FEDERAL REGISTER

Vol. 80 Wednesday,
No. 130 July 8, 2015

Pages 38913–39376

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.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.ofr.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.fdsys.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 80 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

Contents

Federal Register

Vol. 80, No. 130

Wednesday, July 8, 2015

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

14 CFR
33.....38913
Proposed Rules:
39 (2 documents) 38990, 38992

17 CFR
Proposed Rules:
240.....38995

18 CFR
Proposed Rules:
342.....39010

21 CFR
20.....38915
310.....38915
314.....38915
600.....38915

26 CFR
1 (2 documents) 38940, 38941

33 CFR
165 (5 documents) 38941, 38943, 38944, 38946

38 CFR
Proposed Rules:
4.....39011

40 CFR
52 (4 documents) 38951, 38959, 38966, 38969
180 (2 documents) 38976, 38981
Proposed Rules:
52.....39020

42 CFR
Proposed Rules:
410.....39200
412.....39200
416.....39200
419.....39200

49 CFR
Proposed Rules:
1201.....39021
1241.....39045
1242.....39045
1243.....39045
1244.....39045
1245.....39045
1246.....39045
1247.....39045
1248.....39045

50 CFR
300.....38986

Rules and Regulations

Federal Register
Vol. 80, No. 130
Wednesday, July 8, 2015

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 33

[Docket No.FAA–2015–1771; Special Conditions No. 33–016–SC]

Special Conditions: Pratt and Whitney Canada, PW210A; Flat 30-Second and 2-Minute One Engine Inoperative Rating

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Pratt and Whitney Canada PW210A engine model. This engine will have a novel or unusual design feature—an additional one engine inoperative (OEI) rating that combines the 30-second and 2-minute OEI ratings into a single rating. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Effective August 7, 2015.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning these special conditions, contact Tara Fitzgerald, ANE–111, Engine and Propeller Directorate, Aircraft Certification Service, 12 New England Executive Park, Burlington, Massachusetts, 01803–5213; telephone (781) 238–7130; facsimile (781) 238–7199; email *tara.fitzgerald@faa.gov.* For legal questions concerning these special conditions, contact Vincent Bennett, ANE–7, Engine and Propeller Directorate, Aircraft Certification Service, 12 New England Executive Park, Burlington, Massachusetts, 01803–5299; telephone (781) 238–7044; facsimile (781) 238–7055; email *vincent.bennett@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On February 14, 2013, Pratt and Whitney Canada applied for an amendment to Type Certificate No. E00083EN–E to include the new PW210A engine model. The PW210A, which is a derivative of the PW210S currently approved under E00083EN–E, is intended for rotorcraft use. For their PW210A engine model, Pratt and Whitney Canada requests an additional OEI rating that combines the 30-second and 2-minute OEI rating into a single rating to satisfy the rotorcraft requirements for increased power in OEI scenarios. This additional OEI rating is named ''Flat 30-second and 2-minute OEI.''

These special conditions are necessary because the applicable airworthiness regulations do not contain adequate or appropriate safety standards for combining the requirements of the flat 30-second and 2-minute OEI rating.

Type Certification Basis

Under the provisions of § 21.101, Pratt and Whitney Canada must show that the PW210A meets the applicable provisions of 14 CFR part 33, as amended by Amendments 33–1 through 33–30. These regulations will be incorporated into Type Certificate No. E00083EN after type certification approval of the PW210A. The regulations incorporated by reference in the type certificate are commonly referred to as the ''original type certification basis.'' The regulations incorporated by reference in Type Certificate No. E00083NE are as follows:

Title 14 of the Code of Federal Regulations (14 CFR part 33), effective February 1, 1965, Amendments 33–1 through 33–24 and two special conditions:

33–008–SC: for on ground engine operation in auxiliary power unit (APU) mode, and

33–009–SC: for 30-minutes all engines operating (AEO) hovering power engine rating

For the PW210A the certification basis is:

1. Airworthiness Standards: 14 CFR part 33, effective February 1, 1965, Amendments 33–1 through 33–30, inclusive.

2. Environmental Standards: 14 CFR part 34, effective September 10, 1990, as amended by 34–1 through 34–4 and 40 CFR part 87, effective (ICAO Annex 16, Volume II—Aircraft Engine Emissions, as amended up to and including Amendment 6).

In addition, the certification basis includes other regulations, special conditions and exemptions that are not relevant to these special conditions. Type Certificate No. E00083EN will be updated to include a complete description of the certification basis for this model engine.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 33) do not contain adequate or appropriate safety standards for the PW210A because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

Accordingly, should type certificate E00083EN be amended to include another model that incorporates the ''Flat 30-second and 2-minute OEI,'' the special conditions as defined would apply to models whose certification basis is amendment 33–25 or later.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The PW210A will incorporate the following novel or unusual design features: The design feature is a ''Flat 30-second and 2-minute'' one engine inoperative (OEI) rating. The Flat 30-second and 2-minute OEI rating represents a case where the power levels and associated operating limitations for the 30-second OEI and 2-minute OEI ratings (defined in Part 33) are the same.

Discussion

These special conditions are necessary because current part 33 regulations do not contain airworthiness standards for extending the 2-minute OEI rating for 30-seconds. These special conditions extend the time dependent requirements applicable to the 30-second OEI or 2-minute OEI to the 2.5 minutes time duration of the ''Flat 30-second and 2-minute OEI'' Power.

The 2.5 minutes time duration for the rating may affect the engine's structural and operational characteristics that are time dependent, such as the values for transients, time duration for stabilization to steady state, and part growth due to deformation. To address these aspects, we propose special conditions based on revised requirements of §§ 33.27, 33.87(a)(7), and 33.88(b).

The 2.5 minutes time duration for the rating affects the test conducted for the endurance test. For the 30-second OEI and 2-minute OEI the test schedule of § 33.87(f) is divided among the two ratings. We propose special conditions based on revised requirements of § 33.87(f) to ensure the test will be run for 2.5 minutes duration with no interruption.

The 2.5 minutes time duration for the rating necessitates extending the time duration requirement of § 33.28(k) applicable to the 30-second OEI rating from 30 seconds to 2.5 minutes. This requirement is for automatic availability and control of the engine for the entire duration of the rating's usage.

The 2.5 minutes time duration for the rating necessitates extending the requirements of § 33.29(c) that are applicable to 30-second OEI and 2-minute OEI ratings to the single Flat 30-second and 2-minute OEI Power rating. We propose special conditions to ensure that the instrumentation requirements normally reserved for 30-second OEI and 2-minute OEI ratings are applied to the Flat 30-second and 2-minute OEI Power rating over its whole duration. The pilot does not have to be alerted at the end of 30 seconds use of the Flat 30-second and 2-minute OEI Power rating, only after the entire 2 minutes 30 seconds has expired. Paragraph 2.(e)(3) of these special conditions states that the engine must provide means or provision of means to alert maintenance of use of the Flat 30-second and 2-minute OEI Power rating, 'alert' means after the aircraft lands, so any required maintenance actions can be completed before next flight.

Applicability

As discussed above, these special conditions are applicable to the PW210A. Should Pratt and Whitney Canada apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only the Flat 30-second and 2-minute OEI design features on the PW210A engine model. It is not a rule of general applicability and applies only to Pratt and Whitney Canada, who requested FAA approval of this engine feature.

List of Subjects in 14 CFR Part 33

Aircraft, Engines, Aviation Safety, Reporting and Recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Pratt and Whitney Canada PW210A engine model.

Flat 30-second and 2-minute OEI

1. Part 1.1 Definitions

''Rated Flat 30-second and 2-minute One Engine Inoperative (OEI) Power,'' with respect to rotorcraft turbine engines, means (1) a single rating for which the shaft horsepower and associated operating limitations of the 30-second OEI and 2-minute OEI ratings are equal, and (2) the shaft horsepower is that developed under static conditions at the altitude and temperature for the hot day, and within the operating limitations established under Part 33. The rating is for continuation of flight operation after the failure or shutdown of one engine in multiengine rotorcraft, for up to three periods of use no longer than 2.5 minutes each in any one flight, and followed by mandatory inspection and prescribed maintenance action.

2. Part 33 requirements

(a) The airworthiness standards in Part 33 Amendment 30 for the 30-second OEI and 2-minute OEI ratings are applicable to the Flat 30-second and 2-minute OEI Power rating. In addition the following special conditions apply;

(b) Section 33.7 Engine ratings and operating limitations. Flat 30-second and 2-minute OEI Power rating and operating limitations are established for power, torque, rotational speed, gas temperature, and time duration.

(c) Section 33.27 Turbine, compressor, fan, and turbosupercharger rotor overspeed. The requirements of § 33.27, except that following the test, the rotor may not exhibit conditions such as cracking or distortion which preclude continued safe operation.

(d) Section 33.28 Engine controls systems. Must incorporate a means, or a provision for a means, for automatic availability and automatic control of the Flat 30-second and 2-minute OEI Power within the declared operating limitations.

(e) Section 33.29 Instrument Connection. In lieu of the requirements of 33.29(c) the PW210A must incorporate a means or a provision for a means to:

(1) Alert the pilot when the engine is at the Flat 30-second and 2-minute OEI Power level, when the event begins, and when the time interval expires;

(2) Automatically record each usage and duration of power at the Flat 30-second and 2-minute OEI Power rating;

(3) Following each flight when the Flat 30-second and 2-minute OEI Power rating is used, alert maintenance personnel in a positive manner that the engine has been operated at the Flat 30-second and 2-minute OEI Power level, and permit retrieval of the recorded data; and

(4) Enable routine verification of the proper operation of the above means.

(f) Section 33.87 Endurance test. The requirements applicable to 30-second and 2-minute OEI ratings, except for:

(1) The test of § 33.87(a)(7) for the purposes of temperature stabilization, must be run with a test period time of 2.5 minutes.

(2) The tests in § 33.87(f)(2) and (3) must be run continuously for the duration of 2.5 minutes, and

(3) The tests in § 33.87(f)(6) and (7) must be run continuously for the duration of 2.5 minutes.

(g) Section 33.88 Engine overtemperature test. The requirements of § 33.88(b) except that the test time is 5 minutes instead of 4 minutes.

Issued in Burlington, Massachusetts, on June 26, 2015.

Ann C. Mollica,

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

[FR Doc. 2015–16713 Filed 7–7–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 310, 314, and 600

[Docket No. FDA–2011–N–0898]

RIN 0910–AG88

Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is amending its regulations to implement certain drug shortages provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA). The rule requires all applicants of covered approved drugs or biological products—including certain applicants of blood or blood components for transfusion and all manufacturers of covered drugs marketed without an approved application—to notify FDA electronically of a permanent discontinuance or an interruption in manufacturing of the product that is likely to lead to a meaningful disruption in supply (or a significant disruption in supply for blood or blood components) of the product in the United States.

DATES: The rule is effective September 8, 2015.

FOR FURTHER INFORMATION CONTACT: Jouhayna Saliba, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6206, Silver Spring, MD 20993, 301–796–1300; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary

Purpose of the Rule

FDASIA (Pub. L. 112–144) significantly amended provisions in the FD&C Act related to drug shortages. Among other things, FDASIA amended section 506C of the FD&C Act (21 U.S.C. 356c) to require all manufacturers of certain drugs to notify FDA of a permanent discontinuance or an interruption in manufacturing of these drugs 6 months in advance of the permanent discontinuance or interruption in manufacturing, or as soon as practicable. FDASIA also added section 506E to the FD&C Act (21 U.S.C. 356e), requiring FDA to maintain a current list of drugs that are determined by FDA to be in shortage in the United States and to include on that public list certain information about those shortages. Finally, FDASIA permits FDA to apply section 506C to biological products by regulation and requires FDA to issue a final rule implementing certain drug shortages provisions in FDASIA by January 9, 2014. FDA believes this final rule will improve FDA's ability to identify potential drug shortages and to prevent or mitigate the impact of these shortages.

Summary of the Major Provisions of the Rule

The rule modifies FDA's regulations to implement sections 506C and 506E of the FD&C Act as amended by FDASIA. Sections 310.306, 314.81(b)(3)(iii), and 600.82 (21 CFR 310.306, 314.81(b)(3)(iii), and 600.82) require all applicants of certain approved drugs or biological products,[1] including applicants of blood or blood components [2] for transfusion (''blood or blood components'') that manufacture a significant percentage of the U.S. blood supply, and all manufacturers of certain drugs marketed without an approved application (''unapproved drug manufacturers''), to notify FDA electronically of a permanent discontinuance or an interruption in manufacturing of the product that is likely to lead to a meaningful disruption in supply (for drugs and biological products other than blood or blood components) or a significant disruption in supply (for blood or blood components) of the product in the United States. Applicants [3] are required to notify FDA of a permanent discontinuance or an interruption in supply if the drug or biological product is a prescription product that is life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery, and excluding radiopharmaceutical products (referred to in this document as ''covered'' drugs or biological products). The rule requires notification to FDA at least 6 months prior to date of the permanent discontinuance or interruption in manufacturing, or, if 6 months' advance notice is not possible, as soon as practicable thereafter, but in no case later than 5 business days after the permanent discontinuance or interruption in manufacturing occurs.

The rule also provides that FDA will issue a noncompliance letter to an applicant for failure to notify FDA under the rule; specifies minimum information that must be included in the notification; codifies FDA's current practice of publicly disseminating information on shortages and maintaining public lists of drugs and biological products in shortage (subject to certain confidentiality protections); and defines the terms ''drug shortage,'' ''biological product shortage,'' ''meaningful disruption,'' ''significant disruption,'' ''life supporting or life sustaining,'' and ''intended for use in the prevention or treatment of a debilitating disease or condition.''

[1] As used throughout this document, the term ''biological product'' refers to a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), other than a biological product that also meets the definition of a device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)). This rule does not apply to biological products that also meet the definition of a device in section 201(h) of the FD&C Act.

[2] As used throughout this rule, the term ''blood and blood components'' refers to blood and blood components for transfusion other than Source Plasma, which is outside the scope of this rule.

[3] In this document, for the sake of convenience, we collectively refer to applicants holding an abbreviated new drug application (ANDA), new drug application (NDA), or biologics license application (BLA) and unapproved drug manufacturers subject to this rule as the ''applicant'' (although we recognize that an unapproved drug manufacturer is not an applicant). We may also individually refer to the ANDA, NDA, and BLA applicant or unapproved drug manufacturer as needed, if the context requires distinguishing between these entities.

Finally, the rule includes a technical revision to § 20.100 (21 CFR 20.100) (public disclosure regulations) to include a cross-reference to the disclosure provisions in §§ 310.306, 314.81, and 600.82; and removes § 314.91 related to reducing the 6-month notification period for ''good cause,'' since it is no longer applicable under section 506C of the FD&C Act as amended by FDASIA.

Summary of the Costs and Benefits of the Rule

The rule imposes annual reporting costs of up to $16,827 on those applicants affected by the rule, and up to $441,000 on FDA in review costs. Undertaking mitigation strategies, as measured by labor resources, is estimated to cost FDA between $1.85 and $5.94 million, and industry between $2.97 and $9.55 million. We also estimate annual costs for industry between $9.57 and $30.97 million associated with increasing production. Estimated total annual costs of the interactions between industry and FDA range between $14.54 and $46.92 million. Discounting over 20 years, annualized quantified benefits from avoiding the purchase of alternative products, managing product shortages, and life-years gained, would range from $30.45 million to $98.65 million using a 3 percent discount rate, and from $30.39 million to $98.42 million using a 7 percent discount rate. The public health benefits, mostly nonquantified, include the value of information that would assist FDA, manufacturers, health care providers, and patients in evaluating, mitigating, and preventing shortages of drugs and biological products that could otherwise result in delayed patient treatment or interruption in clinical trial development.

I. Introduction

Recent experience with shortages of drugs and biological products in the United States has shown the serious and immediate effects they can have on patients and health care providers. According to information from FDA's drug and biological product shortages databases, the number of drug and biological product shortages quadrupled from approximately 61 in 2005 to more than 250 shortages in 2011. Although the number of new drug shortages significantly decreased in 2012 to 117 shortages, in 2013 to 44 shortages, and stayed at 44 new shortages in 2014, drug and biological product shortages still represent an ongoing challenge to public health.[4] Shortages can involve critical drugs used to treat cancer, to provide required parenteral nutrition, or to address other serious medical conditions and can delay or deny needed care for patients. Shortages can also result in providers prescribing second-line alternatives, which may be less effective or higher risk than first-line therapies.

In response to the increasing concerns about the impact of shortages on health care in the United States, on October 31, 2011, President Obama issued Executive Order 13588 directing FDA to ''take steps that will help to prevent and reduce current and future disruptions in the supply of lifesaving medicines'' and noting that ''one important step is ensuring that FDA and the public receive adequate advance notice of shortages whenever possible'' (Ref. 1). In response to the Executive Order's directive to address the growing problem of drug shortages, FDA published an interim final rule (IFR) on December 19, 2011 (effective January 18, 2012), modifying the regulation at § 314.81 related to drug shortages (76 FR 78530).

As a result of the Executive order and IFR, early notifications to FDA of potential shortages increased from an average of 10 a month before the Executive order to approximately 60 a month in the months after the IFR. This dramatic increase in early notifications enabled FDA to work with manufacturers and other stakeholders to successfully prevent numerous shortages by using tools such as:

- Working with manufacturers to resolve manufacturing and quality issues contributing to short supply.
- Expediting FDA inspections and reviews of submissions from manufacturers to prevent and/or alleviate shortages.
- Identifying and working with manufacturers willing to initiate or increase production to cover expected gaps in supply.
- Exercising regulatory flexibility and discretion in appropriate circumstances, if this would not cause undue risk to patients.

FDA was able to prevent just under 200 drug and biological product shortages in 2011, more than 280 such shortages in 2012, 170 shortages in 2013, and 101 shortages in 2014.

In July 2012, FDASIA amended the FD&C Act to modify existing drug shortages requirements and to add new drug shortages provisions. Section 506C(i) of the FD&C Act, added by FDASIA, directs FDA to adopt a final rule to implement the drug shortages provisions. The final rule supersedes the IFR.

II. The Proposed Rule

In the **Federal Register** of November 4, 2013 (78 FR 65904), FDA published a proposed rule to implement certain drug shortages provisions of the FD&C Act, as amended by FDASIA.[5] The preamble to the proposed rule explained that section 1001 of FDASIA made substantial changes to section 506C of the FD&C Act related to reporting and addressing ''permanent discontinuances'' or ''interruptions in manufacturing'' of certain drug products. Most significantly, section 506C of the FD&C Act as amended:

- Requires all manufacturers of a prescription drug that is life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery, and excluding radiopharmaceutical products, to notify FDA of a permanent discontinuance in the manufacture of the drug or an interruption in the manufacturing of the drug that is likely to lead to a meaningful disruption in the supply of that drug in the United States at least 6 months prior to the date of the permanent discontinuance or interruption in manufacturing, or, if that is not possible, as soon as practicable.
- Requires the manufacturer to include in the notification the reason for the permanent discontinuance or interruption in manufacturing.
- Requires FDA to issue a letter to a ''person'' who fails to comply with the notification requirements in section 506C.
- Defines the terms ''drug,'' ''drug shortage,'' and ''meaningful disruption,'' and requires FDA to define the terms ''life supporting,'' ''life sustaining,'' and ''intended for use in the prevention or treatment of a debilitating disease or condition.''
- Permits FDA to apply section 506C to biological products, including vaccines and plasma-derived products

[4] Information on product shortages can be found at *http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm* (for products regulated by the Center for Drug Evaluation and Research) and *http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/default.htm* (for products regulated by the Center for Biologics Evaluation and Research).

[5] Section 506C(i)(4) of the FD&C Act specifies that in promulgating a regulation to implement the FD&C Act's drug shortage provisions, FDA must issue a notice of proposed rulemaking that includes the proposed rulemaking and provide a period of no less than 60 days for public comment on the proposed rule.

and their recombinant analogs, if FDA determines the inclusion would benefit public health, taking into account existing supply reporting programs and aiming to reduce duplicative notifications.

• Requires FDA to distribute information on drug shortages to the public, to the maximum extent possible, subject to certain confidentiality protections.

In addition to modifying section 506C, FDASIA added several new drug shortage-related sections to the FD&C Act, including section 506E. Section 506E of the FD&C Act requires FDA to maintain an up-to-date list of drugs that are determined by FDA to be in shortage, including the names and the National Drug Codes (NDCs) of such drugs in shortage, the name of each manufacturer of the drug, the reason for each shortage as determined by FDA (choosing from a list of reasons enumerated in the statute), and the estimated duration of each shortage. Section 506E of the FD&C Act also includes confidentiality provisions.

The Agency proposed to implement sections 506C and 506E of the FD&C Act by amending § 314.81(b)(3)(iii) (permanent discontinuance or interruption in manufacturing of approved prescription drugs) and § 20.100 (cross-reference to disclosure provisions); adding new § 310.306 (permanent discontinuance or interruption in manufacturing of marketed prescription unapproved new drugs) and § 600.82 (permanent discontinuance or interruption in manufacturing of prescription biological products); and removing § 314.91 (reduction in the discontinuance notification period) (see 78 FR 65904).

