEA that the temporary scheduling of these three synthetic phenethylamine substances was necessary to avoid an imminent hazard to public safety pursuant to 21 U.S.C. 811(h)(1). At the time the final order took effect, section 201(h)(2) of the CSA, 21 U.S.C. 811(h)(2), required that the temporary scheduling of a substance expire at the end of two years from the date of issuance of the scheduling order, and it provided that, during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, temporary scheduling of that substance could be extended for up to 1 year. Pursuant to 21 U.S.C. 811(h)(2), the temporary scheduling of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe expires on November 14, 2015, unless extended. An extension of the temporary order is being ordered by the DEA Administrator in a separate action.

As described in the final order published on November 15, 2013, 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are structurally and pharmacologically similar to 2,5-dimethoxy-4-iodophenethylamine (2C-I), 2,5-dimethoxy-4-chlorophenethylamine (2C-C), and 2,5-dimethoxy-4-bromophenthylamine (2C-B). While 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have been used as research chemicals and/or studied due to their misuse and abuse, based on the review of the scientific literature, there are no known medical uses for 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe. The Assistant Secretary of Health for the U.S. Department of Health and Human Services (HHS) has advised that there are no exemptions or approvals in effect for 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe under section 505 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 355. As stated by the HHS, 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have no known accepted medical use. They are not the subject of any approved new drug applications (NDAs) or investigational new drug applications (INDs), and are not currently marketed as approved drug products.

Proposed Determination to Schedule 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe

Pursuant to 21 U.S.C. 811(a)(1), proceedings to add a drug or substance to those controlled under the CSA may be initiated by the Attorney General, or her delegate, the DEA Administrator. On July 23, 2014, the DEA requested a scientific and medical evaluation and scheduling recommendations from the Assistant Secretary of Health for the HHS for 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe pursuant to 21 U.S.C. 811(b). Upon receipt of the scientific and medical evaluation and scheduling recommendations from the HHS dated

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

August 12, 2015, the DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe pursuant to 21 U.S.C. 811(c).

Included below is a brief summary of each of the eight factors as analyzed by the HHS and the DEA, and as considered by the DEA in this proposed action. Please note that both the DEA and the HHS analyses are available under ''Supporting Documents'' of the public docket for this proposed rule at *http://www.regulations.gov* under docket number DEA–423.

1. *The Drug's Actual or Relative Potential for Abuse:* As described by the HHS, the abuse potentials of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are associated with their abilities to produce psychoactive effects that are similar to those produced by other schedule I hallucinogens that have a high potential for abuse such as 2,5-dimethoxy-4-methylamphetamine (DOM), 2,5-dimethoxy-4-iodophenethylamine (2C-I), 2,5-dimethoxy-4-chlorophenethylamine (2C-C), 2,5-dimethoxy-4-bromophenthylamine (2C-B), and lysergic acid diethylamide (LSD).

The legislative history of the CSA suggests the DEA consider the following factors when determining whether a particular drug or substance has a potential for abuse: [2]

(1) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community;

(2) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels;

(3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

(4) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

The substances 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have no approved medical uses in the United States and they have been encountered on the illicit market with adverse outcomes on the public health and safety. Human use of these substances is due to the individual's own initiative and it has been established that they are being abused for their psychoactive properties. For these reasons, there are no legitimate drug channels for NBOMEs as marketed drugs and these substances should be limited to scientific research. Reports from public health and law enforcement communicate that these substances are being abused and taken in amounts sufficient to create a hazard to one's own health as evidenced by the emergency department admissions and deaths and this misuse is also a significant safety issue for those in the community. Data from forensic databases are used as indicators of illicit activity with drugs and abuse [3] within the United States and include the System to Retrieve Information from Drug Evidence (STRIDE),[4] STARLiMS, and the National Forensic Laboratory Information System (NFLIS).[5] From January 2011 through August 2015 (query dates: September 22 & 23, 2015), STRIDE, STARLiMS, and NFLIS databases registered a total of 4,868 reports containing the three NBOMes (25I-NBOMe—2,714 reports; 25C-NBOMe—1,291 reports; 25B-NBOMe—863 reports). These drug reports represent NBOMe data reported to these databases by participating DEA, Customs and Border Protection (CBP), state, and local/municipal forensic laboratories in the United States. 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have been reported to produce hallucinogenic effects. There have been numerous anecdotal self-reports substantiating that 25I-NBOMe, 25C-NBOMe, and/or 25B-NBOMe and their products are abused by humans for their hallucinogenic effects, as well as published reports indicating an increase in the abuse of these substances. These reports of abuse are in agreement with the large number of encounters of these substances by law enforcement.