FDA provided 60 days for public comment on the proposed rule. Based on the comments received and FDA's experience to date receiving notifications, maintaining public lists of drug and biological product shortages, and working with manufacturers and stakeholders to prevent and mitigate drug and biological product shortages, the Agency is finalizing the rule as proposed.

III. Description of the Final Rule

A. Persons Subject to the Rule

Sections 310.306, 314.81(b)(3)(iii), and 600.82 require notification to FDA of a permanent discontinuance or an interruption in manufacturing of a covered drug or biological product. The following persons are subject to these notification requirements:

• All applicants with an approved NDA or ANDA for a covered drug product (§ 314.81(b)(3)(iii)).

• All applicants with an approved BLA for a covered biological product, other than blood or blood components (§ 600.82(a)(1)).

• Applicants with an approved BLA for blood or blood components, if the applicant is a manufacturer of a significant percentage of the U.S. blood supply (§ 600.82(a)(2)).

• All manufacturers of a covered drug product marketed without an approved NDA or ANDA (§ 310.306, which applies § 314.81(b)(3)(iii) in its entirety to covered drug products marketed without an approved NDA or ANDA).

Section 506C of the FD&C Act as amended by FDASIA requires a ''manufacturer'' to notify FDA of a permanent discontinuance or an interruption in manufacturing. The rule requires the ANDA, NDA, or BLA applicant (for approved drugs or biological products) or the unapproved drug manufacturer (for marketed, unapproved drugs) to notify FDA of a permanent discontinuance or an interruption in manufacturing.

For purposes of section 506C of the FD&C Act, under the rule an ANDA, NDA, or BLA applicant is considered the manufacturer of an approved, covered product, even if the ANDA, NDA, or BLA applicant contracts that function out to another entity. In other words, the rule makes clear that for approved, covered drugs and biological products, the ANDA, NDA, or BLA applicant bears the responsibility for reporting to FDA a permanent discontinuance or an interruption in manufacturing, whether the product is manufactured by the applicant itself or for the applicant under contract with one or more different entities. As such, the ANDA, NDA, or BLA applicant should establish a process with any relevant contract manufacturer, active pharmaceutical ingredient (API) supplier, or other non-applicant entity that ensures the applicant's compliance with this rule.

Section 506C(i)(3) of the FD&C Act, as amended by FDASIA, directs FDA to ''take into account any supply reporting programs [for biological products] and . . . aim to reduce duplicative notification'' in applying section 506C to biological products by regulation. Accordingly, with respect to blood or blood components, the rule applies only to applicants that are manufacturers of a ''significant percentage of the United States blood supply.'' As described more fully in sections III.B.2.c and III.C.1.b.ii, FDA believes that this approach with respect to blood or blood components will ensure that the Agency receives information that is essential to preventing shortages of these products, without unnecessarily duplicating existing systems and without being unduly burdensome for industry. FDA intends to consider an applicant that holds a BLA for blood or blood components to be a manufacturer of a ''significant percentage'' of the U.S. blood supply if the applicant manufactures 10 percent or more of the U.S. blood supply.[6]

B. Products Covered by the Rule

1. Prescription Drug and Biological Products That Are Life Supporting, Life Sustaining, or Intended for Use in the Prevention or Treatment of a Debilitating Disease or Condition

The rule applies to all prescription drug products approved under an NDA or ANDA (§ 314.81(b)(3)(iii)), all marketed unapproved prescription drug products (§ 310.306), and all prescription biological products approved under a BLA (§ 600.82) that are:

• Life supporting; life sustaining; or intended for use in the prevention or treatment of a debilitating disease or condition, including any such product used in emergency medical care or during surgery; and

• Not radiopharmaceutical products.[7]

FDASIA does not define the terms ''life supporting,'' ''life sustaining,'' or ''intended for use in the prevention or treatment of a debilitating disease or condition,'' but instead requires FDA to define them (section 506C(i)(2) of the FD&C Act). Sections 314.81(b)(3)(iii)(*f*) and 600.82(f) define a ''life supporting or life sustaining'' drug or biological product as one that is ''essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.'' As explained in the preamble to the proposed rule (78 FR 65904 at 65909), this definition of ''life supporting or life sustaining'' is consistent with language used to describe this term in the preamble to the final rule implementing pre-FDASIA section 506C (72 FR 58993 at 58994, October 18, 2007), and in

[6] Based on 2011 National Blood Collection and Utilization Survey (NBCUS) data, 10 percent or more of the U.S. blood supply would mean more than 1.5 million units of whole blood annually or approximately 125,000 units per month. We note, however, that these numbers may fluctuate year to year. See 2011 National Blood Collection and Utilization Survey Report, available at *http://www.hhs.gov/ash/bloodsafety/nbcus/*.

[7] With respect to blood and blood components for transfusion, the reporting requirement applies only to an applicant that manufactures a significant percentage of the U.S. blood supply.

medical device regulations (see 21 CFR 821.3(g)).

The final rule defines ''intended for use in the prevention or treatment of a debilitating disease or condition'' to mean ''intended for use in the prevention or treatment of a disease or condition associated with mortality or morbidity that has a substantial impact on day-to-day functioning'' (§§ 314.81(b)(3)(iii)(*f*) and 600.82(f)). FDA equates ''debilitating disease or condition'' with ''serious disease or condition'' under this definition, and we have defined it according to the definition of ''serious'' found in § 312.300 (21 CFR 312.300), which governs expanded access to investigational new drugs. This definition of ''intended for use in the prevention or treatment of a debilitating disease or condition'' is also consistent with our discussion of the term in the preamble to the proposed rule implementing the pre-FDASIA section 506C (65 FR 66665 at 66666, November 7, 2000).

It is important to note that the definitions of ''life supporting or life sustaining'' and ''intended for use in the prevention or treatment of a debilitating disease or condition'' are, in important respects, different than FDA's definition of ''medically necessary'' as used in the context of the existing Center for Drug Evaluation and Research (CDER) Manual of Policies and Procedures (MAPP) on shortages of CDER-regulated products (CDER MAPP 4190.1 Rev. 2) (Ref. 2) and the existing Center for Biologics Evaluation and Research (CBER) Standard Operating Policy and Procedure (SOPP) on shortages of CBER-regulated products (CBER SOPP 8506) (Ref. 3). In general, FDA considers a product to be medically necessary under the internal MAPP and SOPP if there is no other product that is judged by CDER or CBER medical staff to be an appropriate substitute or there is an inadequate supply of an acceptable alternative, as determined by appropriate CDER and CBER personnel. In contrast, under this rule, an applicant is required to notify FDA of a permanent discontinuance or an interruption in manufacturing of a drug or biological product that is life supporting, life sustaining, or intended for use in the prevention or treatment of debilitating disease or condition, whether or not the product is considered ''medically necessary'' under the MAPP or SOPP. Under the MAPP and SOPP, FDA uses the definition of medically necessary to prioritize the Agency's response to specific shortages or potential shortages and to allocate resources appropriately.

2. Biological Products

Section 506C of the FD&C Act, as amended, states that for purposes of section 506C, the term ''drug'' does not include biological products as defined in section 351(i) of the Public Health Service Act, unless the Secretary of Health and Human Services (HHS) (the Secretary) applies section 506C to such products by regulation. Section 506C(i)(3) of the FD&C Act provides that FDA may, by regulation, apply section 506C to biological products, ''including plasma products derived from human plasma protein and their recombinant analogs'' if ''the Secretary determines that such inclusion would benefit the public health,'' taking into account ''any [existing] supply reporting programs'' and aiming to reduce ''duplicative notification.'' Additionally, FDA may apply section 506C of the FD&C Act to vaccines, but the Secretary must determine whether notification of a vaccine shortage to the Centers for Disease Control and Prevention (CDC) under its ''vaccine shortage notification program'' could satisfy a vaccine manufacturer's obligation to notify FDA of a permanent discontinuance or an interruption in manufacturing under section 506C.

As proposed, FDA is applying section 506C of the FD&C Act to all biological products, including recombinant therapeutic proteins, monoclonal antibody products, vaccines, allergenic products, plasma-derived products and their recombinant analogs, blood or blood components, and cellular and gene therapy products. Shortages of biological products can have serious negative consequences for patients who rely on these products for their treatment. FDA anticipates that early notification of a permanent discontinuance or an interruption in the manufacturing of biological products will allow the Agency to address, prevent, or mitigate a shortage of these products, greatly benefiting the public health. In addition, we have determined that requiring manufacturers of biological products to notify FDA under this rule will not duplicate the existing reporting programs of which we are aware.

a. *Plasma-derived products and their recombinant analogs.* Under § 600.82(a), the requirements of section 506C of the FD&C Act apply to all biological products, including plasma products derived from human plasma protein and their recombinant analogs (referred to in this document as plasma-derived products and their recombinant analogs). As explained in the preamble to the proposed rule (78 FR 65904 at 65910), with respect to plasma-derived products and their recombinant analogs, FDA recognizes that the Plasma Protein Therapeutics Association (PPTA) has developed a voluntary data system that captures the distribution and supply of five plasma product groups in the United States: Plasma-Derived Factor VIII, Recombinant Factor VIII, Immune Globulin (Ig), Albumin 5%, and Albumin 25%. The PPTA, in consultation with a third party, voluntarily submits a monthly report to FDA of aggregate distribution data for these five product groups. This information provides a picture of the total supply and distribution of these five products in any given month as compared to the last 12 months.

FDA recognizes and greatly appreciates the efforts by PPTA to provide plasma product supply information to FDA and the public. However, as described in detail in the preamble to the proposed rule (78 FR 65904 at 65910), FDA concluded that it would benefit the public health for the Agency to receive direct notification under this rule from all manufacturers of these products. Because the PPTA program does not serve the same purpose as notification under this rule, including plasma-derived products and their recombinant analogs in this rule will not duplicate the PPTA system. FDA believes that including these products within the scope of the rule is essential to FDA's efforts to identify permanent discontinuances and interruptions in manufacturing of these products, and consequently, essential to our efforts to address, prevent, or mitigate shortages of these products.

b. *Vaccines.* Under section 506C(i)(3)(B) of the FD&C Act, if FDA applies section 506C to vaccines, the Secretary must specifically consider whether the notification requirement may be satisfied by submitting a notification to CDC under CDC's ''vaccine shortage notification program.''

CDC contracts with vaccine manufacturers as part of the Vaccines for Children (VFC) program.[8] FDA recognizes that CDC includes language

[8] The VFC program is a federally funded program that provides vaccines at no cost to children and adults who might not otherwise be vaccinated because of inability to pay. VFC was created by the Omnibus Budget Reconciliation Act of 1993 as a new entitlement program to be a required part of each state's Medicaid plan. CDC buys vaccines at a discount from the manufacturers and distributes them to awardees—*i.e.,* State health departments and certain local and territorial public health Agencies—who in turn distribute them at no charge to those private physicians' offices and public health clinics registered as VFC providers. (See *http://www.cdc.gov/vaccines/programs/vfc/index.html.*)

in its contracts with vaccine manufacturers requiring the manufacturer to notify CDC of vaccine supply issues that could affect the manufacturer's ability to fulfill its contract with CDC.[9] As explained in the preamble to the proposed rule (78 FR 65904 at 65910), only certain vaccines are included under the existing CDC program, and thus, only manufacturers of certain vaccines are obligated to provide notification of supply issues to CDC. Based on information from CDC, FDA estimates that approximately 30 percent of vaccines licensed in the United States are not subject to CDC notification.

Moreover, even for the vaccines that are subject to CDC notification, the information collected is not adequate for purposes of this rule, because the existing CDC program does not require vaccine manufacturers to provide notice 6 months in advance of a permanent discontinuance or interruption in manufacturing. Early notice of permanent discontinuances and interruptions is critically important to the prevention of drug shortages. Although FDA and its HHS partners work together closely on vaccine supply issues, and the current framework for CDC notification is useful for contractual purposes, FDA has determined that including vaccines within the scope of this rule is necessary to fully support FDA's efforts to identify, address, prevent, or mitigate a vaccine shortage and would not be duplicative of existing notification systems.

c. *Blood or blood components for transfusion.* The rule applies section 506C of the FD&C Act to blood or blood components, but in a more limited manner than for other biological products (§ 600.82(a)(2)). The rule requires blood or blood component applicants (*i.e.,* blood collection establishments subject to licensure) that manufacture a significant percentage of the U.S. blood supply to notify FDA of a permanent discontinuance or an interruption in manufacturing that is likely to lead to a ''significant disruption'' in the applicant's supply of blood or blood components. The rule is intended to require reporting of large-scale, permanent discontinuances, or interruptions in manufacturing of blood or blood components.

FDA anticipates that the rule will ensure that FDA receives information essential to the Agency in preventing, mitigating, or addressing shortages of blood or blood components, while avoiding duplication with existing programs that monitor local and regional supplies of blood or blood components by ABO blood group.

As explained in detail in the preamble to the proposed rule (78 FR 65904 at 65911), we are aware of two significant efforts to monitor local and regional supplies of blood or blood components: (1) America's Blood Centers (ABC) and the Blood Availability and Safety Information System (BASIS) and (2) the Interorganizational Task Force on Domestic Disasters and Acts of Terrorism (Task Force), which is managed by the AABB (formerly the American Association of Blood Banks).

The ABC and BASIS systems monitor the supply and demand of blood or blood components on a daily and weekly basis, and in the event of a national disaster. In other words, ABC and BASIS are tools for local blood centers and hospitals to track their day-to-day inventory of blood or blood components. Unlike the notifications required under this rule, ABC and BASIS are not designed to predict large-scale or nationwide disruptions in the supply of blood or blood components. Moreover, ABC and BASIS are voluntary systems, whereas the rule requires reporting.

The Task Force was formed in January 2002 to help make certain that blood collection efforts resulting from domestic disasters and acts of terrorism are managed properly, and to deliver clear and consistent messages to the public regarding the status of the U.S. blood supply. The Task Force's efforts, although critical to public health, are focused on inventory management and are not intended to predict large-scale disruptions in the supply of blood or blood components. The Task Force coordinates the movement of blood throughout the United States and appeals to the public for blood donations, but Task Force information is not sufficient for FDA in the context of predicting a permanent discontinuance or an interruption in manufacturing of these products that would have a large-scale impact.

In short, although the information already available to FDA from the ABC, BASIS, and Task Force programs is useful, the existing frameworks are voluntary, do not result in a direct notification from an applicant to FDA, and only capture short-term, day-to-day supply and distribution information. In addition, in contrast to this rule, the existing systems are not equipped to predict large-scale, significant disruptions of blood or blood components. Accordingly, FDA has determined that including blood or blood components within the scope of this rule would benefit the public health, providing information that is essential to FDA's efforts to address shortages of these products.

However, recognizing that the existing ABC, BASIS, and Task Force programs do provide certain information concerning the supply of blood or blood components, the reporting requirements apply only to applicants of blood or blood components that manufacture a significant percentage of the U.S. blood supply, and only to a permanent discontinuance of manufacture or an interruption in manufacturing that is likely to lead to a ''significant disruption'' in supply of that blood or blood component, as further described in sections III.A and III.C.1.

3. Scope of the Term ''Product''

Under this rule, ''product'' refers to a specific strength, dosage form, and route of administration of a drug or biological product. For example, if Applicant X experiences an interruption in manufacturing of the 50-milligram (mg) strength of a drug product that would be subject to § 314.81(b)(3)(iii), but the 100-mg strength continues to be manufactured without delay, under the rule, Applicant X must notify FDA of the interruption in manufacturing of the 50-mg strength if the interruption is likely to lead to a meaningful disruption in the applicant's supply of the 50-mg strength.

C. Notification of a Permanent Discontinuance or an Interruption in Manufacturing

1. Notification

a. *Permanent discontinuance.* Section 506C of the FD&C Act requires manufacturers to notify FDA of a permanent discontinuance of manufacture of a covered drug. Sections 314.81(b)(3)(iii) and 600.82 require the applicant to report all permanent discontinuances of covered drugs and biological products to FDA. For purposes of this rule, we interpret a permanent discontinuance to be a decision by the applicant for business or other reasons to cease manufacturing and distributing the product indefinitely.

[9] The Biomedical Advanced Research and Development Authority (BARDA), which is responsible for the procurement of certain vaccines related to medical countermeasures, also includes similar language in its procurement contracts. Contracts for the procurement of medical countermeasures against chemical, biological, nuclear, and radiological threat agents (*e.g.,* smallpox and anthrax vaccines) are administered by BARDA, part of the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services (HHS). (See *http://www.hhs.gov/aspr.*)

b. *Interruption in manufacturing.* In addition to permanent discontinuances, section 506C of the FD&C Act requires manufacturers to notify FDA of an interruption in manufacturing of a covered drug that is likely to lead to a meaningful disruption in supply of that drug in the United States. The statute defines ''meaningful disruption'' to mean a change in production that is reasonably likely to lead to a reduction in the supply of a drug *by a manufacturer* that is more than negligible and affects the ability of *the manufacturer* to fill orders or meet expected demand for its product; and does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

i. *Drugs and biological products other than blood or blood components.* Sections 314.81(b)(3)(iii)(*a*) and 600.82(a)(1) require the applicant for a product other than blood or blood components to report to FDA an interruption in manufacturing of the drug or biological product that is likely to lead to a meaningful disruption in supply of that drug or biological product in the United States. Sections 314.81(b)(3)(iii)(*f*) and 600.82(f) adopt the statutory definition of ''meaningful disruption in supply.''

Consistent with the statutory definition of meaningful disruption, the rule requires an applicant to report an interruption in manufacturing likely to lead to a meaningful disruption in its *own supply* of a covered drug or biological product. In other words, when evaluating whether an interruption in manufacturing is reportable to FDA under the rule, rather than considering the potential impact of the interruption on the market as a whole, the relevant question (regardless of how large or small the applicant's market share may be) is whether the interruption is likely to lead to a reduction in the applicant's supply of a covered drug or biological product that is more than negligible, and affects the ability of the applicant to fill its own orders or meet the expected demand of its clients for the covered product. Consistent with the statute, the rule does not require an applicant to predict the market-wide impact of an interruption in its own manufacturing, which can be difficult to accurately assess and could lead to inconsistent interpretation of the regulation, less accurate predictions, and under- or overreporting.

Under the rule, reportable discontinuances or interruptions in manufacturing of a covered drug or biological product include:

- A business decision to permanently discontinue manufacture of a covered drug or biological product.
- A delay in acquiring APIs or inactive ingredients that is likely to lead to a meaningful disruption in the applicant's supply of a covered drug or biological product while alternative API suppliers are located.
- Equipment failure or contamination affecting the quality of a covered drug or biological product that necessitates an interruption in manufacturing while the equipment is repaired or the contamination issue is addressed and that is likely to lead to a meaningful disruption in the applicant's supply of the product.
- Manufacturing shutdowns for maintenance or other routine matters, if the shutdown extends for longer than anticipated or otherwise is likely to lead to a meaningful disruption in the applicant's supply of a covered drug or biological product.
- A merger of firms or transfer of an application for a covered drug or biological product to a new firm, if the merger or transfer is likely to lead to a meaningful disruption in the applicant's supply of the product.
- An interruption in manufacturing (*e.g.,* contamination of a manufacturing line) that in the applicant's view may not meaningfully disrupt the market-wide supply of the covered drug or biological product (for example, because the applicant holds only a small share of the market for the product), but that the applicant determines is likely to lead to a meaningful disruption in its own supply of the covered product.

Conversely, an applicant is not required, under the rule, to notify FDA if an interruption in manufacturing is not likely to lead to a meaningful disruption in the applicant's supply of the drug or biological product. For example, FDA does not need to be notified in the following circumstances:

- A scheduled shutdown of an applicant's manufacturing facility for routine maintenance, if the shutdown is anticipated and planned for in advance and, therefore, is not expected to lead to a meaningful disruption in the applicant's supply of a covered drug or biological product.
- An unexpected power outage that results in an unscheduled interruption in manufacturing of a covered drug or biological product, if the applicant expects to resume normal operations within a relatively short timeframe and does not expect to experience a meaningful disruption in its supply of the covered drug or biological product.

In either of these circumstances, if the interruption in manufacturing subsequently appears likely to lead to a meaningful disruption in the applicant's supply of the covered drug or biological product, then it would become a reportable interruption in manufacturing under the rule and the applicant must notify FDA.

The list of examples described in this document is intended to assist industry in understanding what would (or would not) be required to be reported under amended section 506C of the FD&C Act, but the list is not exhaustive. The rule requires that any permanent discontinuance or any interruption in manufacturing that is likely to lead to a meaningful disruption in the applicant's supply of a covered drug or biological product be reported to FDA, even if not specifically described in this preamble.

ii. *Blood or blood components for transfusion.* Section 600.82(a)(2) requires an applicant that manufactures a significant percentage of the U.S. blood supply to report to FDA an interruption in manufacturing of a blood or blood component that is likely to lead to a ''significant disruption'' in supply of that product in the United States. As explained in section III.A, FDA intends to consider an applicant that manufactures 10 percent or more of the U.S. blood supply to manufacture a significant percentage of the U.S. blood supply for purposes of this rule.[10] Section 600.82(f) defines ''significant disruption'' as a change in production that is reasonably likely to lead to a reduction in the supply of blood or blood components by a manufacturer that substantially affects the ability of the manufacturer to fill orders or meet expected demand for its product; and does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time. This definition of ''significant disruption'' closely follows, but is not identical to, the statutory and regulatory definition of ''meaningful disruption.''

For purposes of the rule, FDA intends to consider an interruption in manufacturing that leads to a reduction of 20 percent or more of an applicant's own supply of blood or blood components over a 1-month period to ''substantially affect'' the ability of the applicant to fill orders or meet expected demand; accordingly, such an

[10] Based on 2011 NCBUS data, this would be more than 1.5 million units of whole blood annually or approximately 125,000 units per month. However, we note that the number may fluctuate year to year.

interruption would be considered a ''significant disruption'' in supply. Again, when determining whether an interruption in manufacturing is likely to lead to a significant disruption in supply, the blood or blood component applicant should not consider the market as a whole, but rather, should consider only its own supply of product.

The definition of ''significant disruption'' (interpreted to mean affecting 20 percent or more of an individual applicant's supply over a 1-month period) as applied to blood or blood components, in combination with limiting the rule only to applicants of blood or blood components that manufacture a significant percentage (10 percent or more) of the nation's blood supply, is intended to avoid duplication with existing programs to monitor the daily and weekly distribution of blood or blood components described in section III.B.2.c of this document and in the preamble to the proposed rule (78 FR 65904 at 65911). In general, existing programs maintained by ABC, BASIS, and the Task Force monitor and resolve temporary, local shortfalls of a particular ABO blood group or a particular blood component. Accordingly, the definition of ''significant disruption'' is intended to capture events that are likely to precipitate large-scale disruptions in an applicant's blood supply and are unlikely to be identified and corrected by the existing ABC, BASIS, and Task Force programs. The additional limitation of the rule to applicants that manufacture a significant percentage of the nation's blood supply further ensures that reporting to FDA will not unnecessarily duplicate reporting to the ABC, BASIS, and Task Force systems, but still allows FDA to receive information that is essential to the Agency in preventing large-scale shortages of these products.

Circumstances that trigger notification to FDA of a permanent discontinuance or an interruption in manufacturing of blood or blood components include the following examples. We recognize that, with the exception of the first example of a permanent discontinuance, the following interruptions are unlikely to be reasonably anticipated 6 months in advance; they would be reportable as soon as practicable, but in no case later than 5 business days after the interruption in manufacturing occurs:

- A business decision by an applicant that manufactures 10 percent or more of the nation's blood supply to permanently discontinue manufacture of blood or blood components;
- A computer system failure that causes an applicant of a blood establishment that collects 10 percent or more of the nation's blood supply to be unable to label blood for 2 weeks, resulting in a 20 percent monthly shortfall of blood for that applicant;
- An issue with blood collection bags, such that they are unavailable, causing an applicant that manufactures 10 percent or more of the nation's blood supply to experience a 20 percent monthly shortfall in normal production for that applicant;
- An issue with apheresis collection devices that causes an applicant of a blood establishment that collects 10 percent or more of the nation's blood supply to be unable to collect platelets by apheresis, resulting in a 20 percent monthly shortfall in platelet supply for that applicant;
- An explosion or fire that damages a large testing laboratory that performs blood testing for an applicant that manufactures 10 percent or more of the nation's blood supply, resulting in a 20 percent monthly shortfall of blood or blood components for that applicant.

Conversely, a covered blood or blood component applicant is not required under the rule to notify FDA if an interruption in manufacturing is not likely to lead to a significant disruption in the applicant's supply of blood or blood components. For example, FDA does not need to be notified if a covered blood or blood component applicant experiences a temporary drop in blood donations at one of its local blood donation centers, such that it is unable to fully supply its hospital customers with blood for several days, provided the donation center quickly returns to its normal donation and supply levels and the dip in blood donations is not likely to lead to a 20 percent decrease in the applicant's overall supply of blood over a 1-month period. We expect that this type of situation would be identified and resolved through the ABC, BASIS, and Task Force systems (*e.g.,* these systems would identify the issue and locate temporary, alternative blood supplies for the applicant's customers). If such an event does lead to a significant disruption in a covered applicant's supply of blood or blood components, it must be reported to FDA under the final rule.

Again, the list of examples described in this document is intended to assist industry in understanding what must be reported under amended section 506C of the FD&C Act, but the list is not exhaustive. The rule requires any permanent discontinuance or any interruption in manufacturing that is likely to lead to a significant disruption (as defined by the rule) in a covered applicant's supply of blood or blood components to be reported to FDA, even if not specifically discussed in this preamble.

2. Timing and Submission of Notification

a. *Timing of notification.* Section 506C of the FD&C Act requires notification to FDA: (1) At least 6 months prior to the date of the permanent discontinuance or interruption in manufacturing or (2) if 6 months' advance notice is not possible, as soon as practicable. Consistent with the statute, §§ 314.81(b)(3)(iii)(*b*) and 600.82(b) require an applicant to notify FDA of a permanent discontinuance or an interruption in manufacturing at least 6 months in advance of the date of the permanent discontinuance or interruption in manufacturing; or, if 6 months' advance notice is not possible, as soon as practicable thereafter, but in no case later than 5 business days after the permanent discontinuance or interruption in manufacturing occurs.

The Agency's most powerful tool for addressing drug and biological product shortages is early notification, which provides lead time for FDA to work with manufacturers and other stakeholders to prevent a shortage or to mitigate the impact of an unavoidable shortage. As such, FDA expects that applicants would provide 6 months' advance notice whenever possible. In particular, FDA believes that an applicant will generally know of a permanent discontinuance at least 6 months in advance, and in that case, the applicant must provide notification of a permanent discontinuance to FDA at least 6 months in advance. We understand that an applicant may not reasonably be able to anticipate 6 months in advance certain interruptions in manufacturing that are likely to lead to a meaningful disruption. For example, if an applicant discovers fungal contamination that requires an immediate, temporary shutdown of its manufacturing plant for a covered product, the applicant will not be able to provide FDA with 6 months' advance notice of the interruption in manufacturing. Instead, the rule requires that the applicant notify FDA ''as soon as practicable,'' but in no case more than 5 business days after the interruption in manufacturing occurs. In this example, the applicant must notify FDA as soon as it reasonably anticipates that an interruption in manufacturing caused by fungal contamination is likely to result in a meaningful disruption in supply of the applicant's product. The applicant should not wait until it or its

manufacturer begins rejecting or delaying fulfillment of orders for the product from available inventory (*i.e.,* the applicant should not wait until the interruption in manufacturing actually begins to disrupt supply and affect patient access to the product).

In our experience, even if it is not possible for an applicant to notify the Agency before a permanent discontinuance or an interruption in manufacturing occurs, it should generally be possible for the applicant to provide notice within a day or two, and it should always be possible for the applicant to notify the Agency no later than 5 days after the permanent discontinuance or interruption occurs, even in the event of a natural disaster or some other catastrophic incident. Accordingly, the 5-day provision represents a date certain after which FDA would be able to take action under section 506C(f) of the FD&C Act against an applicant for failure to comply with the notification requirements (see section III.C.6 for further discussion of the consequences of failure to notify FDA). Additionally, it is important to note that an applicant that could have notified the Agency before 5 days had passed, but waited until the end of the 5-day period is in violation of the rule. Consistent with the statutory intent, whenever possible, applicants are required to provide us with advance notice, whether 6 months' advance notice, or ''as soon as practicable'' thereafter (*e.g.,* 3 months' advance notice).

b. *Submission of notification.* Sections 314.81(b)(3)(iii)(*b*) and 600.82(b) require an applicant to notify FDA of a permanent discontinuance or an interruption in manufacturing electronically in a format FDA can process, review, and archive. Applicants must email notifications to *drugshortages@fda.hhs.gov* (for products regulated by CDER) or *cbershortage@fda.hhs.gov* (for products regulated by CBER). In the future, the Agency may consider creating an electronic notification portal linked to the Agency's internal drug shortages database to facilitate submission of these notifications. Unless and until this portal is created, however, email notifications will be used.

c. *Reduction in notification period for ''good cause.''* As described in the preamble to the proposed rule (78 FR 65904 at 65915), under the pre-FDASIA section 506C(b), a manufacturer could seek, and FDA could grant, a reduction in the required 6-month advance notification period for ''good cause.'' The regulation at § 314.91 implemented the pre-FDASIA section 506C(b). Because section 506C of the FD&C Act as amended by FDASIA does not include an option for formally seeking a reduction in the 6-month advance notification period based on ''good cause,'' this rule eliminates § 314.91 in its entirety.

3. Contents of the Notification

Sections 314.81(b)(3)(iii)(*c*) and 600.82(c) require an applicant to include the following items in notifications submitted under section 506C(a) of the FD&C Act:

- The name of the drug or biological product subject to the notification, including the NDC for the drug or biological product (or, for a biological product that does not have an NDC, an alternative standard for identification and labeling that has been recognized as acceptable by the Center Director);
- The name of the applicant of the drug or biological product;
- Whether the notification relates to a permanent discontinuance of the drug or biological product or an interruption in manufacturing of the drug or biological product;
- A description of the reason for the permanent discontinuance or interruption in manufacturing; and
- The estimated duration of the interruption in manufacturing.

FDA requires applicants to include the minimum information listed in the initial notification to assist the Agency in complying with section 506E of the FD&C Act, which requires FDA to maintain a publicly available list of drugs in shortage, as described in section III.C.4. We recognize that the duration of an interruption in manufacturing can be difficult to accurately predict. Therefore the applicant should provide FDA with its best estimate of the expected duration of the interruption in manufacturing. If, after the initial notification is submitted, the estimated duration changes, the applicant should notify FDA of the new expected duration of the interruption in manufacturing so that FDA can respond appropriately. In addition, the applicant should include a detailed, factual description of the reason for the shortage in the notification to assist FDA in responding to the notification.

Along with the required elements of the notification, applicants are encouraged to include any other information in the notification that may assist the Agency in working with the applicant to resolve the permanent discontinuance or interruption in manufacturing. This information could include the applicant's market share, inventory on hand or in distribution channels, allocation procedures and/or plans for releasing available product, copies of communications to patients and providers regarding the shortage (*e.g.,* Dear Healthcare Professional letters), or initial proposals to prevent or mitigate the shortage. As appropriate, the Agency will also followup with the applicant after the notification is submitted to obtain additional information and to work with the applicant to facilitate resolution of any shortage or potential shortage.

4. Public Lists of Products in Shortage

Section 506E of the FD&C Act requires FDA to maintain a publicly available list of drugs and biological products (if FDA applies section 506C of the FD&C Act to biological products by regulation) that are determined by FDA to be in shortage, including providing the names and NDCs of the drugs, the name of each manufacturer of the drug, the reason(s) for the shortage, and the estimated duration of the shortage. Section 506C(h)(2) of the FD&C Act defines ''drug shortage'' to mean a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug. For purposes of section 506E of the FD&C Act, under the rule, the ANDA, NDA, or BLA applicant is considered the manufacturer of an approved drug or biological product, even if the ANDA, NDA, or BLA applicant contracts that function out to another entity.

Section 506E of the FD&C Act further requires FDA to include on the drug and biological product shortages lists the reason for the shortage, choosing from the following list of categories specified in the statute:

- Requirements relating to complying with current good manufacturing practices (CGMPs);
- Regulatory delay;
- Shortage of an active ingredient;
- Shortage of an inactive ingredient component;
- Discontinuation of the manufacture of the drug;
- Delay in shipping of the drug; and
- Demand increase in the drug.

Consistent with the statute, and with FDA's current practice, under §§ 310.306(c), 314.81(b)(3)(iii)(*d*), and 600.82(d), FDA will maintain publicly available lists of drugs and biological products that are determined by FDA to be in shortage, whether or not FDA has received a notification under this rule concerning the product in shortage. Sections 314.81(b)(3)(iii)(*f*) and 600.82(f) adopt the statutory definition of drug shortage (substituting ''biological product shortage'' for ''drug shortage'' in § 600.82(f)). As specified in the rule, the

shortages lists will include the following required statutory elements for drugs or biological products in shortage: Names and NDCs (or the alternative standard for certain biological products) of the drugs or biological products, names of each applicant, reason for each shortage, and estimated duration of each shortage.

If FDA has received a notification under the rule for the drug or biological product, FDA will consider the reason for the shortage supplied by the applicant in its notification and, where applicable, other relevant information before the Agency in determining how to categorize the reason for the shortage. Consistent with the statute, the Agency, not the applicant, is responsible for determining which categorical reason best fits a particular situation. In general, FDA intends to choose the categorical reason that best fits the applicant's supplied description. To facilitate FDA's determination of the categorical reason for the shortage, under the final rule we expect applicants to supply as many details and facts as possible concerning the reason for the permanent discontinuance or interruption in manufacturing when submitting a section 506C notification. This information will also assist FDA in responding quickly to the notification. If FDA has not received a notification under the rule, but becomes aware of a shortage through other means, FDA intends to consider information before the Agency when determining and choosing the reason for the shortage to be included on the public list.

In addition to the list of statutory reasons for the shortage that FDA may choose from, the final rule also adds an eighth category, entitled ''Other reason.'' The Agency intends to choose ''Other reason'' only if none of the other listed reasons is applicable. For example, an interruption in manufacturing as a result of a natural disaster or other catastrophic loss would fall into the ''Other reason'' category. Moreover, although FDA may choose the ''Other reason'' category, the public shortages list will also include a brief summary of the reason for the shortage submitted by the applicant, thus providing additional information to the public on the cause of the shortage.

The final rule codifies, consistent with FDASIA, FDA's current practice of maintaining public lists of drugs and biological products in shortage, available on FDA's Web site at *http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm* (for products regulated by CDER) and *http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/default.htm* (for products regulated by CBER).

The list of CDER-regulated products includes six categories of information about each drug product on the list: Company (manufacturer of product and contact information); Product (name, strength, formulation, dosage, and NDC); Availability and Estimated Shortage Duration; Related Information (includes applicant's submitted description of reason for shortage); Shortage Reason (FDA-determined reason for the shortage, chosen from the list in § 314.81(b)(3)(iii)(*d*)); and Date Updated (last date FDA updated the information for that particular product). The list of CBER-regulated products includes similar information in fields for Product Name, Reason for Shortage, and Status.

5. Confidentiality and Disclosure

In general, as required by sections 506C(c) and 506E of the FD&C Act, and as described in this document, FDA will publicly disclose, to the maximum extent possible, information on drug shortages, including information provided by applicants in a notification of a permanent discontinuance or an interruption in manufacturing. Sections 314.81(b)(3)(iii)(*d*) and 600.82(d), however, specify that FDA may choose not to make information collected under the authority of the rule available to the public on the drug or biological product shortages lists or under its general obligation to disseminate drug shortage information under section 506C(c) of the FD&C Act if the Agency determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of the drug or biological product to patients). These provisions closely track the statutory language in sections 506C(c) and 506E(c)(3) of the FD&C Act.

In addition, §§ 310.306(c), 314.81(b)(3)(iii)(*d*), and 600.82(d), as finalized, state that FDA will not provide on the public drug or biological product shortages lists or under section 506C(c) of the FD&C Act information that is protected by 18 U.S.C. 1905 or 5 U.S.C. 552(b)(4), including trade secrets and commercial or financial information that is considered confidential or privileged under § 20.61. These provisions provide appropriate protection for commercial and trade secret information protected by other Federal law and are consistent with sections 506C(d) and 506E(c)(2) of the FD&C Act, which clarify that the information provisions in sections 506C and 506E do not alter or amend 18 U.S.C. 1905 or 5 U.S.C. 552(b)(4). The final rule also implements a technical amendment to § 20.100 to include a cross-reference to §§ 310.306, 314.81, and 600.82. Section 20.100 describes, by cross-reference to other regulations, the rules on public availability of certain specific categories of information.

6. Failure To Notify

Consistent with section 506C(f) of the FD&C Act, §§ 310.306(b), 314.81(b)(iii)(3)(*e*), and 600.82(e), as finalized, provide that FDA will issue a noncompliance letter to an applicant (or, for a covered, unapproved drug, to a manufacturer) who fails to submit a section 506C notification as required under §§ 314.81(b)(iii)(3)(*a*) and 600.82(a) within the timeframe stated in §§ 314.81(b)(iii)(3)(*b*) and 600.82(b). It is important to note that failure to notify FDA includes failure to *timely* notify FDA. For example, if FDA discovers that an applicant did not notify FDA of the permanent discontinuance of a covered drug or biological product 6 months in advance, even though the applicant anticipated the permanent discontinuance 6 months in advance, FDA will issue a noncompliance letter. Similarly, if FDA determines that an applicant experienced a reportable interruption in manufacturing that it could not reasonably anticipate 6 months in advance, but the applicant failed to notify FDA ''as soon as practicable,'' FDA will issue a noncompliance letter. Refer to section III.C.2.a for a discussion of the required timing for section 506C notifications.

As required by section 506C(f) of the FD&C Act, the rule provides the applicant with 30 calendar days from the date of issuance of the noncompliance letter to respond to the letter. The applicant's response must set forth the basis for noncompliance and provide the required notification with the required information. Not later than 45 calendar days after the date of issuance of the noncompliance letter, FDA will make the letter and the applicant's response public, after appropriate redaction to protect any trade secret or confidential commercial information. FDA will not make the letter and the applicant's response public if FDA determines, based on the applicant's response, that the applicant had a reasonable basis for not notifying FDA as required.

IV. Comments on the Proposed Rule

The Agency received submissions from 34 commenters, including public health associations, pharmaceutical industry, hospital groups, consumer

groups, and individuals. A summary of the comments contained in the submissions received and FDA's responses follow.

To make it easier to identify comments and our responses, the word ''Comment,'' in parentheses, appears before the comment's description, and the word ''Response,'' in parentheses, appears before our response. We have numbered each comment to help distinguish between different comments. Similar comments are grouped together under the same number. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

A. Persons Subject to the Rule

(Comment 1) One comment suggested that the notification requirement should be extended to API manufacturers. The comment stated that API manufacturers are further upstream in the drug development chain and that early warning of issues at this level, before they impact manufacturers formulating the drugs, would give FDA, other manufacturers of the drug, and programs more time to prepare and prevent shortages from affecting patients.

(Response) FDA does not agree that the notification requirement should be applied to API manufacturers. While interruptions in API supply may lead to a meaningful disruption in supply of the finished drug or biological product, they do not always have this effect. Therefore, notification to FDA of disruption in API supply would be premature and would not provide information that the Agency can take definitive action on. FDA believes that the notification requirement, which is derived from section 506C of the FD&C Act, generally provides the Agency with adequate notice to allow the Agency to work with the applicant and other stakeholders to prevent a shortage. As explained in section III.A, however, it is important that the applicant establish a process with any relevant contract manufacturer, API supplier, or other non-applicant entity to ensure that the applicant complies with this rule.

(Comment 2) One comment requested clarification on how a blood establishment will know if it is subject to the reporting requirements of the rule. The comment noted that the preamble to the proposed rule (78 FR 65904 at 65908) stated that FDA intends to consider a BLA-holder for blood or blood components to be a manufacturer of a significant percentage of the U.S. blood supply if the applicant manufactures 10 percent or more of the U.S. blood supply. The comment explained that the National Blood Collection and Utilization Survey (NBCUS) supplies the best data available nationally on collection and utilization of blood in the United States, but notes that the survey is voluntary and does not occur on an annual basis. The comment stated that it is not possible for a BLA holder to know what percentage of the U.S. blood supply it is collecting. Accordingly, the comment recommended that FDA identify an annual whole blood collection number to be used as the threshold for reporting.

(Response) FDA declines to identify an annual whole blood collection number to be used as a threshold for reporting because these numbers may fluctuate year to year. Because of their coordination with other BLA holders through the ABC, BASIS, and Task Force programs, we believe that BLA holders will generally be aware of whether they manufacture a significant percentage of the U.S. blood supply. Accordingly, we do not believe there will be significant uncertainty among BLA holders about whether they are subject to the notification requirements. If an applicant is unsure of whether it is subject to the notification requirements, we recommend that the applicant contact CBER at *cbershortages@fda.hhs.gov.*

(Comment 3) One comment noted that the proposed rule did not discuss the effect of the notification provision on product allocation systems. The comment explained that products with inherently limited supply have been historically put on allocation systems by manufacturers to prioritize the allocation of these products. The comment explained that these allocation systems help manage and track product supplies, curb gray market distribution, and prevent price hikes. The comment stated that section 506(D)(d) of the FD&C Act directs FDA to establish a mechanism by which health care providers and other third party organizations may report to the Agency evidence of a drug shortage. The comment requested confirmation that a notification under section 506D(d) of the FD&C Act does not extend to situations where a receiving entity (*e.g.,* a hospital) reaches its allocation limits.