2. *Scientific Evidence of the Drug's Pharmacological Effects, If Known:* Studies show that 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are full agonists at the 5-HT_{2A} serotonin receptor based on the receptor binding and functional activity profiles in *in vitro* studies. *In vivo* experimental animal studies have reported that 25I-NBOMe and 25B-NBOMe significantly increase the head twitch response, a response associated with hallucinogens that act on the 5-HT_{2A} serotonin receptor. In addition, 25I-NBOMe was more potent than the schedule I hallucinogen 2C-I, and 25B-NBOMe was more potent than the hallucinogen DOI in eliciting the head twitch response.

According to the HHS, there are no reported human clinical trials with 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe but there is evidence that these substances are abused for their hallucinogenic effects. Clinical case reports indicate that 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe produce a number of stimulant-like adverse effects. According to the HHS, adverse health effects associated with products containing synthetic phenethylamines include: Hallucinations (open and closed eye visuals), nausea, excessive sweating, tachycardia, psychomotor agitation, prolonged seizures, rhabdomyolysis, and renal failure.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* 25I-NBOMe, 25C-NBOMe and 25B-NBOMe are classified as 2C compounds, a structural class with a phenethylamine core substituted with methoxy groups on the 2 and 5 positions of the phenyl ring. 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are structurally similar to the 2C-X compounds (2C-I, 2C-C, and 2C-B, respectively) which are controlled as schedule I hallucinogenic substances under the CSA. Data indicate that 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are rapidly distributed from the blood into the brain, liver, and bile. Studies examining elimination of NBOMes have reported that 90% of the parent compound is eliminated from the plasma within 90 minutes and urine samples suggest that the corresponding 2C compounds (*i.e.,* 2C-I, 2C-C, and 2C-B) may be metabolites of the NBOMes. According to the HHS, 25I-NBOMe,

[2] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 2 (1970); *reprinted in* 1970 U.S.C.C.A.N. 4566, 4601.

[3] While law enforcement data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011.

[4] STRIDE was a database that collected analyses of results from drug evidence sent to DEA laboratories. Evidence was submitted by the DEA, other Federal agencies, and select local law enforcement agencies. On October 1, 2014, STARLiMS replaced STRIDE as the DEA system of record for forensic laboratory drug evidence data.

[5] NFLIS is a DEA program and a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. The NFLIS database also contains Federal data from CBP. NFLIS includes drug chemistry results from completed analyses only.

25C-NBOMe and 25B-NBOMe are not U.S. Food and Drug Administration (FDA)-approved drug products. The DEA is not aware of any currently accepted medical use or NDAs for 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe. Furthermore, the Assistant Secretary of the HHS responded that there were no current INDs or NDAs for these synthetic phenethylamines in the scientific and medical evaluations and recommendations addressed to the DEA Deputy Administrator dated August 12, 2015.

4. *Its History and Current Pattern of Abuse:* Law enforcement has encountered 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe in the illicit drug market. These synthetic substances are available over the Internet and sold through illicit channels, often purported to be schedule I hallucinogens, like LSD. Market names for products found to contain NBOMe include, but are not limited to: ''Smiles,'' ''N-bomb,'' ''Cimbi-5,'' ''25I,'' and others. 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have been seized as powders, as solutions, on blotter paper, and laced on food items. According to the HHS, 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are abused in the same manner as schedule I hallucinogens such as LSD, DOM, 2C-I, 2C-B, and 2C-C. Furthermore, evidence indicates that youth appear to be the primary abusers of these synthetic substances.

5. *The Scope, Duration, and Significance of Abuse:* Evidence from law enforcement indicates that the abuse of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe is widespread. Law enforcement databases registered a total of 4,868 drug reports involving 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe (query date: September 22 & 23, 2015) spanning a time period from January 2011 through August 2015. Law enforcement encounters of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe have occurred in at least 43 states and the District of Columbia. As stated by the HHS, based on the pharmacological properties of the substances, it is reasonable to assume that, if uncontrolled, the scope, duration, and significance of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe abuse could be similar to that of LSD. Concerns over the abuse of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe have prompted state, military, and international control of these substances.