(Response) The comment is beyond the scope of this rulemaking. The final rule implements sections 506C and 506E of the FD&C Act by amending §§ 20.100 and 314.81(b)(3)(iii) and adding new §§ 310.306 and 600.82. The rule does not address section 506D of the FD&C Act. Consistent with section 506D(d), however, we do encourage patients, providers, pharmacists, and other non-applicants to communicate with FDA about potential shortages or disruptions in supply by email at *drugshortages@fda.hhs.gov* (for products regulated by CDER) or *cbershortages@fda.hhs.gov* (for products regulated by CBER), so that the Agency can take appropriate steps to address these situations.

B. Products Covered by the Rule

1. Prescription Drug and Biological Products That Are Life Supporting, Life Sustaining, or Intended for Use in the Prevention or Treatment of a Debilitating Disease or Condition

(Comment 4) In the preamble to the proposed rule (78 FR 65904 at 65909), FDA requested comment on the proposed definitions of ''life supporting or life sustaining'' and ''intended for use in the prevention or treatment of a debilitating disease or condition'' and in particular, whether the definitions might lead to ''over-notification.'' The majority of commenters supported the proposed definitions and agreed that they are consistent with current understanding of these terms. Some commenters noted that there might be the potential for over-notification but agreed that more information, rather than less, will enhance FDA's ability to prevent drug and biological product shortages. One comment stated that the definitions could lead to over-notification if they are broadly interpreted but noted that it is difficult to predict whether over-notification will actually occur. The comment suggested that within 1 year of implementation of the final rule, FDA can assess whether overnotification has occurred and can revise the draft guidance for industry entitled ''Notification to FDA of Issues that May Result in a Prescription Drug or Biological Product Shortage'' to include additional examples of products that are or are not likely to fall within the scope of products subject to the notification provision.

(Response) FDA appreciates the commenters' input. We continue to believe that the proposed definitions provide sufficient clarity without overly restricting the categories of products subject to the rule. We have therefore finalized the definitions that were proposed and believe that these definitions will result in appropriate notifications under the rule. If, however, FDA finds that over-notification has occurred, the Agency may consider further clarification in guidance or by other suitable means.

(Comment 5) Three comments stated that the proposed definitions were overly broad, potentially encompassing the majority of approved drug and biological products, and may be subject to inconsistent interpretation. Two comments recommended using definitions based on the definitions of ''immediately life-threatening disease or condition'' and ''serious disease or condition'' in § 312.300. One of those comments specifically proposed the following definitions:

• ''A life supporting or life sustaining drug product means a drug product that is essential to, or yields information that is essential to, the restoration or continuation of a bodily function associated with a stage of disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.''

and

• ''A debilitating disease or condition means a serious disease or condition associated with morbidity that has a substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.''

(Response) FDA does not believe it is appropriate to incorporate the comment's proposed definitions or alternative definitions based on the definitions set forth in § 312.300. As explained in section III.B.1, under §§ 314.81(b)(3)(iii)(*f*) and 600.82(f) of this final rule, FDA equates ''debilitating disease or condition'' with ''serious disease or condition,'' and we have defined ''debilitating disease or condition'' according to the definition of ''serious disease or condition'' found in § 312.300. In the Agency's view, the definitions suggested in the comment would be too restrictive and could exclude certain products, such as anesthetic products, that are critical to patient care and should appropriately be considered ''life supporting or life sustaining'' or ''intended for use in the prevention or treatment of a debilitating disease or condition.'' As noted in the previous response, FDA believes that the definitions in this final rule provide sufficient clarity without overly restricting the categories of products subject to the rule. If, following implementation of the rule, it appears that further clarification is necessary, FDA will consider what type of clarification may be beneficial and take appropriate steps.

(Comment 6) Three comments suggested that FDA should consider providing a list, in guidance or otherwise, of examples of drug products or classes of drug products that are likely to meet the definitions of ''life supporting or life sustaining'' or ''intended for use in the prevention or treatment of a debilitating disease or condition.'' The commenters suggested that such a list would provide greater clarity and facilitate compliance with the rule.

(Response) FDA does not believe it is appropriate to provide a list of products that are likely to meet the definitions of ''life supporting or life sustaining'' or ''intended for use in the prevention or treatment of a debilitating disease or condition.'' Such a list would be difficult to maintain and keep up to date as products come off the market and new products enter the market. We are also concerned that applicants and the public may misinterpret the list as an exhaustive list of all products that would be subject to the notification requirement, rather than as examples of drug products or classes of drug products that are likely to meet the definitions.

If an applicant is uncertain whether a particular discontinuance or interruption in manufacturing of a drug or biological product should be reported to FDA, we encourage the applicant to proceed with notification. It is important to note that, under section 1001(b) of FDASIA, submission of a notification will not be construed as: (1) An admission that any product that is the subject of the notification violates any provision of the FD&C Act or (2) evidence of an intention to promote or market the product for an unapproved use or indication.

(Comment 7) One comment requested that FDA recognize attention-deficit hyperactivity disorder (ADHD) as an example of a debilitating condition. The comment stated that FDA could do so by adding to the definition in the final rule a list of some debilitating diseases and conditions and including ADHD in that list.

(Response) FDA has recognized ADHD as an example of a debilitating condition. We note further that when products used to treat ADHD have gone into shortage, they have been included on FDA's drug shortages Web site. However, FDA declines to add a list of examples of debilitating conditions to the rule.

(Comment 8) One comment requested clarification that drugs used to treat a ''debilitating disease or condition'' include sedatives, anesthetics, analgesics, and anti-inflammatory drugs.

(Response) FDA has considered sedatives, anesthetics, analgesics, and anti-inflammatory drugs to be drugs that are intended for use in the prevention or treatment of a debilitating disease or condition.

(Comment 9) One comment suggested that the rule be modified to give FDA the option of including a statement in the approval letter for new NDAs, ANDAs, or BLAs indicating that the product is covered by the rule. The comment noted that this type of statement about the product's status would provide clarity and could be beneficial, especially to applicants entering the U.S. market for the first time.

(Response) FDA understands that including a statement in the approval letter that the product is covered by this rule would clarify that particular product's status. The Agency is concerned, however, that such action may create confusion about the status of other already-approved products where the approval letter does not include a statement regarding notification under this rule. Applicants and other stakeholders may believe that the notification requirement only applies with respect to products whose approval letter contains a statement about notification under this rule. Therefore, FDA does not think it would be appropriate to add a provision to the rule as suggested by the comment.

(Comment 10) One comment requested clarification that the definition of ''medically necessary'' in the drug shortage MAPP solely relates to the allocation of internal Agency staffing and resources and that it has no bearing on the scope of products subject to notification under the proposed rule or FDA's determination of an actual shortage and public notification of a shortage.

(Response) As explained in section IV.B.1 of this document and in the preamble to the proposed rule, under this rule, an applicant is required to notify FDA of a permanent discontinuance or an interruption in manufacturing of a drug or biological product that is life supporting, life sustaining, or intended for use in the prevention or treatment of debilitating disease or condition, whether or not the product is considered medically necessary under the MAPP. Under the MAPP, FDA uses the definition of medically necessary to prioritize the Agency's response to specific shortages

or potential shortages and to allocate resources appropriately.

(Comment 11) One comment expressed support for the inclusion of prescription drug products marketed without an approved NDA or ANDA and noted that such products are often critical to patient care.

(Response) FDA agrees that prescription drug products marketed without approved applications are important in patient care and accordingly § 310.306 is being finalized as proposed to ensure that the Agency is notified of a permanent discontinuance or an interruption in manufacturing of such products, as appropriate.

(Comment 12) Three comments raised questions about off-label uses. One comment requested clarification that off-label indications are not included within the scope of ''marketed unapproved prescription drugs.'' Two comments noted that many prescription drug products used to treat children and nearly all prescription drug products used to treat neonates are not labeled for use in those populations. Accordingly, those two comments stated that the rule should require notification based on off-label uses in addition to the uses in the labeling.

(Response) Off-label uses of drug and biological products are not included within the scope of ''marketed unapproved prescription drugs.'' FDA is not requiring applicants to consider off-label uses when determining whether a product is a covered product for purposes of the notification requirement in section 506C of the FD&C Act and implemented in this rule. The Agency understands that off-label uses can, in certain circumstances, be an important part of patient care. In fact, as explained in the MAPP on drug shortages (CDER MAPP 4190.1 Rev. 2), FDA considers off-label uses when classifying products as medically necessary for purposes of prioritization. However, off-label uses are based on a practitioner's professional judgment about what will benefit an individual patient, and we do not believe it would be reasonable to expect applicants to take account of individual practitioners' therapeutic decisionmaking in assessing whether their products are subject to the notification requirement. We note that in many cases, though, products that would be covered by the rule if it applied based on an off-label use may nevertheless be covered products based on a labeled use, in which case the applicant would be subject to the notification requirement for that product.

2. Biological Products

(Comment 13) Many comments strongly supported applying section 506C of the FD&C Act to biological products. These comments expressed the view that early notification of a permanent discontinuance or an interruption in manufacturing of biological products would benefit the public health by facilitating prompt action on FDA's part to address, prevent, or mitigate a shortage of these products.

(Response) FDA appreciates these comments and agrees that extending the notification requirement to biological products will benefit the public health. Therefore, consistent with section 506C(i)(3), the Agency is finalizing § 600.82 as proposed.

(Comment 14) Two comments requested that the Agency make clear that biosimilars are subject to the provisions of section 506C of the FD&C Act. The comments stated that while the approval process for biosimilars is still under development, it is important that such products be included in the requirements of the final rule.

(Response) This rule applies to prescription biological products licensed under section 351 of the PHS Act,[11] including prescription biosimilar biological products licensed under section 351(k) of the PHS Act, that are life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including any such product used in emergency medical care or during surgery, and excluding radiopharmaceutical products.

(Comment 15) One comment expressed support for the inclusion of blood or blood components for transfusion but requested clarification on how FDA will determine which blood or blood components would be exempt from the rule and how FDA plans to address shortages of products determined to be exempt. In particular, the comment sought clarification on whether the rule would apply to reagents used to cross-match platelets for transfusion. The comment stated that there have been shortages of these reagents recently, which has impacted patient care.

(Response) As explained in section III.B.2.c, the notification requirement applies only to applicants of blood or blood components for transfusion that manufacture a significant percentage of the U.S. blood supply, and only when there is a permanent discontinuance of manufacture or an interruption in manufacturing that is likely to lead to a ''significant disruption'' in supply of that blood or blood component. As noted in footnote 1 in the Executive Summary, the rule does not apply to biological products that meet the definition of a device in section 201(h) of the FD&C Act. Accordingly, this rule does not apply to reagents or other products that CBER regulates as devices, such as products intended for screening or confirmatory clinical laboratory testing associated with blood banking practices and other testing procedures (*e.g.,* blood typing and compatibility testing).

(Comment 16) Two comments stated that blood and blood components should not be included in the rule. The comments cited the current systems described in the preamble to the proposed rule (78 FR 65904 at 65911) that monitor local and regional supplies of blood or blood components and coordinate during domestic disasters. The comments noted that blood and blood components do not have a history of shortages and stated that given the existing reporting systems and acknowledged successful record of planning activities in the blood community, coordination among the major blood organizations, and cooperation with FDA and HHS during and following disasters, it is not necessary to add another layer of reporting that is unlikely to provide additional security.

(Response) As explained in the preamble to the proposed rule (75 FR 65904 at 65911) and in section III.B.2.c, FDA agrees that the information available from ABC and BASIS and the efforts by the Task Force are critical to public health, and the Agency appreciates the willingness of applicants to coordinate. However, there are limitations to these existing systems. These systems are voluntary, they do not result in a direct notification from an applicant to FDA, and they only capture short-term, day-to-day supply and distribution information. In addition, the existing systems are not equipped to predict large-scale, significant disruptions of blood or blood components. We believe that including blood and blood components in the final rule will allow FDA to anticipate large-scale, significant disruptions of blood or blood components and take appropriate action. Accordingly, FDA has determined that including blood and blood components within the scope of this rule will benefit the public health

[11] As noted in footnote 1 to the Executive Summary, the term ''biological product'' refers to a biological product licensed under section 351 of the PHS Act, other than a biological product that also meets the definition of a device in section 201(h) of the FD&C Act.

by ensuring that the Agency is provided with information essential to FDA's efforts to address shortages of these products without duplicating existing programs.

(Comment 17) One comment stated that cellular and gene therapy products should not be included in the rule. The comment stated these are relatively new products and that the notification requirements are not necessary for them. The comment noted that BLA holders should be reporting to FDA, at least annually, what products are being manufactured under the license, and if an applicant is experiencing difficulty manufacturing a product, the applicant can communicate with FDA. The comment stated further that it is difficult to understand the ''meaningful'' process FDA would initiate if a report is received from a cellular or gene therapy manufacturer, and recommended that if cellular and gene therapy products are included in the final rule, FDA should provide a specific guidance document addressing these products.

(Response) FDA does not agree that cellular and gene therapy products should be excluded from the rule, nor do we agree that periodic distribution reporting or voluntary communication with FDA regarding manufacturing difficulties are adequate to allow the Agency to address shortages of cellular and gene therapy products. Shortages of biological products can have serious health consequences for patients who rely on these products for their treatment. Early notification of a permanent discontinuance or an interruption in the manufacturing of biological products is crucial for allowing FDA to take steps to prevent, or mitigate a shortage of these products.

The required distribution reports referred to in the comment do not provide sufficient notice for FDA to anticipate a shortage or take appropriate action to address a shortage. As explained in the preamble to the proposed rule (78 FR 65904 at 65911), under § 600.81, applicants are required to submit to CBER or CDER information about the quantity of product distributed under the license, including the quantity of product distributed to distributors. As part of the safety reporting requirement, manufacturers provide distribution data to FDA every 6 months or at other intervals as may be required by FDA. Although distribution reports submitted by applicants are helpful in the analysis of safety reporting data, these reports do not include information about a permanent discontinuance or an interruption of the manufacture of a biological product that is likely to lead to a meaningful disruption in the supply of that product. In addition, any distribution data received from the applicant at 6-month intervals may not be current. Accordingly, FDA has determined that including cellular and gene therapy products within the scope of this rule would benefit the public health by ensuring that FDA is provided with information that is essential to Agency's efforts to address shortages of these products. If, following implementation of the rule, it appears that guidance or further clarification is necessary for cellular and gene therapy products, FDA will consider what type of guidance may be beneficial and take appropriate steps in accordance with good guidance practices set out in 21 CFR 10.115.

(Comment 18) Two comments recommended that the rule not be applied to vaccines. The comments stated that, in response to the unique nature of vaccines, the CDC has successfully partnered with vaccine applicants to reduce, if not eliminate completely, impacts to public health that may arise due to a supply shortage. The comments stated that CDC continues to be in the best position to monitor and manage vaccine supply. The comments suggested that the CDC should continue to act as a confidential facilitator of critical supply information that is provided by applicants or manufacturers, to maintain these data as proprietary and confidential, and to allow CDC to use the information so that other applicants or manufacturers can fill the gap in the event of an imminent shortage. In addition, the comments noted that, for over a decade, the vaccine industry has voluntarily strived to provide FDA with the requested minimum 6-month notice when making a determination to discontinue production of a particular vaccine, where such a decision was foreseeable.

Alternatively, the comments proposed that FDA consider limiting the scope of the proposed rule to cover only non-VFC vaccines since there already are effective notification and distribution systems in place under the VFC program. The comments noted that CDC maintains a stockpile of VFC vaccines as part of its vaccine shortage notification program. Due to the CDC's regular collaboration with vaccine manufacturers, this program has proven highly successful in mitigating or completely eliminating supply disruptions.

(Response) FDA does not agree with the commenters' suggestion that the rule should not apply to vaccines or, in the alternative, should only apply to non-VFC vaccines. FDA recognizes that CDC includes language in its contracts with vaccine manufacturers requiring the manufacturer to notify CDC of vaccine supply issues that could affect the manufacturer's ability to fulfill its contract with CDC. FDA does not intend this rule to disrupt the contractual process and procedures that exist between manufacturers and CDC. However, as explained in the preamble to the proposed rule (78 FR 65904 at 65910), approximately 30 percent of vaccines licensed in the United States are not subject to CDC notification, including vaccines for rabies, yellow fever, and typhoid. Even for the vaccines that are subject to CDC notification, the information collected by CDC is not adequate for purposes of this rule. The existing CDC program does not require vaccine manufacturers to provide notice 6 months in advance of a permanent discontinuance or interruption in manufacturing. Early notice of permanent discontinuances and interruptions is critically important to prevention of drug and biological product shortages. Although FDA and its HHS partners work together on vaccine supply issues, FDA believes that including vaccines within the scope of this rule is essential to fully support FDA's efforts to identify, address, prevent, or mitigate a vaccine shortage.

(Comment 19) Two comments noted that by design, influenza vaccine is a seasonal product and consequently, is unavailable for a significant portion of each year. The comments stated that for this reason, both seasonal influenza and pandemic influenza vaccines should not be covered by the rule.

(Response) We acknowledge that some vaccines, such as those for influenza, are seasonal products by design and consequently may be unavailable for a significant portion of the year. It is important to note that ''meaningful disruption'' is defined as a ''reduction in the supply of a drug . . . that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product.'' In the case of a seasonal product, we anticipate that demand would decrease during the off-season; therefore, we would not expect that an interruption in manufacture of a seasonal product would be likely to lead to a meaningful disruption in the off-season. Accordingly, we decline to exempt vaccines intended for seasonal and pandemic use. We believe shortages of biological products, including seasonal influenza vaccines, can have serious health consequences for patients who rely on these products. Early notification of a permanent discontinuance or an interruption in the

manufacturing of these products will allow FDA to promptly take steps to prevent or mitigate a shortage of these products that could otherwise result in delayed patient access.

3. Scope of the Term ''Product''

(Comment 20) Two comments noted that the proposed rule would apply individually to all strengths, dosage forms, or routes of administration for a given product regardless of the supply status for other presentations and dosages of the same product. The commenters suggested that the rule should allow greater flexibility and should not apply to a product if an alternate presentation of the same therapeutic product is available.[12]

(Response) FDA does not agree. As we explained in the preamble to the proposed rule (78 FR 65904 at 65912), we understand that the permanent discontinuance or interruption in manufacturing of a specific strength, dosage form, or route of administration can have a significant impact on the targeted needs of particular patients. The Agency strives to ensure the availability of appropriate treatment options for patients. We also note that shortages of a specific strength, dosage form, or route of administration may lead to a shortage of another strength, dosage form, or route of administration, thereby exacerbating difficulties in obtaining the product. Furthermore, as explained in other comments on the proposed rule (available in Docket No. FDA–2011–N–0898), requiring notification based on the status of each strength, dosage form, and route of administration helps to ensure that patients and their health care providers have the most accurate information about potential shortages, and can make treatment decisions accordingly.

If the applicant has available an alternate presentation of the same product, the applicant should include that information in the notification as a proposal to mitigate the shortage.

(Comment 21) One comment requested confirmation that notification is not required when there is a shortage of a particular ''count'' of product but overall the quantity of that product is not in shortage (*e.g.,* a manufacturer is in short supply of a 50-count bottle of 10-mg pills, but there are sufficient numbers of 25-count bottles of 10-mg pills to meet patient need).

(Response) FDA would not require notification in the situation described in the example provided.

[12] We understand the comment to mean that the rule should not apply to a particular applicant if that applicant has available the same product in a different presentation, *e.g.,* a different strength.

C. Notification of a Permanent Discontinuance or an Interruption in Manufacturing

1. Notification

(Comment 22) One comment expressed concern about the notification requirement as applied to blood or blood components. The comment cited the proposed rule (78 FR 65904 at 65913) and stated that monthly reporting of a decrease in any blood component produced by an affected BLA holder is overly burdensome and would result in reports that are meaningless. The comment recommended that FDA provide information and recommendations in a draft guidance to more fully explain the goals of this particular data collection.

(Response) The rule requires the notification of a permanent discontinuance or an interruption in manufacturing of blood or blood components that is likely to lead to a significant disruption in supply of the product in the United States. FDA intends to consider an interruption in manufacturing that leads to a reduction of 20 percent or more of an applicant's own supply of blood or blood components over a 1-month period to ''substantially affect'' the ability of the applicant to fill orders or meet expected demand. Such an interruption would be considered a significant disruption in supply. The rule does not require manufacturers to submit or report monthly data. The rule, as applied to BLA holders for blood or blood components for transfusion, is intended to capture events that are likely to precipitate large-scale disruptions in an applicant's blood supply.

(Comment 23) One comment expressed concern that the requirement that applicants report an ''interruption in manufacturing'' that is likely to cause a disruption in the manufacturer's own supply of a drug or biological product could keep important information from being reported to FDA. The comment explained that a manufacturer that is not experiencing ''an interruption in manufacturing,'' but rather is experiencing a lack of available product due to an increase in demand would not be required to notify the Agency. The comment suggested that FDA consider expanding the notification requirement to include those applicants experiencing a shortage in supply due to an increase in product demand.

(Response) FDA agrees that notification by an applicant lacking available product because of an increase in demand, and not because of an interruption in manufacturing, could be helpful in anticipating and addressing potential shortages. However, such a notification requirement is beyond the scope of section 506C of the FD&C Act implemented by the final rule. FDA does encourage applicants to communicate with FDA if there is an increase in demand that the applicant is not able to meet. We also note that if an applicant experiences an increase in demand because of another applicant's permanent discontinuance or interruption in manufacturing, FDA would expect to receive notification about the situation from the applicant that has experienced the discontinuance or interruption.

(Comment 24) Two comments recommended specific modifications to the definition of ''meaningful disruption,'' believing it to be unclear and potentially subject to inconsistent interpretation. First, the comments stated that terms within the definition, such as ''reasonably likely,'' ''more than negligible,'' and ''short period'' are insufficiently precise and recommended that the terms be removed from the definition. Second, the comments stated that, under the definition, applicants would be required to notify FDA if any products are under allocation or the demand for the product exceeds the available supply. Accordingly, the comments suggested adding language to the definition with the clarification that ''meaningful disruption'' means that the adverse impact to supply is unable to be remediated or minimized through allocation or other means of prioritization. Last, the comments noted that many factors could potentially affect the ability of applicants to fill orders, including some that are not within an applicant's control. The comments noted that applicants do not ultimately determine, nor can they in all cases accurately predict, volumes of orders or product demand. One of the comments accordingly recommended that FDA consider including language to clarify that the definition of ''meaningful disruption'' is intended to reflect situations in which the availability of a product to patients would be impacted. The comment suggested that the rule should clarify whose orders the applicant needs to be able to fill, in order to distinguish between the temporary inability to fulfill an order to a wholesaler, as opposed to the inability of a patient to obtain a prescription or receive appropriate therapy.

(Response) The final rule is being issued to implement sections 506C and 506E of the FD&C Act, consistent with section 506C(i). Section 506C(h) defines ''meaningful disruption'' as ''a change in production that is reasonably likely

to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product'' and that ''does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.'' The final rule adopts the statutory definition. In our view, the language used in the statute provides flexibility to accommodate the wide variety of circumstances that may result in drug or biological product shortages. If there is any uncertainty about whether a particular circumstance must be reported to FDA under the rule, we encourage applicants to submit a notification. Early notification is FDA's best tool for addressing shortages. Moreover, submission of a notification will not be construed as: (1) An admission that any product that is the subject of the notification violates any provision of the FD&C Act or (2) as evidence of an intention to promote or market the product for an unapproved use or indication.

(Comment 25) One comment noted that the preamble to the proposed rule (78 FR 65904 at 65912 and 65913) provides a number of examples of reportable discontinuances or interruptions in manufacturing of a covered drug or biological product. The comment stated that not all of the examples would result in a shortage of product to patients and may result in industry ''over-reporting'' events to the Agency. Accordingly, the comment requested that FDA further clarify the requisite link between the examples provided and an actual ''meaningful disruption'' in supply.

(Response) The list of examples provided in the preamble to the proposed rule are intended to assist applicants in understanding what must be reported under section 506C of the FD&C Act. As implemented by the final rule, section 506C requires that applicants notify FDA of a permanent discontinuance in the manufacture of a covered drug or biological product or an interruption of the manufacture of the drug or biological product that is likely to lead to a meaningful disruption in the supply of that product in the United States, and the reasons for such discontinuance or interruption. The list of examples is not intended to include only situations that will necessarily result in a meaningful disruption in supply. The list includes examples of events (*i.e.,* permanent discontinuance and interruption in manufacturing) that are *likely* to lead to a meaningful disruption in supply and therefore must be reported to the Agency.

(Comment 26) One comment suggested that FDA amend the rule to require blood component manufacturers to report a decrease in donations when it is due to their own decision to close donation sites versus the natural ebb and flow of blood donation cycles. The comment stated that companies have the ability to create shortages with the purpose of increasing prices by closing donation sites.

(Response) FDA does not agree the suggested change is necessary or appropriate. As explained in the preamble to the proposed rule (78 FR 65904 at 65913), FDA need not be notified if a covered blood or blood component applicant experiences a temporary drop in blood donations at one of its local blood donation centers, such that it is unable to fully supply its hospital customers with blood for several days, provided the donation center quickly returns to its normal donation and supply levels and the dip in blood donations is not likely to lead to a 20 percent decrease in the applicant's overall supply of blood over a 1-month period. We expect that this type of situation would be identified and resolved through the existing programs that coordinate local and regional supplies of blood or blood components (*e.g.,* these systems would identify the issue and locate temporary, alternative blood supplies for the applicant's customers). If such an event does lead to a significant disruption in a covered applicant's supply of blood or blood components, it would need to be reported to FDA under this rule.

(Comment 27) One comment noted that some of the quality issues subject to notification under the rule also would be subject to reporting under Field Alert Reports for drugs and Biological Product Deviation Reports for biological products. In an effort to avoid dual reporting requirements, the comment suggested that FDA attempt to coordinate these reports and the Agency's followup in order to minimize the burden on both FDA and applicants.

(Response) FDA recognizes that some quality issues that result in interruptions in manufacturing subject to this rule could also be subject to reporting under Field Alert Reports (FARs) for drugs and Biological Product Deviation Reports (BPDRs) for biological products. However, FARs and BPDRs are not supply reporting programs and do not serve the same purpose as notification under this rule. Applicants with approved NDAs and ANDAs are required to submit FARs to FDA if they find any significant problems with an approved drug; the purpose of the Field Alert Program is to quickly identify drug products that pose potential safety threats. Similarly, BPDRs are used by biological product manufacturers to report biological product deviations that may affect the safety, purity, or potency of a distributed product. Problems reported through FARs and BPDRs may not lead to a shortage. Moreover, we note that the timing of these reports and the information provided in them may not be adequate for FDA to address potential shortages. Therefore, we have determined that requiring manufacturers of drugs and biological products to notify FDA under this rule will not duplicate existing reporting programs and will provide the Agency with necessary information and lead time to take appropriate action to prevent or mitigate a shortage.

(Comment 28) One comment proposed that additional factors be taken into consideration and used as ''filters'' when manufacturers report drug and biologics shortages in order to limit the reporting of potential supply chain disruptions that are not ''true drug shortage'' events. The comment stated that these factors might include market dynamics and duration of supply chain shortage. With regard to market dynamics, the comment stated that FDA should consider the number of active suppliers and the percentage of the market supplied by such active suppliers. The comment stated that using this as a filter would help alert FDA to identify suppliers that are providing a significant percent of the market and that truly have the potential to create a drug shortage. For example, a market supplied by 10 active suppliers of equal market share would not likely experience a drug shortage if 1 of the active suppliers had a supply chain disruption. According to the comment, the market void could be absorbed by the nine other active suppliers via safety stock, additional production, etc. Therefore, the comment recommended the addition of a ''primary suppliers'' filter to separate those active suppliers who are supplying a significant percent to the market (*i.e.,* such as 20 percent or more of the market).

In addition, the comment stated that the duration of a supply chain shortage should be taken into consideration and utilized as a filter regarding drug shortage reporting. This filter would consider the typical inventory levels carried in the retail and wholesale channels. For example, an active supplier may have a supply disruption (*i.e.,* product out of stock) for 30 days; however, the market may not experience

a drug shortage given the inventory levels in the retail and wholesale channels. Typical inventory levels within these channels could range from 30 to 60 days of supply; therefore, the comment proposed a 60-day potential supply disruption as the minimum duration for drug shortage reporting to avoid chances of inventory hoarding and artificial increases in market demand that ultimately undermine the intent of FDASIA.

(Response) FDA declines to adopt the ''filters'' proposed to reduce reporting under the rule. FDA does not agree that these proposed ''filters'' are consistent with the language or intent of FDASIA. As explained in the preamble to the proposed rule (78 FR 65904 at 65912), ''meaningful disruption'' means a disruption in the applicant's own supply. This interpretation avoids the problem of expecting an applicant to predict the market-wide impact of its own interruption in manufacturing, which can be difficult to assess and could lead to inconsistent interpretation and less accurate predictions.

(Comment 29) Two comments addressed the stockpile of VFC vaccines maintained by CDC as part of its vaccine shortage notification program and noted the success of the program in mitigating or completely eliminating supply disruptions. One of the comments requested that FDA permit applicants to take into consideration the existence of a CDC stockpile in assessing whether an interruption in manufacturing is reasonably likely to disrupt supply chains.

(Response) We acknowledge the importance of the stockpile of VFC vaccines maintained by CDC. CDC and HHS are required to maintain a stockpile of routinely recommended vaccines for the United States in the event of vaccine shortages or other unanticipated supply problems. The national pediatric vaccines stockpile currently maintains 14 pediatric vaccines that protect infants, children, and adolescents from 15 vaccine-preventable diseases excluding influenza.[13] Where appropriate, FDA and the manufacturers work together with CDC and take into consideration the existence of a CDC stockpile in assessing the impact of supply disruptions and the likelihood of a shortage. However, for the purposes of reporting under this rule, we do not agree that applicants should be permitted to take into consideration the existence of the CDC stockpile. As explained in section III.C.1.b.i, consistent with the statutory definition of meaningful disruption, the rule requires an applicant to report an interruption in manufacturing that is likely to lead to a meaningful disruption in its *own supply* of a covered drug or biological product. The rule does not require an applicant to predict the market-wide impact of an interruption in its own manufacturing, which can be difficult to accurately assess and could lead to inconsistent interpretation of the regulation, less accurate predictions, and under- or overreporting.

2. Timing and Submission of Notification

(Comment 30) Three comments requested clarification of when the notification ''clock'' would start, in other words, exactly when the notification requirement would be triggered. Two of the comments explained that at the outset, a meaningful disruption might not appear ''likely'' but may become ''likely'' as the events progress. The comments expressed concern that the Agency and the applicant may disagree about which event would trigger the notification requirement if it was not obvious to the applicant initially that a meaningful disruption would be likely. The comments suggested that the appropriate trigger to start the notification ''clock'' is the date on which information becomes available to the applicant from which it could be reasonably determined that a meaningful disruption is likely to occur. Another comment noted that the notification clock could begin on the date of the event causing the interruption, or on the date the applicant becomes aware that an interruption could cause a shortage. The comment cautioned that if the latter were considered the trigger, it may be difficult to determine the exact point in time.

(Response) FDA expects that an applicant will notify FDA as soon as information becomes available to the applicant from which the applicant could reasonably determine that a meaningful disruption is likely to occur. As explained in section III.C.2.a of this document and the preamble to the proposed rule (78 FR 65904 at 65914), the applicant should not wait until the interruption in manufacturing actually begins to disrupt supply and affect patient access to the product. Early notification is the Agency's best tool for addressing shortages because it provides FDA with lead time to work with stakeholders to prevent the shortage or mitigate the impact of an unavoidable shortage. Accordingly, while not required, we encourage applicants to communicate with FDA even in situations where a meaningful disruption may appear to be possible though not necessarily likely.

We understand the commenters' concern that FDA and the applicant may disagree about which event would trigger the notification requirement. FDA has sent and intends to continue sending noncompliance letters when the Agency believes an applicant failed to notify FDA as soon as practicable or within 5 business days of the discontinuance or interruption.[14] If an applicant receives a noncompliance letter but believes the failure to notify was reasonable, the applicant should provide a full explanation of the circumstances in the applicant's response to the noncompliance letter. Consistent with section 506C(f)(3) of the FD&C Act, FDA will carefully consider the explanation provided in determining whether there was a reasonable basis for not notifying the Agency. If FDA determines that there was a reasonable basis for not notifying the Agency in accordance with section 506C of the FD&C Act and this rule, we will not post the noncompliance letter or the applicant's response to FDA's Web site.

(Comment 31) Several comments addressed the proposal that if 6 months' advance notice is not possible, notification must be submitted as soon as practicable thereafter, but in no case later than 5 business days after the permanent discontinuance or interruption in manufacturing occurs. Some comments expressed concern that FDA would allow an applicant to report as late as 5 days after a permanent discontinuance or interruption in manufacturing occurs. One comment stated that this would significantly weaken the rule and limit its effectiveness. The comment further stated that for an unforeseen disruption or discontinuation, FDA should require immediate notification or should outline what situations could arise that would appropriately necessitate a 5-day reporting delay. One comment expressed the view that reporting 5 days after the interruption should only be considered acceptable in rare circumstances, such as natural disaster. Another comment stated that applicants should be required to notify FDA a minimum of 6 months prior to the discontinuance or interruption, the only

[13] See *http://www.cdc.gov/phpr/documents/VacStockpileManual.pdf.*

[14] As noted in section III.C.2.a, even if an applicant notifies FDA within 5 business days of the discontinuance or interruption, the applicant may be issued a noncompliance letter if FDA believes the applicant did not notify the Agency as soon as practicable.

exception being a natural disaster or catastrophic incident. The comment stated that the proposed language is vague and lenient and creates a loophole in mandatory reporting that ultimately serves neither the public health nor that of patients, while shielding manufacturers from their own failure to plan adequately.

In contrast, some comments expressed concern that requiring notification no later than 5 business days after the discontinuance or interruption would not provide sufficient time for applicants to investigate and get a complete understanding of the issue. The comments explained that more than 5 business days may be necessary to confirm whether actions taken in response to the interruption will affect the manufacturer's ability to fill orders or meet expected demand. One comment stated that requiring notification before a full investigation has been completed is likely to lead to overreporting and less reliable information being provided to FDA. The comment stated that the ''as soon as practicable'' standard set forth in FDASIA provides the necessary flexibility and should not be altered by adding a 5 business day limit. One comment recommended that, if FDA believes a definite reporting timeframe is necessary, it should be no shorter than 15 days after the permanent discontinuance or interruption in manufacturing. Another comment proposed that if a timeframe is necessary, it could be extended to 15 days along with qualifying language, such as ''once it can conclusively be determined that a manufacturing issue will adversely impact supply.''

(Response) FDA's most powerful tool for addressing drug and biological product shortages is early notification, which provides lead time for the Agency to work with manufacturers and other stakeholders to prevent a shortage or to mitigate the impact of unavoidable shortages. Accordingly, we expect that applicants will provide 6 months' advance notice whenever possible. FDA understands, though, that an applicant may not reasonably be able to anticipate certain interruptions in manufacturing that are likely to lead to a meaningful disruption in supply 6 months in advance. In those situations, FDA requires notification ''as soon as practicable,'' but in no case more than 5 business days after the interruption in manufacturing occurs. The Agency has determined that 5 business days is adequate time for an applicant to assess whether the discontinuance or interruption in manufacturing is likely to lead to a meaningful disruption. As the situation evolves, FDA expects that applicants will provide the Agency with appropriate updates that will facilitate FDA's efforts. We believe that this timeframe appropriately balances the need for early notification and the understanding that applicants may not be able to immediately assess the impact of an interruption in manufacturing.

If notification was required only when an applicant has confirmed that a meaningful disruption will occur, then it might be appropriate to provide additional time for applicants to make this determination. However, the statute requires notification when a discontinuance or interruption in manufacturing is likely to lead to a meaningful disruption. The statute takes account of the fact that there may be a degree of uncertainty about the outcome of the discontinuance or interruption. As such, we note that the qualifying language proposed by one comment (*i.e.,* adding ''once it can conclusively be determined that a manufacturing issue will adversely impact supply'' to the notification requirement) would not be consistent with the statutory requirement to notify FDA when a discontinuance or interruption is likely to lead to a meaningful disruption. FDA believes it is reasonable for an applicant to make a determination about whether an interruption is likely to lead to a meaningful disruption in supply within 5 business days of the discontinuance or interruption. The Agency does not believe that 15 business days should be necessary to make such a determination, and a delay of 15 business days in notification could have a significant impact on FDA's ability to prevent or mitigate a shortage.

We note that if an applicant receives a noncompliance letter for failure to notify the Agency within 5 business days of a discontinuance or interruption in manufacturing and believes that it would not have been reasonable to expect the applicant to determine that the event was likely to lead to a meaningful disruption, such information should be provided in the applicant's response to the noncompliance letter. The Agency, in turn, will consider that information in determining whether the applicant had a reasonable basis for not notifying FDA within the required timeframe and therefore whether the noncompliance letter should not be made public.

(Comment 32) One comment suggested that the rule should specifically include ''natural disaster'' as a potential trigger for notification. The comment acknowledged that the preamble to the proposed rule notes that reportable interruptions in manufacturing may include natural disasters, but the commenter was concerned that the examples provided in the proposed rule were all circumstances under the control of the manufacturer.

(Response) A wide variety of situations may lead to a reportable interruption in manufacturing (including natural disasters, equipment failure, or a delay in acquiring APIs or inactive ingredients), and FDA does not believe it is necessary or appropriate to include specific examples within the regulation itself. The Agency believes that the information and examples provided in the preamble to the proposed rule are adequate to assist applicants in determining whether a given interruption in manufacturing must be reported to FDA.

(Comment 33) One comment recommended that FDA require manufacturers to provide periodic updates on actions they are taking to bring drugs that are in shortage back to the market. The comment stated that this would help FDA understand the reasons for any continued delays in delivering drugs into the supply chain and allow the Agency to work with manufacturers in a more informed manner to reduce shortages.

(Response) Once FDA is notified of a situation that might lead to a shortage, FDA is in frequent contact with the applicant to seek ways to prevent the shortage. At this time, we do not believe that requiring periodic updates would be necessary, because we do not anticipate that requiring such updates would provide information that the Agency does not already have.

(Comment 34) Two comments provided suggestions about the electronic submission of 506C notifications to FDA. One of the comments suggested that the rule should include the specific office within FDA that notifications should be sent to. The other comment noted that applicants currently submit information in a nonspecified format via email and stated that FDA should provide greater clarity on whether this practice is intended to continue once the rule goes into effect and whether FDA will be specifying a uniform process for applicants to follow when submitting notifications.

(Response) As explained in the preamble to the proposed rule (78 FR 65904 at 65915), applicants must email notifications to *drugshortages@fda.hhs.gov* (for products regulated by CDER) and *cbershortages@fda.hhs.gov* (for products regulated by CBER). In the future, the Agency may consider creating an electronic notification portal

to facilitate submission of these notifications. At that time, the Agency would provide any instructions necessary to use the portal. Because we expect that such a portal would be available on FDA's Web site, we do not believe it is necessary or appropriate to include the name of a specific receiving office in the regulation itself.

3. Contents of the Notification

(Comment 35) Two comments recommended that information about mitigation be required in the notification. One of the comments suggested that FDA require the notification to include a description of the efforts by the applicant to prevent or mitigate the shortage. The other comment recommended that FDA require the notification to include a mitigation strategy or, at least, suggestions for mitigation.

(Response) FDA agrees that input from the applicant about ways to prevent or mitigate the shortage is crucial. The Agency, however, does not agree that it is appropriate to require information about mitigation to be included in the notification. We are concerned that there could be a delay in the notification if applicants are required to develop a mitigation strategy to include in the notification while also working to resolve the underlying issue. Instead, we have determined that it is appropriate to require basic information that is necessary for the Agency to take action and that the Agency is required to include in the shortages list under section 506E of the FD&C Act. We strongly encourage applicants to provide additional information, including proposals to prevent or mitigate the shortage, inventory on hand or in distribution channels, allocation procedures and/or plans for releasing available product, market share, or other information that may assist FDA.

(Comment 36) One comment suggested that FDA require the notification to indicate whether the drug or biological product is being used in an FDA- or National Cancer Institute-approved clinical trial. The comment explained that many clinical trials, especially for cancer treatments, are designed to test the safety and efficacy of the standard of care against, or in combination with, a new treatment being investigated. Accordingly, drug shortages have an impact on clinical trials, not just on patients undergoing standard treatment.

(Response) FDA understands that drug and biological product shortages may have an impact on clinical trials in addition to patients receiving standard treatment. However, we believe that requiring an applicant to state, in its notification, whether the product is currently being used in a clinical trial would require additional investigation by the applicant and would be unnecessarily burdensome. FDA updates the drug and biological product shortage lists regularly, and we encourage investigators to sign up for email updates or the RSS feed to make sure they are aware of the latest information regarding product shortages.

(Comment 37) One comment requested clarification on what information must be included in a notification provided by the manufacturer of a covered drug marketed without an approved application.

(Response) As required by § 310.306, manufacturers of a covered drug marketed without an approved application must provide the same information in a notification as do applicants under § 314.81(b)(3)(iii)(*c*).

4. Public Lists of Products in Shortage

(Comment 38) Two comments requested clarification about whether FDA will maintain a single list that includes shortages of both drugs and biological products.

(Response) At the present time, FDA intends to maintain separate lists of CDER-regulated and CBER-regulated products that are in shortage. The lists are available on FDA's Web site at *http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm* (for products regulated by CDER) and *http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/default.htm* (for products regulated by CBER).