6. *What, if Any, Risk There is to the Public Health:* Law enforcement, medical community representatives, and public health officials have reported exposure incidents that demonstrate the dangers associated with the abuse of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe to individual abusers as well as to the public. Furthermore, the HHS stated that the NBOMe series of drugs have much narrower ''therapeutic'' ratios and much smaller margins of safety than most other known hallucinogens, and so carry greater risk of acute toxicity and death.

There have been numerous reports of deaths associated with the abuse of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe. Published case reports have also described deaths associated with the ingestion of the NBOMe substances. As of October 2013, the DEA has obtained medical examiner and postmortem toxicology reports implicating some combination of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe in the death of 17 individuals. The average age of these individuals is 20 years (range 15 to 29 years). The circumstances surrounding the deaths include acute toxicity (14) or unpredictable, violent behavior due to 25I-NBOMe toxicity ultimately leading to death (3). As detailed above, there are reported instances of emergency department admissions and deaths associated with the abuse of these synthetic substances. There is no accepted medical use of these substances in the United States.

7. *Its Psychic or Physiological Dependence Liability:* According to the HHS, the pharmacologic profiles of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe strongly suggest that they possess physiological and psychological dependence liability that is similar to that of schedule I hallucinogens such as LSD, 2C-I, 2C-C, 2C-B, and DOM, although there are no studies or case reports that document the psychic or physiological dependence potential of these substances. However, based on the structural similarity between the NBOMes (25I-NBOMe, 25C-NBOMe, and 25B-NBOMe) and other schedule I hallucinogens (2C-I, 2C-B, 2C-C) and the similarity in pharmacological actions and resulting effects in the hallucinogen drug class (*e.g.* LSD, psilocybin), it is expected that the NBOMes will share a similar psychic and psychological dependence liability.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are not considered immediate precursors of any controlled substance of the CSA as defined by 21 U.S.C 802(23).

Conclusion: Based on consideration of the scientific and medical evaluations and accompanying recommendation of the HHS, and based on the DEA's considerations of its own eight-factor analysis, the DEA finds that these facts and all other relevant data constitute substantial evidence of the potential for abuse of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe. As such, the DEA hereby proposes to schedule 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe as controlled substances under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

(1) 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have a high potential for abuse that is comparable to other schedule I substances such as 2C-I, 2C-C, 2C-B, LSD and DOM;

(2) 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have no currently accepted medical use in treatment in the United States; and

(3) There is a lack of accepted safety for use of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe under medical supervision.

Based on these findings, the Administrator of the DEA concludes that 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5), 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82) and 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36), including their salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe

If this rule is finalized as proposed, persons who handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe would continue [6] to be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, possession, importing, and exporting of schedule I controlled substances, including those listed below:

[6] 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 78 FR 68716.

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe, or who desires to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe would be required to be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe would be subject to schedule I security requirements and would need to be handled and stored pursuant to 21 U.S.C. 821, 823, and 871(b), and in accordance with 21 CFR 1301.71-1301.93.

3. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe would need to be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers would be permitted to manufacture 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person who becomes registered with the DEA on or after the effective date of the final rule must take an initial inventory of all stocks of controlled substances (including NBOMes) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including NBOMes) on hand every two years pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports with respect to 25I-NBOMe, 25C-NBOMe, and/or 25B-NBOMe pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304 and 1312.

7. Order Forms. Every DEA registrant who distributes 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe would be required to comply with the order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305.

8. Importation and Exportation. All importation and exportation of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe would need to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. Liability. Any activity involving 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe not authorized by, or in violation of, the CSA or its implementing regulations would be unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures done ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. On November 15, 2013, the DEA published a final order to temporarily place these three synthetic phenethylamines into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The DEA estimates that all entities handling or planning to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe are currently registered to handle these substances. There are currently 18 registrations authorized to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 18 registrations represent 13 entities, of which 6 are small entities. Therefore, the DEA estimates six small entities are affected by this proposed rule.