(Comment 39) One comment expressed support for the proposed addition of ''other reason'' to the list of statutory reasons for the shortage that FDA could choose from. The comment noted that the seven reasons outlined in FDASIA may be difficult to apply in certain situations.

(Response) FDA agrees that the categories provided in FDASIA do not necessarily cover certain quality or manufacturing problems that may result in a shortage. Therefore, the Agency is finalizing ''other reason'' as an additional category that the Agency may identify.

(Comment 40) Three comments requested clarification of whether FDA would include potential drug and biological product shortages in the public lists, in addition to actual shortages. The comments expressed concern that disseminating information about potential shortages could result in unintended consequences, such as hoarding.

(Response) Under section 506E of the FD&C Act, FDA maintains an up-to-date list of drugs that are determined by FDA to be in shortage in the United States. Section 506C(h)(2) of the FD&C Act defines a shortage as ''a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.''

(Comment 41) Two comments requested clarification on the process and criteria FDA uses to determine whether there is an actual shortage and the process and criteria FDA uses to determine whether to remove a product from the shortages list.

(Response) The MAPP on shortages of CDER-regulated products (MAPP 4190.1 Rev. 2, p. 14) and SOPP on shortages of CBER-regulated Products explain in detail the process and criteria FDA uses to verify if an actual shortage exists. The MAPP (p. 17) also explains the process and criteria FDA uses to determine whether a product should be removed from the shortages list.

(Comment 42) Several comments noted that FDA is responsible for determining whether, in fact, an actual shortage exists as well as the categorical reason for the shortage that best fits the particular situation. The comments requested that FDA consult with applicants about these determinations before making the information public. One comment noted that this has been FDA's practice and requested that the Agency continue this collaborative approach. Another comment specifically requested that FDA develop a process by which the Agency shares its intended public communication prior to posting it on FDA's Web site to allow applicants the opportunity to make corrections, including those related to unintentional disclosure of confidential or proprietary information.

(Response) FDA verifies all information with the applicants prior to posting information on FDA's Web site. Applicants also review the information posted on the Web site regularly and provide updates to FDA as new information becomes available.

(Comment 43) One comment noted that the rule does not address how the estimated shortage durations are determined. The comment stated that the estimated duration of shortages of some common medications, such as injectable calcium and phosphate preparations, listed on FDA's Web site have been inaccurate, which has made it difficult to develop strategies to prioritize care for those patients most in need of these drugs. The comment also expressed concern that there are no

consequences for gross underestimations of durations of shortages. The comment recommended that FDA address these issues in the final rule.

(Response) The estimated shortage duration that is provided on FDA's Web site is intended to capture the particular applicant's anticipated recovery time and is based on information provided by the applicant. FDA communicates with applicants on a daily basis and updates the Web site with estimated recovery time as information becomes available from the applicants. The Agency makes every effort to provide as much information as possible and works closely with applicants to ensure that the Web site lists the most current information.

(Comment 44) One comment expressed concern about including each presentation of a drug product (*e.g.,* strength, dosage form, route of administration) that is determined to be in shortage in the public shortage list when alternate presentations of the same product remain available. The comment stated that section 503B of the FD&C Act (21 U.S.C. 353b) permits a compounder to begin manufacturing a drug once it is on the section 506E shortage list. As such, the comment stated that compounders may begin manufacturing a product on the list, even if there are other available presentations that would be adequate substitutes. The comment stated that compounded products raise grave public health concerns and urged FDA to provide examples of situations in which the Agency will not list a drug or biological product because a suitable substitute is available. The comment stated that such a clarification would be consistent with the public health exception to the statutory requirement for FDA to publicly disclose, to the maximum extent possible, information on drug shortages.

(Response) The Agency does not agree that withholding particular presentations of a drug from the shortage list because other presentations are available would be appropriate or beneficial to the public health. Other comments received on the proposed rule, and our own experience, indicate the importance to health care professionals of being made aware of shortages of any presentation of a given drug product to ensure that they have the most accurate information about products in shortage and can make treatment decisions accordingly. We do not think the potential risk identified by the comment outweighs the benefit to health care providers and patients of having this information. We note further that while section 503B of the FD&C Act does permit compounding of drug products listed in the drug shortages list, only the specific presentations included in the drug shortages list may be compounded. Moreover, facilities that compound under section 503B must comply with the current good manufacturing practice requirements under section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)).

(Comment 45) One comment suggested that FDA communicate directly with physician organizations and affected specialty societies about shortages so that the impact of the shortage can be minimized.

(Response) FDA agrees that communication about products that are in shortage is essential to ensure that health care providers have the information they need to make appropriate treatment decisions. We note that in FDA's drug and biological products shortages Web pages, individuals may sign up to receive email updates of shortage information. Drug and biological product shortage updates are also available by RSS feed.

(Comment 46) One comment recommended that FDA establish a mechanism whereby physicians can receive shortage information about specific therapeutic categories via email updates, an RSS feed, or through a smartphone application. The comment stated that these targeted communications would allow physicians to receive only the information they need.

(Response) Physicians and other interested stakeholders can receive information about specific therapeutic categories or specific products via email updates and RSS feed by signing up on FDA's Web site. In addition, in March 2015, FDA launched a mobile application (app) designed to facilitate access to information about drug shortages. The app identifies current drug shortages, resolved shortages, and discontinuances of drug products. The app allows users to search by a drug's generic name or active ingredient and also by therapeutic category. The app is available for free download via iTunes (for Apple devices) and the Google Play store (for Android devices) by searching ''FDA Drug Shortages.''

(Comment 47) One comment stated that it would be helpful if the information contained in FDA's Drug Shortage Web site were categorized by specific classes of drugs in shortage that are relative to a particular area of research, such as oncology. The comment stated that by categorizing the information in this way, FDA could quickly notify researchers of drug shortages in classes frequently used by researchers in a particular specialty.

(Response) FDA's Drug Shortage Web site, which was redesigned after publication of the proposed rule, currently lists products alphabetically as well as by therapeutic category. This enables health care providers and other interested parties to access information relevant to particular specialties more easily.

(Comment 48) One comment recommended that FDA include information on the shortages Web sites indicating whether the drug or biological products listed are being utilized in an FDA-approved clinical trial. The comment also stated a link should be provided to the clinicaltrials.gov Web site for each clinical trial in which the product is being used.

(Response) FDA shares the commenter's concern about the impact that drug and biological product shortages may have on clinical trials that test investigational products against the standard of care. However, the shortages Web sites as well as clinicaltrials.gov are updated regularly, and it would not be feasible, at this time, to maintain links between the products on the shortages lists and the separate Web site that lists clinical trials in which the products may be used. FDA encourages investigators and sponsors to sign up for email updates or RSS feed and to visit FDA's Web site for the most up-to-date information about drug and biological product shortages. We also encourage sponsors to discuss with the appropriate review division any contingency plans if there is a shortage of products being used in a clinical trial.

5. Confidentiality and Disclosure

(Comment 49) Two comments noted the provision in the proposed rule that ''FDA may choose not to make information . . . available on the drug shortages list . . . if FDA determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of the drug to patients).'' The comments stated that the provision presumes that FDA is uniquely qualified to determine the relative value and/or risk associated with public dissemination of information related to product supply and product shortages. The comments suggest that, at a minimum, FDA should incorporate applicants' input into the decisionmaking regarding public dissemination of information related to supply constraints.

(Response) The provision of the proposed rule referenced in the comment codifies section 506E(c)(3), which reflects Congress' intent that FDA should have the discretion not to make information public if the Agency determines that disclosure would adversely affect public health. We welcome stakeholder input on all shortage-related matters. However, consistent with the statute, it is ultimately FDA's determination whether disclosure of information would adversely affect public health.

6. Failure To Notify

(Comment 50) Three comments requested that FDA establish a process for issuing and adjudicating noncompliance letters sent to an applicant for failure to notify FDA as required by section 506C(a) of the FD&C Act. The comments expressed concern about potential disagreements between the Agency and the applicant about what constitutes timely notification and stressed the importance of a dialogue between FDA and the applicant before a noncompliance letter is issued. One comment specifically requested a process by which an applicant may appeal a decision to issue a noncompliance letter and confirmation from FDA that it will retract and remove any noncompliance letter from the Web site if the appeal is successful.

(Response) FDA believes that the process set forth in section 506C(f) of the FD&C Act (and codified in the final rule) is sufficiently clear. The Agency will send a noncompliance letter to an applicant for failure to notify FDA, which includes failure to timely notify FDA, of a permanent discontinuance or interruption in manufacture that is likely to lead to a meaningful disruption in the supply of a drug in the United States. As provided in the statute, not later than 30 calendar days following issuance, the applicant must submit a response to the noncompliance letter. If an applicant believes it received a noncompliance letter in error, the applicant should provide in its response a full explanation, including relevant dates surrounding the event in question, and any other information of which FDA should be made aware. The Agency, in turn, will consider the information provided in determining whether the noncompliance letter was issued in error or there was a reasonable basis for not notifying the Agency. If FDA determines that the original letter was issued in error or that the recipient had a reasonable basis for not notifying FDA, then the Agency will not post the noncompliance letter or response to the Web site. In light of the process and timeframes specified in section 506C(f) of the FD&C Act, FDA does not believe that a separate appeals process or any further clarification is necessary at this time.

(Comment 51) Two comments requested that FDA establish a process to ensure that no confidential or proprietary information is released when a noncompliance letter and the applicant's response is posted to FDA's Web site.

(Response) As required by section 506C(f)(3) of the FD&C Act, appropriate redactions will be made before a noncompliance letter and the applicant's response are posted to FDA's Web site. FDA has extensive experience redacting confidential and proprietary information, *e.g.,* from NDA and BLA approval packages, before posting documents to the Web site. We believe that the systems the Agency has in place are adequate to address the redaction of noncompliance letters and any response submitted by the applicant.

(Comment 52) One comment requested confirmation that FDA intends to address the failure to notify through the noncompliance letter process and not by GMP inspections.

(Response) If an applicant fails to notify FDA as specified in the final rule, the Agency will address such failure through the process outlined in section 506C(f) of the FD&C Act and codified in this rule.

(Comment 53) One comment suggested that FDA should provide notice of noncompliance to the major news services as well as posting the information on FDA's Web site. The comment stated that in this way, consumers, distributors, and other stakeholders will have knowledge of which companies have not complied with the notification requirement.

(Response) Consistent with section 506C(f) of the FD&C Act, FDA intends to make noncompliance letters and any response to such letters public by posting them on FDA's Web site, unless FDA determines that the noncompliance letter was issued in error or, after reviewing the applicant's response, determines that the applicant had a reasonable basis for not notifying.

(Comment 54) One comment stated that FDA should be better empowered to enforce the notification requirement, potentially by being given authority to fine companies that are noncompliant.

(Response) As explained in the comment to the previous response, FDA will address noncompliance in the manner prescribed in section 506C(f) of the FD&C Act.

D. Other Issues Raised

(Comment 55) Multiple comments requested that FDA work with other Agencies and professional societies to develop treatment guidelines when drug and biological products are in shortage.

(Response) FDA does not typically develop treatment guidelines. We note that some professional societies, such as the American Society of Health-System Pharmacists, do provide treatment guidelines that interested parties may consult.

(Comment 56) Several comments stated that notification only of a permanent discontinuance or an interruption in manufacturing is not sufficient to address the drug shortage problem. The comments noted that steps need to be taken to address manufacturing problems that may lead to product shortages. The comments also suggested that, in addition to notification, there should be a plan in place to either import an equivalent drug from other countries or assign a firm to manufacture the drug.

(Response) FDA appreciates and shares the commenters' concern about the problem of drug and biological product shortages. However, these comments are beyond the scope of this rulemaking. The Agency is issuing the final rule to implement sections 506C and 506E of the FD&C Act, which require notification of a permanent discontinuance or an interruption in manufacturing of certain covered products and maintenance by FDA of a publicly available list of drugs that are determined by FDA to be in shortage. As explained in section I, consistent with FDA's authority under the FD&C Act, the Agency uses a variety of tools to prevent or mitigate drug and biological product shortages, and early notification is crucial to FDA's efforts. However, FDA does not have authority over an applicant's business decisions regarding the manufacture of particular products.

(Comment 57) One comment raised issues concerning the preliminary regulatory impact analysis and the Agency's assessment of the net benefit of the rulemaking.

(Response) Our response is provided in the full discussion of economic impacts available in Docket No. FDA–2011–N–0898 (Ref. 4) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

V. Legal Authority

FDA is amending its regulations to implement sections 506C and 506E of the FD&C Act as amended by FDASIA. FDA's authority for this rule also

derives from section 701(a) of the FD&C Act (21 U.S.C. 371(a)).

VI. Economic Analysis of Impacts

A. Introduction

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The estimated per notification cost for small business entities, $227, represents a small percentage of average annual sales (up to 0.10 percent). Although the final rule does not require specific mitigation strategies, for firms that choose to implement mitigation or prevention strategies, it is possible that additional costs of $113,000 associated with implementing mitigation strategies could be significant: 2 to 7.8 percent of average annual sales for companies with fewer than 20 employees. In FDA's experience 4 to 5 small businesses entities per year have been affected by a shortage. The Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Summary

The final rule amends FDA's regulations to implement sections 506C and 506E of the FD&C Act, as amended by FDASIA. The final rule requires all applicants of covered, approved prescription drug or biological products other than blood or blood components for transfusion (referred to as blood or blood components), all applicants of blood or blood components that manufacture a significant percentage of the U.S. blood supply, and all manufacturers of covered prescription drugs marketed without an approved application, to notify FDA electronically of a permanent discontinuance or an interruption in manufacturing of the product that is likely to lead to a meaningful disruption in supply (or a significant disruption in supply for blood or blood components) of the product in the United States 6 months in advance of the permanent discontinuance or interruption in manufacturing, or, if that is not possible, as soon as practicable, but no later than 5 business days after the permanent discontinuance or interruption occurs. The final rule also describes how to submit such a notification, the information required to be included in such a notification, the consequences for failure to submit a required notification, the disclosure of shortage-related information, and the meaning of certain terms.

The final rule would impose annual costs of up to $40.54 million on those applicants or entities affected by the rule, and up to $6.38 million on FDA in preventive costs. Estimated total annual costs of the interactions between industry and FDA range between $14.54 million and $46.92 million. Discounting over 20 years, annual quantified benefits from avoiding the purchase of more expensive alternative products, managing product shortages, and life-years gained, would range from $30.45 million to $98.65 million using a 3 percent discount rate, and from $30.39 million to $98.42 million using a 7 percent discount rate. Annualized over 20 years, net benefits range between $15.90 million and $51.72 million using a 3 percent discount rate; they range between $15.85 million and $51.50 million using a 7 percent discount rate. The public health benefits, mostly non-quantified, include the value of information that would assist FDA, manufacturers, health care providers, and patients in evaluating, mitigating, and preventing shortages of drug and biological products that could otherwise result in non-fatal adverse events, errors, delayed patient treatment, or interruption in clinical trial development. The costs and benefits are summarized in table 1.

Under the current environment all notifications provide meaningful information to identify a shortage or to prevent one, but there is uncertainty whether the scope of the rule could result in notifications that do not provide information about any shortage and lead to additional costs.

The full discussion of economic impacts is available in Docket No. FDA–2011–N–0898 and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (Ref. 4).

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF FINAL RULE

Category	Primary estimate	Low estimate	High estimate	Year dollars	Discount rate (percent)	Period covered	Notes
Benefits							
Annualized Monetized (millions $/year).	$64.545 $64.408	$30.445 $30.390	$98.645 $98.425	2013 2013	3 7	2015–34 2015–34	There is uncertainty surrounding these estimates because some underlying estimates came from non-representative studies.
Annualized Quantified					3 7	2015–34 2015–34	17–55 preventable shortages per year.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF FINAL RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Year dollars	Discount rate (percent)	Period covered	Notes
Qualitative	Reduction in errors and non-fatal adverse events associated with shortages; uninterrupted patient access to drugs and biological products necessary for treatment; continued access to drugs used in clinical trial development.						
Costs							
Annualized Monetized (millions $/year).	$30.731 $30.731	$14.540 $14.540	$46.921 $46.921	2013 2013	3 7	2015–34 2015–34	There is uncertainty about potential noise from notifications that might not provide meaningful information, but which could result in additional review costs. In addition, these estimates assume that applicants will participate in mitigation or preventive strategies.
Annualized Quantified	None estimated.						
Qualitative	None estimated.						
Transfers							
Federal Annualized Monetized (millions $/year).	None estimated.						
Other Annualized Monetized (millions $/year).	None estimated.						
Effects							
State, Local or Tribal Gov't	None.						
Small Business	Based on the analysis small business entities covered by the final rule could incur small costs, $227 per notification or up to 0.10 percent of their average annual sales. Although the final rule would not require it, some firms may choose to incur additional costs associated with mitigation or prevention strategies.						
Wages	No estimated effect.						
Growth	No estimated effect.						

VII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the total reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products; Final Rule

Description: Under the final rule, applicants with an approved NDA or ANDA for a covered drug product, manufacturers of a covered drug product marketed without an approved application, and applicants with an approved BLA for a covered biological product (including certain applications of blood or blood components) must notify FDA in writing of a permanent discontinuance of the manufacture of the drug or biological product or an interruption in manufacturing of the drug or biological product that is likely to lead to a meaningful disruption in the applicant's supply (or a significant disruption for blood or blood components) of that product. The notification is required if the drug or biological product is life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including use in emergency medical care or during surgery, and if the drug or biological product is not a radiopharmaceutical drug product.

The final rule requires that the notification include the following information: (1) The name of the drug or biological product subject to the notification, including the NDC (or, for a biological product that does not have an NDC, an alternative standard for identification and labeling that has been recognized as acceptable by the Center Director); (2) the name of each applicant of the drug or biological product; (3) whether the notification relates to a permanent discontinuance of the drug or biological product or an interruption in manufacturing of the product; (4) a description of the reason for the permanent discontinuance or interruption in manufacturing; and (5) the estimated duration of the interruption in manufacturing.

Under the final rule, the notification must be submitted to FDA electronically at least 6 months prior to the date of the permanent discontinuance or interruption in manufacturing. If 6 months' advance notice is not possible because the permanent discontinuance or interruption in manufacturing was

unanticipated 6 months in advance, the applicant must notify FDA as soon as practicable, but in no case later than 5 business days after the permanent discontinuance or interruption in manufacturing occurs.

If an applicant fails to submit the required notification, FDA will issue a letter informing the applicant or manufacturer of its noncompliance. The applicant must submit to FDA, not later than 30 calendar days after FDA issues the letter, a written response setting forth the basis for noncompliance and providing the required notification.

Description of Respondents: Applicants of prescription drugs and biological products subject to an approved NDA, ANDA, or BLA, and manufacturers of prescription drug products marketed without an approved ANDA or NDA, if the product is life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including use in emergency medical care or during surgery, and is not a radiopharmaceutical product. If the BLA applicant is a manufacturer of blood or blood components, it is only subject to this rule if it manufactures a significant percentage of the nation's blood supply.

Burden Estimates: Based on the number of drug and biological product shortage related notifications we have seen during the past 12 months, we estimate that annually a total of approximately 75 respondents (''Number of Respondents'' in table 2) will notify us of a permanent discontinuance of the manufacture of a drug or biological product or an interruption in manufacturing of a drug or biological product that is likely to lead to a meaningful disruption in the respondent's supply of that product under the final rule. We estimate that these respondents will submit annually a total of approximately 305 notifications as required under §§ 310.306, 314.81(b)(3)(iii), and 600.82. Approximately 80 of these notifications are notifications that we currently receive under OMB control number 0910–0699 for the IFR, thus we expect to receive approximately 225 new notifications under the final rule (''Total Annual Responses'' in table 2).[15] We estimate three notifications per respondent, because a respondent may experience multiple discontinuances or interruptions in manufacturing in a year that require notification (''No. of Responses per Respondent'' in table 2). We also estimate that preparing and submitting these notifications to FDA will take approximately 2 hours per respondent (''Hours per Response'' in table 2).

We base these estimates on our experience with the reporting of similar information to FDA since the issuance of the President's Executive Order 13588 of October 31, 2011 (Ref. 1), and under the interim final rule entitled ''Applications for Food and Drug Administration Approval To Market a New Drug; Revision of Postmarketing Reporting Requirements—Permanent'' (76 FR 78530; December 19, 2011).

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Notifications required under §§ 310.306 (unapproved drugs), 314.81(b)(3)(iii) (products approved under an NDA or ANDA), and 600.82 (products approved under a BLA)	75	3	225	2	450

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

The information collection provisions of this final rule have been submitted to OMB for review, as required by section 3507(d) of the PRA. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency concludes that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Executive Order 13588, ''Reducing Prescription Drug Shortages,'' October 31, 2011, available at *http://www.gpo.gov/fdsys/pkg/FR-2011-11-03/pdf/2011-28728.pdf,* accessed May 2015.