A review of the 18 registrations indicates that all entities that currently handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe handle other schedule I controlled substances, and have established and implemented (or currently maintain) the systems and processes required to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe. Therefore, the DEA anticipates that this proposed rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the six affected small entities. Therefore, the DEA has concluded that this proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* that this action would not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not

required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, 21 CFR part 1308 is proposed to be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

■ 2. In § 1308.11:

■ a. Add paragraphs (d)(48) through (50);

■ b. Remove paragraphs (h)(4), (5), and (6); and

■ c. Redesignate paragraphs (h)(7) through (24) as (h)(4) through (21).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(48) 2-(4-iodo-2,5-dimethoxy-phenyl)-*N*-(2-methoxy-benzyl)ethanamine (25I-NBOMe or 2C-I-NBOMe) ..... (7538)

(49) 2-(4-chloro-2,5-dimethoxy-phenyl)-*N*-(2-methoxy-benzyl)ethanamine (25C-NBOMe or 2C-C-NBOMe) ..... (7537)

(50) 2-(4-bromo-2,5-dimethoxy-phenyl)-*N*-(2-methoxy-benzyl)ethanamine (25B-NBOMe or 2C-B-NBOMe) ..... (7536)

* * * * *

Dated: November 10, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015–29026 Filed 11–12–15; 8:45 am]

BILLING CODE 4410–09–P

FEDERAL REGISTER

Vol. 80 Friday,

No. 219 November 13, 2015

Part V

Department of Justice

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances: Extension of Temporary Placement of Three Synthetic Phenethylamines in Schedule I; Final Order

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–424]

Schedules of Controlled Substances: Extension of Temporary Placement of Three Synthetic Phenethylamines in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order extending the temporary schedule I status for three synthetic phenethylamines into the Controlled Substances Act pursuant to the temporary scheduling provisions of the Act. The substances are: 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5), 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82), and 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36) [hereinafter 25I-NBOMe, 2C-NBOMe, and 25-NBOMe, respectively]. The initial temporary scheduling was based on a finding by the Deputy Administrator that the placement of these synthetic phenethylamines and their optical, positional, and geometric isomers, salts, and salts of isomers into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. The current final order temporarily placing 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe in schedule I is due to expire on November 14, 2015. This final order will extend the temporary scheduling of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe for one year, or until the permanent scheduling action for these three substances is completed, whichever occurs first. As a result of this order, the full effect of the Controlled Substances Act and its implementing regulations, including criminal, civil and administrative penalties, sanctions, and regulatory controls of schedule I substances will be imposed on the manufacture, distribution, possession, importation, and exportation of these synthetic phenethylamines.

DATES: This final order is effective November 13, 2015.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, and are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for purpose of this action. 21 U.S.C. 801–971. The DEA published the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

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

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

Background

On November 15, 2013, the DEA published a final order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place the three synthetic phenethylamines 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe, 2C-I-NBOMe, 25I, Cimbi-5); 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe, 2C-C-NBOMe, 25C, Cimbi-82); and 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36) into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 78 FR 68716. That final order was effective on the date of publication, and was based on findings by the Deputy Administrator of the DEA that the temporary scheduling of these three synthetic phenethylamines was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Section 201(h)(2) of the CSA, 21 U.S.C. 811(h)(2), requires that the temporary control of these substances expire two years from the effective date of the scheduling order, or on or before November 14, 2015. However, the CSA also provides that the temporary scheduling may be extended for up to one year, during the pendency of proceedings under 21 U.S.C. 811(a)(1). 21 U.S.C. 811(h)(2). Proceedings for the permanent scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of the DEA pursuant to 28 CFR 0.100) on his or her own motion, at the request of the Secretary of Health and Human Services,[1] or on the petition of any interested party.

The Administrator of the DEA, on his own motion pursuant to 21 U.S.C. 811(a), has initiated proceedings under 21 U.S.C. 811(a)(1) to permanently schedule 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe. The DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of

[1] Because the Secretary of the Department of Health and Human Services has delegated to the Assistant Secretary for Health of the Department of Health and Human Services the authority to make domestic drug scheduling recommendations, for purposes of this final order, all subsequent references to ''Secretary'' have been replaced with ''Assistant Secretary.''

abuse, and the relative potential for abuse for these three synthetic phenethylamines. On July 23, 2014, the DEA submitted a request to the HHS to provide the DEA with a scientific and medical evaluation of available information and a scheduling recommendation for 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe, in accordance with 21 U.S.C. 811 (b) and (c). Upon evaluating the scientific and medical evidence, on August 12, 2015, the HHS submitted to the Administrator of the DEA its three scientific and medical evaluations entitled, ''Basis for the Recommendation to Place 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe) and its Salts in Schedule I of the Controlled Substances Act (CSA),'' ''Basis for the Recommendation to Place 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe) and its Salts in Schedule I of the Controlled Substances Act (CSA),'' and ''Basis for the Recommendation to Place 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe) and its Salts in Schedule I of the Controlled Substances Act (CSA).'' Upon receipt of the scientific and medical evaluation and scheduling recommendations from the HHS, the DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe in accordance with 21 U.S.C. 811(c). The DEA published a notice of proposed rulemaking for the placement of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe into schedule I elsewhere in this issue of the **Federal Register**.

Pursuant to 21 U.S.C. 811(h)(2), the Administrator of the DEA orders that the temporary scheduling of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe, including their optical, positional, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, be extended for one year, or until the proceedings to permanently schedule these three substances is completed, whichever occurs first.

In accordance with this final order, the schedule I requirements for handling 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe, including their optical, positional, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, will remain in effect for one year, or until the permanent scheduling proceeding is completed, whichever occurs first.

Regulatory Matters

The CSA provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h). The Attorney General may, by order, schedule a substance in schedule I on a temporary basis. *Id.* 21 U.S.C. 811(h) also provides that the temporary scheduling of a substance shall expire at the end of two years from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings to permanently schedule the substance, extend the temporary scheduling for up to one year.

To the extent that 21 U.S.C. 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued and extended, the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this extension of the temporary scheduling action. In the alternative, even assuming that this action might be subject to section 553 of the APA, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for extending the temporary scheduling order would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety. Further, the DEA believes that this final order extending the temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

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

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

Pursuant to section 808(2) of the Congressional Review Act (CRA), ''any rule for which an 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 Federal agency promulgating the rule determines.'' 5 U.S.C. 808(2). It is in the public interest to maintain the temporary placement of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe in schedule I because they pose a public health risk. The temporary scheduling action was taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. Under 21 U.S.C. 811(h), temporary scheduling orders are not subject to notice and comment rulemaking procedures. The DEA understands that the CSA frames temporary scheduling actions as orders rather than rules to ensure that the process moves swiftly, and this extension of the temporary scheduling order continues to serve that purpose. For the same reasons that underlie 21 U.S.C. 811(h), that is, the need to place these substances in schedule I because they pose an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of this extension of the temporary scheduling order. Therefore, in accordance with section 808(2) of the CRA, this final order extending the temporary scheduling order shall take effect immediately upon its publication. The DEA has submitted a copy of this final order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

Dated: November 10, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015–29028 Filed 11–12–15; 8:45 am]

BILLING CODE 4410–09–P

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Part VI

The President

Notice of November 10, 2015—Continuation of the National Emergency With Respect to Iran

Federal Register
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Presidential Documents

Title 3—

The President

Notice of November 10, 2015

Continuation of the National Emergency With Respect to Iran

On November 14, 1979, by Executive Order 12170, the President declared a national emergency with respect to Iran and, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706), took related steps to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the situation in Iran. Our relations with Iran have not yet returned to normal, and the process of implementing the agreements with Iran, dated January 19, 1981, is still under way. For this reason, the national emergency declared on November 14, 1979, must continue in effect beyond November 14, 2015. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to Iran declared in Executive Order 12170.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

THE WHITE HOUSE,
November 10, 2015.

[FR Doc. 2015–29271
Filed 11–12–15; 11:15 am]
Billing code 3295–F6–P

FEDERAL REGISTER

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Part VII

The President

Notice of November 12, 2015—Continuation of the National Emergency With Respect to the Proliferation of Weapons of Mass Destruction

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Presidential Documents

Title 3—

The President

Notice of November 12, 2015

Continuation of the National Emergency With Respect to the Proliferation of Weapons of Mass Destruction

On November 14, 1994, by Executive Order 12938, the President declared a national emergency with respect to the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States posed by the proliferation of nuclear, biological, and chemical weapons (weapons of mass destruction) and the means of delivering such weapons. On July 28, 1998, the President issued Executive Order 13094, amending Executive Order 12938, to respond more effectively to the worldwide threat of weapons of mass destruction proliferation activities. On June 28, 2005, the President issued Executive Order 13382, which, *inter alia,* further amended Executive Order 12938, to improve our ability to combat proliferation. The proliferation of weapons of mass destruction and the means of delivering them continues to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States; therefore, the national emergency first declared on November 14, 1994, and extended in each subsequent year, must continue. In accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing the national emergency declared in Executive Order 12938.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

THE WHITE HOUSE,
November 12, 2015.

[FR Doc. 2015–29285
Filed 11–12–15; 11:15 am]
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