[15] This estimate is based on the number of new notifications we anticipate receiving under the final rule as compared to notifications we currently receive under the IFR. The IFR is our baseline for comparison for purposes of estimating the burden under the PRA, because additional notifications that we may currently receive, but that are not required under the IFR are not covered under any existing OMB control number, and thus must be captured in this PRA estimate. In contrast, the analysis of impacts of the final rule estimates the costs and benefits as compared to current practice. As a result of the use of different baselines for comparison, the estimate of new notifications under the PRA does not match the estimate of new notifications included in the final analysis of impacts.

2. Center for Drug Evaluation and Research, Manual of Policies and Procedures 4190.1 Rev. 2, ''Drug Shortage Management,'' September 3, 2014, available at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm079936.pdf,* accessed May 2015.

3. Center for Biologics Evaluation and Research, Standard Operating Policy and Procedure 8506, ''Management of Shortages of CBER-Regulated Products,'' April 9, 2012, available at *http://www.fda.gov/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/proceduressopps/ucm299304.htm,* accessed May 2015.

4. ''Regulatory Impact Analysis, Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products''; Final Rule, available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 20, 310, 314, and 600 are amended as follows:

PART 20—PUBLIC INFORMATION

■ 1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

■ 2. Revise § 20.100 by adding paragraph (c)(45) to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(45) Postmarket notifications of a permanent discontinuance or an interruption in manufacturing of certain drugs or biological products, in §§ 310.306, 314.81(b)(3)(iii), and 600.82 of this chapter.

PART 310—NEW DRUGS

■ 3. The authority citation for 21 CFR part 310 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356c, 356e, 360b–360f, 360j, 361(a), 371, 374, 375, 379e, 379k–1; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

■ 4. Add § 310.306 to subpart D to read as follows:

§ 310.306 Notification of a permanent discontinuance or an interruption in manufacturing of marketed prescription drugs for human use without approved new drug applications.

(a) *Applicability.* Marketed prescription drug products that are not the subject of an approved new drug or abbreviated new drug application are subject to this section.

(b) *Notification of a permanent discontinuance or an interruption in manufacturing.* The manufacturer of each product subject to this section must make the notifications required under § 314.81(b)(3)(iii) of this chapter and otherwise comply with § 314.81(b)(3)(iii) of this chapter. If the manufacturer of a product subject to this section fails to provide notification as required under § 314.81(b)(3)(iii), FDA will send a letter to the manufacturer and otherwise follow the procedures set forth under § 314.81(b)(3)(iii)(*e*).

(c) *Drug shortages list.* FDA will include on the drug shortages list required by § 314.81(b)(3)(iii)(*d*) drug products that are subject to this section that it determines to be in shortage. For such drug products, FDA will provide the names of each manufacturer rather than the names of each applicant. With respect to information collected under this paragraph, FDA will observe the confidentiality and disclosure provisions set forth in § 314.81(b)(3)(iii)(*d*)(*2*).

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 5. The authority citation for 21 CFR part 314 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 356e, 371, 374, 379e, 379k–1.

■ 6. Revise § 314.81(b)(3)(iii) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(3) * * *

(iii) *Notification of a permanent discontinuance or an interruption in manufacturing.* (*a*) An applicant of a prescription drug product must notify FDA in writing of a permanent discontinuance of manufacture of the drug product or an interruption in manufacturing of the drug product that is likely to lead to a meaningful disruption in supply of that drug in the United States if:

(*1*) The drug product is life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery; and

(*2*) The drug product is not a radiopharmaceutical drug product.

(*b*) Notifications required by paragraph (b)(3)(iii)(*a*) of this section must be submitted to FDA electronically in a format that FDA can process, review, and archive:

(*1*) At least 6 months prior to the date of the permanent discontinuance or interruption in manufacturing; or

(*2*) If 6 months' advance notice is not possible because the permanent discontinuance or interruption in manufacturing was not reasonably anticipated 6 months in advance, as soon as practicable thereafter, but in no case later than 5 business days after the permanent discontinuance or interruption in manufacturing occurs.

(*c*) Notifications required by paragraph (b)(3)(iii)(*a*) of this section must include the following information:

(*1*) The name of the drug subject to the notification, including the NDC for such drug;

(*2*) The name of the applicant;

(*3*) Whether the notification relates to a permanent discontinuance of the drug or an interruption in manufacturing of the drug;

(*4*) A description of the reason for the permanent discontinuance or interruption in manufacturing; and

(*5*) The estimated duration of the interruption in manufacturing.

(*d*)(*1*) FDA will maintain a publicly available list of drugs that are determined by FDA to be in shortage. This drug shortages list will include the following information:

(*i*) The names and NDC(s) for such drugs;

(*ii*) The name of each applicant for such drugs;

(*iii*) The reason for the shortage, as determined by FDA from the following categories: Requirements related to complying with good manufacturing practices; regulatory delay; shortage of

an active ingredient; shortage of an inactive ingredient component; discontinuation of the manufacture of the drug; delay in shipping of the drug; demand increase for the drug; or other reason; and

(*iv*) The estimated duration of the shortage.

(*2*) FDA may choose not to make information collected to implement this paragraph available on the drug shortages list or available under section 506C(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(c)) if FDA determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of the drug to patients). FDA will also not provide information on the public drug shortages list or under section 506C(c) of the Federal Food, Drug, and Cosmetic Act that is protected by 18 U.S.C. 1905 or 5 U.S.C. 552(b)(4), including trade secrets and commercial or financial information that is considered confidential or privileged under § 20.61 of this chapter.

(*e*) If an applicant fails to submit a notification as required under paragraph (b)(3)(iii)(*a*) of this section and in accordance with paragraph (b)(3)(iii)(*b*) of this section, FDA will issue a letter to the applicant informing it of such failure.

(*1*) Not later than 30 calendar days after the issuance of such a letter, the applicant must submit to FDA a written response setting forth the basis for noncompliance and providing the required notification under paragraph (b)(3)(iii)(*a*) of this section and including the information required under paragraph (b)(3)(iii)(*c*) of this section; and

(*2*) Not later than 45 calendar days after the issuance of a letter under paragraph (b)(3)(iii)(*e*) of this section, FDA will make the letter and the applicant's response to the letter public, unless, after review of the applicant's response, FDA determines that the applicant had a reasonable basis for not notifying FDA as required under paragraph (b)(3)(iii)(*a*) of this section.

(*f*) The following definitions of terms apply to paragraph (b)(3)(iii) of this section:

Drug shortage or *shortage* means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.

Intended for use in the prevention or treatment of a debilitating disease or condition means a drug product intended for use in the prevention or treatment of a disease or condition associated with mortality or morbidity that has a substantial impact on day-to-day functioning.

Life supporting or life sustaining means a drug product that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Meaningful disruption means a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product, and does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

* * * * *

§ 314.91 [Removed]

■ 7. Remove § 314.91.

PART 600—BIOLOGICAL PRODUCTS: GENERAL

■ 8. The authority citation for 21 CFR part 600 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 356c, 356e, 360, 360i, 371, 374, 379k–1; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

■ 9. Add § 600.82 to subpart D to read as follows:

§ 600.82 Notification of a permanent discontinuance or an interruption in manufacturing.

(a) *Notification of a permanent discontinuance or an interruption in manufacturing.* (1) An applicant of a biological product, other than blood or blood components for transfusion, which is licensed under section 351 of the Public Health Service Act, and which may be dispensed only under prescription under section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)), must notify FDA in writing of a permanent discontinuance of manufacture of the biological product or an interruption in manufacturing of the biological product that is likely to lead to a meaningful disruption in supply of that biological product in the United States if:

(i) The biological product is life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including any such biological product used in emergency medical care or during surgery; and

(ii) The biological product is not a radiopharmaceutical biological product.

(2) An applicant of blood or blood components for transfusion, which is licensed under section 351 of the Public Health Service Act, and which may be dispensed only under prescription under section 503(b) of the Federal Food, Drug, and Cosmetic Act, must notify FDA in writing of a permanent discontinuance of manufacture of any product listed in its license or an interruption in manufacturing of any such product that is likely to lead to a significant disruption in supply of that product in the United States if:

(i) The product is life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including any such product used in emergency medical care or during surgery; and

(ii) The applicant is a manufacturer of a significant percentage of the U.S. blood supply.

(b) *Submission and timing of notification.* Notifications required by paragraph (a) of this section must be submitted to FDA electronically in a format that FDA can process, review, and archive:

(1) At least 6 months prior to the date of the permanent discontinuance or interruption in manufacturing; or

(2) If 6 months' advance notice is not possible because the permanent discontinuance or interruption in manufacturing was not reasonably anticipated 6 months in advance, as soon as practicable thereafter, but in no case later than 5 business days after such a permanent discontinuance or interruption in manufacturing occurs.

(c) *Information included in notification.* Notifications required by paragraph (a) of this section must include the following information:

(1) The name of the biological product subject to the notification, including the National Drug Code for such biological product, or an alternative standard for identification and labeling that has been recognized as acceptable by the Center Director;

(2) The name of the applicant of the biological product;

(3) Whether the notification relates to a permanent discontinuance of the biological product or an interruption in manufacturing of the biological product;

(4) A description of the reason for the permanent discontinuance or interruption in manufacturing; and

(5) The estimated duration of the interruption in manufacturing.

(d)(1) *Public list of biological product shortages.* FDA will maintain a publicly available list of biological products that are determined by FDA to be in

shortage. This biological product shortages list will include the following information:

(i) The names and National Drug Codes for such biological products, or the alternative standards for identification and labeling that have been recognized as acceptable by the Center Director;

(ii) The name of each applicant for such biological products;

(iii) The reason for the shortage, as determined by FDA, selecting from the following categories: Requirements related to complying with good manufacturing practices; regulatory delay; shortage of an active ingredient; shortage of an inactive ingredient component; discontinuation of the manufacture of the biological product; delay in shipping of the biological product; demand increase for the biological product; or other reason; and

(iv) The estimated duration of the shortage.

(2) *Confidentiality.* FDA may choose not to make information collected to implement this paragraph available on the biological product shortages list or available under section 506C(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(c)) if FDA determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of the biological product to patients). FDA will also not provide information on the public shortages list or under section 506C(c) of the Federal Food, Drug, and Cosmetic Act that is protected by 18 U.S.C. 1905 or 5 U.S.C. 552(b)(4), including trade secrets and commercial or financial information that is considered confidential or privileged under § 20.61 of this chapter.

(e) *Noncompliance letters.* If an applicant fails to submit a notification as required under paragraph (a) of this section and in accordance with paragraph (b) of this section, FDA will issue a letter to the applicant informing it of such failure.

(1) Not later than 30 calendar days after the issuance of such a letter, the applicant must submit to FDA a written response setting forth the basis for noncompliance and providing the required notification under paragraph (a) of this section and including the information required under paragraph (c) of this section; and

(2) Not later than 45 calendar days after the issuance of a letter under this paragraph, FDA will make the letter and the applicant's response to the letter public, unless, after review of the applicant's response, FDA determines that the applicant had a reasonable basis for not notifying FDA as required under paragraph (a) of this section.

(f) *Definitions.* The following definitions of terms apply to this section:

Biological product shortage or *shortage* means a period of time when the demand or projected demand for the biological product within the United States exceeds the supply of the biological product.

Intended for use in the prevention or treatment of a debilitating disease or condition means a biological product intended for use in the prevention or treatment of a disease or condition associated with mortality or morbidity that has a substantial impact on day-to-day functioning.

Life supporting or life sustaining means a biological product that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Meaningful disruption means a change in production that is reasonably likely to lead to a reduction in the supply of a biological product by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product, and does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

Significant disruption means a change in production that is reasonably likely to lead to a reduction in the supply of blood or blood components by a manufacturer that substantially affects the ability of the manufacturer to fill orders or meet expected demand for its product, and does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

Dated: July 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16659 Filed 7–7–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9722]

RIN 1545–BM35

Partnership Transactions Involving Equity Interests of a Partner; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to final and temporary regulations (TD 9722) that were published in the **Federal Register** on June 12, 2015 (80 FR 33402). The final and temporary regulations prevent a corporate partner from avoiding corporate-level gain through transactions with a partnership involving equity interests of the partner.

DATES: This correction is effective on July 2, 2015 and applicable beginning June 12, 2015.

FOR FURTHER INFORMATION CONTACT: Kevin I. Babitz at (202) 317–6852 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9722) that are the subject of this correction are under sections 311(b), 336(a), and 337(d) of the Internal Revenue Code.

Need for Correction

As published, the final and temporary regulations (TD 9722) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.337(d)–3T is amended by revising paragraphs (c)(2)(i) and (f)(2)(ii) to read as follows:

§ 1.337(d)–3T Gain recognition upon certain partnership transactions involving a partner's stock (temporary).

* * * * *

(c) * * *

(2) * * * (i) *In general.* With respect to a Corporate Partner, Stock of the Corporate Partner includes the Corporate Partner's stock, or other equity interests, including options, warrants, and similar interests, in the Corporate Partner or a corporation that controls the Corporate Partner within the meaning of section 304(c), except that section 318(a)(1) and (3) shall not apply. Stock of the Corporate Partner also includes interests in any entity to the extent that the value of the interest is attributable to Stock of the Corporate Partner.

(f) * * *

(2) * * *

(ii) Is not distributed to the Corporate Partner or a corporation that controls the Corporate Partner within the meaning of section 304(c), except that section 318(a)(1) and (3) shall not apply.

* * * * *

§ 1.732–1T [Amended]

■ **Par 3.** Section 1.732–1T paragraph (c)(5)(ii) is amended by removing the word ''Nothwithstanding'' and adding in its place the word ''Notwithstanding''.

Martin V. Franks,

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

[FR Doc. 2015–16674 Filed 7–2–15; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9722]

RIN 1545–BM35

Partnership Transactions Involving Equity Interests of a Partner; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations; correction.

SUMMARY: This document contains corrections to final and temporary regulations (TD 9722) that were published in the **Federal Register** on June 12, 2015 (80 FR 33402). The final and temporary regulations prevent a corporate partner from avoiding corporate-level gain through transactions with a partnership involving equity interests of the partner.

DATES: This correction is effective on July 2, 2015 and applicable beginning June 12, 2015.

FOR FURTHER INFORMATION CONTACT: Kevin I. Babitz at (202) 317–6852 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9722) that are the subject of this correction are under sections 311(b), 336(a), and 337(d) of the Internal Revenue Code.

Need for Correction

As published, the final and temporary regulations (TD 9722) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the final regulations (TD 9722), that are the subject of FR Doc. 2015–14405, are corrected as follows:

1. On page 33404, in the preamble, the first column, the tenth and eleventh lines from the top of the column, the language ''that controls (within the meaning of section 304(c)) the Corporate Partner.'' is corrected to read ''that controls the Corporate Partner within the meaning of section 304(c), except that section 318(a)(1) and (3) shall not apply (section 304(c) control).''.

2. On page 33404, in the preamble, the first column, the eighteenth through the twentieth line from the top of the first full paragraph, the language ''that controls the Corporate Partner within the meaning of section 304(c) (section 304(c) control), whereas the'' is corrected to read ''that possesses section 304(c) control of the Corporate Partner, whereas the''.

Martin V. Franks,

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

[FR Doc. 2015–16673 Filed 7–2–15; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–0527]

Safety Zones; Recurring Events in Captain of the Port Boston Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zones in the Captain of the Port Boston Zone on the specified dates and times listed below. This action is necessary to ensure the protection of the maritime public and event participants from the hazards associated with these annual recurring events. Under the provisions of our regulations, no person or vessel, except for the safety vessels assisting with the event may enter the safety zones unless given permission from the COTP or the designated on-scene representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

DATES: The regulation for the safety zones described in 33 CFR 165.118 will be enforced on July 3, 2015 between 7:00 p.m. to 11:00 p.m., on July 4, 2015 from 9:00 p.m. to 11:00 p.m., on July 10, 2015 from 6:00 a.m. to 4:00 p.m., and on July 11, 2015 from 8:30 a.m. to 10:30 a.m., as listed in the table located in the Supplementary Information.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call or email Mr. Mark Cutter, Coast Guard Sector Boston Waterways Management Division, telephone 617–223–4000, email *Mark.E.Cutter@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones listed in 33 CFR 165.118 on the specified dates and times as indicated in Table 1 below.

TABLE 1

7.1 City of Lynn 4th of July Celebration Fireworks	• Event Type: Firework Display. • Sponsor: City of Lynn. • Date: July 3, 2015. • Time: 7:00 p.m. to 11:00 p.m.

TABLE 1—Continued

	• Location: All waters of Nahant Bay, within a 350-yard radius of the fireworks barge located at position 42°27.62′ N., 070°55.58′ W. (NAD 83).
7.4 Weymouth 4th of July Celebration Fireworks	• Event Type: Fireworks Display. • Sponsor: Town of Weymouth 4th of July Committee. • Date: July 3, 2015. • Time: 8:30 p.m. to 11:00 p.m. • Location: All waters of Weymouth Fore River, within a 350-yard radius of the fireworks launch site located at position 42°15.5′ N., 070°56.1′ W. (NAD 83).
7.6 Beverly Farms 4th of July Celebration Fireworks	• Event Type: Fireworks Display. • Sponsor: Farms-Pride 4th of July Committee. • Date: July 4, 2015. • Time: 9:00 p.m. to 11:00 p.m. • Location: All waters of Manchester Bay within a 350-yard radius of the fireworks launch site near West Beach located at position 42°33.84′ N., 070°48.5′ W. (NAD 83).
7.7 Boston Pops Fireworks	• Event Type: Fireworks Display. • Sponsor: Boston 4 Celebrations. • Date: July 4, 2015. • Time: 9:45 p.m. to 11:00 p.m. • Location: All waters of the Charles River within a 350-yard radius of the fireworks barges located in the vicinity of position 42°21.47′ N., 071°05.03′ W. (NAD 83).
7.8 City of Salem Fireworks	• Event Type: Fireworks Display. • Sponsor: City of Salem. • Date: July 4, 2015. • Time: 9:45 p.m. to 10:15 p.m. • Location: All waters of Salem Harbor, within a 350-yard radius of the fireworks launch site located on Derby Wharf at position 42°31.15′ N., 070°53.13′ W. (NAD 83).
7.9 Marblehead 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: Town of Marblehead. • Date: July 4, 2015. • Time: 9:30 p.m. to 10:00 p.m. • Location: All waters of Marblehead Harbor within a 350-yard radius of the fireworks launch site located at position 42°30.34′ N., 070°50.13′ W. (NAD 83).
7.10 Plymouth 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: July 4 Plymouth, Inc. • Date: July 4th, 2015. • Time: 9:00 p.m. to 10:00 p.m. • Location: All waters of Plymouth Harbor within a 350-yard radius of the fireworks launch site located at position 42°57.3′ N., 070°38.3′ W. (NAD 83).
7.19 Swim Across America Boston	• Event Type: Swim. • Sponsor: Swim Across America. • Date: July 10, 2015. • Time: 6:00 a.m. to 4:00 p.m. • Location: All waters of Boston Harbor between Rowes Warf and Little Brewster Island within the following points (NAD 83): 42°21.4′ N., 071°03.0′ W. 42°21.5′ N., 071°02.9′ W. 42°19.8′ N., 070°53.6′ W. 42°19.6′ N., 070°53.4′ W.
7.21 Swim Across America Nantasket Beach	• Event Type: Swim. • Sponsor: Swim Across America. • Date: July 11, 2015. • Time: 8:30 a.m. to 10:30 a.m. • Location: All waters of Massachusetts Bay near Nantasket Beach within the following points (NAD 83): 42°16.7′ N., 070°51.9′ W. 42°16.9′ N., 070°51.3′ W. 42°16.3′ N., 070°50.5′ W. 42°16.1′ N., 070°51.0′ W.

This document is issued under authority of 33 CFR 165.118 and 5 U.S.C. 552(a). In addition to this document in the **Federal Register**, the Coast Guard will provide mariners with advanced notification of enforcement periods via the Local Notice to Mariners and Broadcast Notice to Mariners. If the COTP determines that the regulated areas need not be enforced for the full duration stated in this document, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated areas.

Dated: June 22, 2015.

C.C. Gelzer,

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

[FR Doc. 2015–16746 Filed 7–7–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–0614]

Safety Zones; Annual Events in the Captain of the Port Buffalo Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: At various times throughout the month of July, the Coast Guard will enforce certain safety zones located in 33 CFR 165.939. This action is necessary and intended for the safety of life and property on navigable waters during this event. During each enforcement period, no person or vessel may enter the respective safety zone without the permission of the Captain of the Port Buffalo.

DATES: The regulations in 33 CFR 165.939 will be enforced on July 5, 2015 from 9:15 p.m. to 10:15 p.m. and on July 10, 2015 from 9:45 p.m. to 10:35 p.m., as specified in the Supplementary Information.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email LT Stephanie Pitts, Chief of Waterways Management Division, U.S. Coast Guard Marine Safety Unit Cleveland; telephone 216–937–0128, email *Stephanie.M.Pitts@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Safety Zones; Annual Events in the Captain of the Port Buffalo Zone listed in 33 CFR 165.939 for the following events:

(1) *Fairport Harbor Mardi Gras Fireworks, Fairport Harbor, OH;* The safety zone listed in 33 CFR 165.939(a)(22) will be enforced from 9:15 p.m. to 10:15 p.m. on July 5, 2015.

(2) *Sheffield Lake Annual Community Days Fireworks, Sheffield Lake, OH;* The safety zone listed in 33 CFR 165.939(a)(27) will be enforced from 9:45 p.m. to 10:35 p.m. on July 10, 2015.

Pursuant to 33 CFR 165.23, entry into, transiting, or anchoring within these safety zones during an enforcement period is prohibited unless authorized by the Captain of the Port Buffalo or his designated representative. Those seeking permission to enter one of these safety zones may request permission from the Captain of Port Buffalo via channel 16, VHF–FM. Vessels and persons granted permission to enter one of these safety zones shall obey the directions of the Captain of the Port Buffalo or his designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice is issued under authority of 33 CFR 165.939 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via Broadcast Notice to Mariners or Local Notice to Mariners. If the Captain of the Port Buffalo determines that one of these safety zones need not be enforced for the full duration stated in this notice he or she may use a Broadcast Notice to Mariners to grant general permission to enter the respective safety zone.

Dated: June 25, 2015.

B.W. Roche,

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

[FR Doc. 2015–16742 Filed 7–7–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–0572]

Safety Zones; Annual Events in the Captain of the Port Buffalo Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: At various times throughout the month of July, the Coast Guard will enforce certain safety zones located in the Captain of the Port Buffalo Zone. This action is necessary and intended for the safety of life and property on navigable waters during this event. During each enforcement period, no person or vessel may enter the respective safety zone without the permission of the Captain of the Port Buffalo.

DATES: The regulations in 33 CFR 165.939 will be enforced on July 3, 2015 from 9:30 p.m. to 10:30 p.m., on July 3 from 9:45 p.m. to 11:30 p.m., on July 4, 2015 from 8:45 p.m. to 10:15 p.m., and on July 11, 2015 from 9:15 p.m. to 11 p.m., as specified in the Supplementary Information.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call or email LTJG Amanda Garcia, Chief of Waterways Management, U.S. USCG Sector Buffalo; telephone 716–843–9343, email *SectorBuffaloMarineSafety@uscg.mil.* Waterways Management Division, Coast Guard Sector Buffalo, 1 Fuhrmann Blvd., Buffalo, NY 14203; Coast Guard telephone 716–843–9343, email *SectorBuffaloMarineSafety@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Safety Zones; Annual Events in the Captain of the Port Buffalo Zone listed in 33 CFR 165.939 for the following events:

(1) *Salute to our Heroes, Hamlin Beach State Park, NY;* The safety zone listed in 33 CFR 165.939(a)(16) will be enforced from 9:45 p.m. to 11:30 p.m. on July 3, 2015.

(2) *North Tonawanda Fireworks, North Tonawanda, NY;* The safety zone listed in 33 CFR 165.939(a)(18) will be enforced from 8:45 p.m. to 10:15 p.m. on July 4, 2015.

(3) *French Festival Fireworks, Cape Vincent, NY;* The safety zone listed in 33 CFR 165.939(a)(3) will be enforced from 9:15 p.m. to 11 p.m. on July 11, 2015.

(4) *Village Fireworks, Sodus Point, NY;* The safety zone listed in 33 CFR 165.939(a)(14) will be enforced from 9:30 p.m. to 10:30 p.m. on July 3, 2015.

Pursuant to 33 CFR 165.23, entry into, transiting, or anchoring within these safety zones during an enforcement period is prohibited unless authorized by the Captain of the Port Buffalo or his designated representative. Those seeking permission to enter one of these safety zones may request permission from the Captain of Port Buffalo via channel 16, VHF–FM. Vessels and persons granted permission to enter one of these safety zones shall obey the directions of the Captain of the Port Buffalo or his designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This document is issued under authority of 33 CFR 165.939 and 5 U.S.C. 552(a). In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via Broadcast Notice to Mariners or Local Notice to Mariners. If the Captain of the Port Buffalo determines that one of these safety zones need not be enforced for the full duration stated in this document he or she may use a Broadcast Notice to

Mariners to grant general permission to enter the respective safety zone.

Dated: June 25, 2015.

B.W. Roche,

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

[FR Doc. 2015–16743 Filed 7–7–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2015–0570]

RIN 1625–AA00

Safety Zone; 520 Bridge Construction, Lake Washington; Seattle, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on Lake Washington around the east span of the 520 Bridge in Seattle, Washington due to ongoing construction. The safety zone is necessary to ensure the safety of the maritime public and workers involved in the bridge construction when construction barges are located in the east span of the bridge. The safety zone will prohibit any person or vessel from entering or remaining in the safety zone unless authorized by the Captain of the Port or his Designated Representative.

DATES: This rule is effective without actual notice from July 8, 2015 through September 4, 2015. For the purposes of enforcement, actual notice will be used from June 22, 2015 until July 8, 2015.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2015–0570] to view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Ryan Griffin, Waterways Management Division, Coast Guard Sector Puget Sound; telephone (206) 217–6051, email *SectorPugetSoundWWM@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

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

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because publishing an NPRM would be impracticable, as delayed promulgation to accommodate a notice and comment period would endanger the safety of the maritime public and workers involved in the bridge construction.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date until 30 days after publication would be impracticable, as doing so would endanger the safety of the maritime public and workers involved in the bridge construction.

B. Basis and Purpose

The 520 Bridge is the longest floating bridge in the world with a span of 1.4 miles across Lake Washington supported by 33 pontoons. The 520 Bridge is being replaced in order to upgrade the bridges floating pontoons for larger ones. During the bridge replacement project the east span on the 520 Bridge will at times require construction barges to block the waterway that runs beneath that span of the bridge. As a result, the Coast Guard is establishing a temporary safety zone to ensure the safety of the maritime public and workers involved in the bridge construction when the east span is being used by construction barges.

C. Discussion of the Final Rule

The safety zone established in this rule encompasses all waters within 100 yards of the east span of the 520 Bridge, located on Lake Washington and is effective from June 22, 2015, through September 4, 2015, when a construction barge is present in the safety zone. Vessels wishing to enter the safety zone must request permission to do so from the Captain of the Port by contacting the Joint Harbor Operations Center at 206–217–6001 or VHF Channel 16. If permission for entry is granted, vessels must proceed at a minimum speed for safe navigation.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. This rule is not a significant regulatory action as the safety zone established by it is both limited in size and duration and there is an alternative route for vessels with an air draft that permits safe passage under the west span of the bridge.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit the affected waterway during the time the safety zone is in effect. This safety zone will not have a significant economic impact

on a substantial number of small entities, however, because the zone established in this rule is limited in size and duration and there is an alternative route for vessels with an air draft that permits safe passage under the west span of the bridge.

3. Assistance for Small Entities

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

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

4. Collection of Information

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

5. Federalism

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

6. Protest Activities

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

7. Unfunded Mandates Reform Act

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

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T13–290 to read as follows:

§ 165.T13–290 Safety Zone; 520 Bridge, Lake Washington; Seattle, WA.

(a) *Location.* The following area is designated as a safety zone: all waters within 100 yards of the east span of the 520 Bridge located on Lake Washington in Seattle, Washington.

(b) *Regulations.* In accordance with the general regulations in 33 CFR part 165, subpart C, no person may enter the safety zone or bring or cause to be brought any vessel into the safety zone without permission of the Captain of the Port. Persons wishing to enter the safety zone must request permission from the Captain of the Port by contacting the Joint Harbor Operation Center at 206–217–6001 or VHF Channel 16. If permission for entry is granted, vessels must proceed at a minimum speed for safe navigation.

(c) *Dates.* This rule is effective from June 22, 2015 through September 4, 2015 when a construction barge is present inside the safety zone.

Dated: June 19, 2015.

M. W. Raymond,

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

[FR Doc. 2015–16701 Filed 7–7–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2015–0438]

RIN 1625–AA00

Safety Zones; Marine Events Held in the Sector Long Island Sound Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing thirteen safety zones for fireworks displays within the Coast Guard Sector Long Island Sound (LIS) Captain of the Port (COTP) Zone. This temporary final rule is necessary to provide for the safety of life on navigable waters during these events. Entry into, transit through, mooring or anchoring within these safety zones is prohibited unless authorized by COTP Sector Long Island Sound.

DATES: This rule is effective without actual notice from 12:01 a.m. on July 8, 2015 until 10:30 p.m. on August 1, 2015. For the purposes of enforcement, actual notice will be used from the date the rule was signed, June 17, 2015, until July 8, 2015.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2015–0438]. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, contact Petty Officer Ian Fallon, Prevention Department, Coast Guard Sector Long Island Sound, telephone (203) 468–4565, email *Ian.M.Fallon@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

This rulemaking establishes thirteen safety zones for thirteen fireworks displays. Each event and its corresponding regulatory history are discussed below.

Barnum Festival, LLC (fireworks): A safety zone was established in 2014 for the Barnum Festival, LLC fireworks display by enforcing 33 CFR 165.151, Table 1, 6.1. This event has been included in this rule due to deviation from the cite date and location.

Salute to Veterans (fireworks): A safety zone was established in 2014 for the Salute to Veterans fireworks display by enforcing 33 CFR 165.151, Table 1, 6.4. This event has been included in this rule due to deviation from the cite date and location.

City of Stamford (fireworks): A safety zone was established in 2014 for the City of Stamford fireworks display by enforcing 33 CFR 165.151, Table 1, 7.12. This event has been included in this rule due to deviation from the cite date.

Freeport Chamber of Commerce (fireworks): A safety zone was established in 2014 for Freeport Chamber of Commerce fireworks display when the Coast Guard issued a temporary rule entitled, ''Safety Zone; Freeport Chamber of Commerce Fireworks Display; South Bay; Freeport, NY''. This rulemaking was published on June 27, 2014 in the **Federal Register** (79 FR 36412).

City of Norwich (fireworks): A safety zone was established in 2014 for the City of Norwich fireworks display by enforcing 33 CFR 165.151, Table 1, 7.11. This event has been included in this rule due to deviation from the cite date and location.

Go 4th Connetquot (fireworks): This event was previously named Connetquot River Summer Fireworks. A safety zone was established in 2014 for the Connetquot River Summer Fireworks display by enforcing 33 CFR 165.151, Table 1, 7.42. This event has been included in this rule due to deviation from the cite name and location.

Madison Fireworks Organization (fireworks): A safety zone was established in 2014 for the Madison Fireworks Organization fireworks display by enforcing 33 CFR 165.151, Table 1, 7.38. This event has been included in this rule due from the cite date and location.

City of Middletown (fireworks): A safety zone was established in 2014 for the City of Middletown fireworks display by enforcing 33 CFR 165.151, Table 1, 7.9. This event has been included in this rule due to deviation from the cite date and location.

Fairfield Independence Day Celebration (fireworks): A safety zone was established in 2014 for the Fairfield Independence Day Celebration fireworks display by enforcing 33 CFR 165.151, Table 1, 7.16. This event has been included in this rule due to deviation from the cite date and location.

City of West Haven: A safety zone was established in 2014 for the City of West Haven Fireworks display by enforcing 33 CFR 165.151, Table 1, 7.13. This event has been included in this rule due to deviation from the cite location.

Village of Port Jefferson Independence Day Celebration (fireworks): This event was previously named Village of Port Jefferson Fourth of July Celebration Fireworks. A safety zone was established in 2014 for the Village of Port Jefferson Fourth of July Celebration Fireworks display by enforcing 33 CFR 165.151, Table 1, 7.25. This event has been included in this rule due to deviation from the cite name and location.

Shelter Island (fireworks): A safety zone was established in 2014 for the Shelter Island fireworks display by enforcing 33 CFR 165.151, Table 1, 7.30. This event has been included in this rule due to deviation from the cite location.

Sebonack Golf Club (fireworks): This event was previously named National Golf Links Fireworks. A safety zone was established in 2014 for the National Golf Links Fireworks display by enforcing 33 CFR 165.151, Table 1, 7.44. This event has been included in this rule due to deviation from the cite name, date and location.

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a NPRM with respect to this rule because

doing so would be impracticable. There is insufficient time to publish a NPRM and solicit comments from the public before these events take place. Thus, waiting for a comment period to run would inhibit the Coast Guard's ability to fulfill its mission to keep the ports and waterways safe.

Under 5 U.S.C. 553(d)(3), and for the same reasons stated in the preceding paragraph, the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

B. Basis and Purpose

The legal basis for this temporary rule is 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5 and Department of Homeland Security Delegation No. 0170.1 which collectively authorize the Coast Guard to define regulatory safety zones.

As discussed in the Regulatory History and Information section, thirteen fireworks displays will take place in the Coast Guard Sector LIS COTP Zone between June 26, 2015 and August 1, 2015. The COTP Long Island Sound has determined that thirteen safety zones are necessary to provide for the safety of life on navigable waterways during those events.

Barnum Festival, LLC fireworks display will be held on Bridgeport Harbor, Bridgeport, CT.

Salute to Veterans fireworks display will be held on Reynolds Channel off Hempstead, NY.

City of Stamford fireworks display will be held on Fisher's Westcott Cove, Stamford, CT.

Freeport Chamber of Commerce fireworks display will be a land launch near Guy Lombardo Marina, Freeport, NY.

City of Norwich fireworks display will be held on the Thames River, Norwich, CT.

Go 4th Connetquot fireworks display will be held on Great South Bay off Snapper Inn, Oakdale, NY.

Madison Fireworks Organization fireworks will be held on Long Island Sound off Madison Beach, Madison, CT.

City of Middletown fireworks display will be held on the Connecticut River, Middletown Harbor, Middletown, CT.

Fairfield Independence Day Celebration fireworks display will be held on Long Island Sound off Fairfield, CT.

City of West Haven fireworks display will be held on New Haven Harbor off Bradley Point, West Haven, CT.

Village of Port Jefferson Independence Day Celebration will be held on Port Jefferson Harbor, Port Jefferson, NY.

Shelter Island fireworks display will be held on Gardiner Bay, Shelter Island, NY.

Sebonack Golf Club fireworks display will be held on Peconic Bay off Southampton, NY.

The fireworks displays listed above will launch pyrotechnics from either a barge on a waterway or a landsite near a waterway. A regulated area, specifically a safety zone, is required for each of these fireworks displays to protect both spectators and participants from the safety hazards created by the fireworks displays, including unexpected pyrotechnics detonation and burning debris.

C. Discussion of the Final Rule

This rule establishes thirteen safety zones for thirteen fireworks displays. The location of these safety zones are as follows:

FIREWORKS DISPLAYS SAFETY ZONES

1 Barnum Festival, LLC Fireworks	Location: All waters of Bridgeport Harbor, Bridgeport, CT within 800 feet of the land launch site located in approximate position 41°09′34″ N., 073°11′18″ W. (NAD 83).
2 Salute to Veterans Fireworks	Location: All waters of Reynolds Channel off Hempstead, NY within 600 feet of the fireworks barge located in approximate position 40°35′36.87″ N., 073°35′20.72″ W. (NAD 83).
3 City of Stamford Fireworks	Location: All waters of the Fisher's Westcott cove, Stamford, CT within 800 feet of the fireworks barge in approximate position 41°02′09.56″ N., 072°30′57.76″ W. (NAD 83).
4 Freeport Chamber of Commerce Fireworks	Location: All waters of Guy Lombardo Marina, Freeport, NY within 300 feet of the land launch site located in approximate position 40°37′27.27″ N., 073°34′34.64″ W. (NAD 83).
5 City of Norwich Fireworks	Location: All waters of the Thames River, Norwich, CT in approximate positions, 41°31′14.64″ N., 072°04′43.60″ W. (NAD 83).
6 Go 4th Connetquot Fireworks	Location: All waters of Great South Bay within 600 feet of the fireworks barge at approximate position, 40°43′30.03″ N.; 073°08′40.25″ W. (NAD 83).
7 Madison Fireworks Organization Fireworks	Location: All waters of Long Island Sound off Madison Beach, Madison, CT within 800 feet of the fireworks barge located in approximate position 41°16′09.04″ N., 072°36′18.30″ W. (NAD 83).
8 City of Middletown Fireworks	Location: Waters of the Connecticut River, Middletown Harbor, Middletown, CT within 600 feet of the fireworks barge in approximate position, 41°33′43″ N., 072°38′32″ W. (NAD 83).
9 Fairfield Independence Day Celebration Fireworks	Location: All waters of Long Island Sound, Fairfield, CT within 800 feet of the fireworks barge at approximate position, 41°08′16.92″ N.; 073°14′01.02″ W. (NAD 83).
10 City of West Haven Fireworks	Location: All waters of New Haven Harbor off Bradley Point, West Haven, CT within 800 feet of the fireworks barge at approximate position, 41°15′07″ N.; 072°57′25″ W. (NAD 83).

FIREWORKS DISPLAYS SAFETY ZONES—Continued

11 Village of Port Jefferson Independence Day Celebration	Location: All waters of Port Jefferson Harbor within 500 feet of the land launch at approximate position, 40°57′53.189″ N.; 073°03′09.72″ W. (NAD 83).
12 Shelter Island Fireworks	Location: All waters of Gardiner's Bay, Shelter Island, NY in approximate position, 41°04′27.60″ N., 072°22′13.50″ W. (NAD 83).
13 Sebonack Golf Club Fireworks	Location: All waters of Peconic Bay, Southampton, NY within 600 feet of the fireworks barge at approximate position, 40°54′49.92″ N.; 072°27′39.28″ W. (NAD 83).

This rule prevents vessels from entering, transiting, mooring, or anchoring within areas specifically designated as safety zones and restricts vessel movement around the locations of the marine events to reduce the safety risks associated with them during the periods of enforcement unless authorized by the COTP or designated representative.

Consistent with 33 CFR 165.7, the Coast Guard will notify the public and local mariners of this safety zone through appropriate means, which may include, but are not limited to, publication in the **Federal Register**, the Local Notice to Mariners, and Broadcast Notice to Mariners. The specific dates, including rain dates, for the events are listed in the regulatory text.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

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

The Coast Guard determined that this rulemaking is not a significant regulatory action for the following reasons: The enforcement of these safety zones will be relatively short in duration. Additionally, persons or vessels desiring to enter a safety zone may do so with permission from the COTP Sector Long Island Sound or a designated representative. Furthermore, these safety zones are designed in a way to limit impacts on vessel traffic, permitting vessels to navigate in other portions of the waterways not designated as a safety zone. Finally, to increase public awareness of these safety zones, the Coast Guard will notify the public of the enforcement of this rule via appropriate means, such as Local Notice to Mariners and Broadcast Notice to Mariners.

2. Impact on Small Entities

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

This temporary final rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to enter, transit, anchor, or moor within a safety zone during the periods of enforcement, from June 26, 2015 to August 1, 2015. However, this temporary final rule will not have a significant economic impact on a substantial number of small entities for the same reasons discussed in the REGULATORY PLANNING AND REVIEW section. Additionally, before the effective period, public notifications will be made to local mariners through appropriate means, which may include but are not limited to, the Local Notice to Mariners as well as Broadcast Notice to Mariners.

3. Assistance for Small Entities

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

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

4. Collection of Information

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

5. Federalism

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

6. Protest Activities

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

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In

particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children From Environmental Health Risks

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

11. Indian Tribal Governments

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

12. Energy Effects

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

13. Technical Standards

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

14. Environment

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01–0438 to read as follows:

§ 165.T01–0438 Safety Zones; Fireworks Displays in Captain of the Port Long Island Sound Zone.

(a) *Regulations.* The general regulations contained in § 165.23 as well as the following regulations apply to the events listed in the TABLE to § 165.T01–0438.

(b) *Enforcement period.* This rule will be enforced on the dates and times listed for each event in TABLE to § 165.T01–0438. If the event is delayed by inclement weather, the safety zone will be enforced on the rain date indicated in TABLE to § 165.T01–0438.

(c) *Definitions.* The following definitions apply to this section: A ''designated representative'' is any commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port (COTP), Sector Long Island Sound, to act on his or her behalf. An ''official patrol vessel'' may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP.

(d) *Operations.* (1) Vessels desiring to enter or operate within a safety zone should contact the COTP or the designated representative via VHF channel 16 or by telephone at (203) 468–4401 to obtain permission to do so. Vessels given permission to enter or operate in a safety zone must comply with all directions given to them by the COTP Sector Long Island Sound or the designated on-scene representative.

(2) Upon being hailed by an official patrol vessel or the designated representative, by siren, radio, flashing light or other means, the operator of the vessel shall proceed as directed. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. While members of the Coast Guard Auxiliary will not serve as the designated representative, they may be present to inform vessel operators of this regulation.

(e) *Compliance.* Failure to comply with a lawful direction may result in expulsion from the area, citation for failure to comply, or both.

TABLE TO § 165.T01–0438

Fireworks events	
1 Barnum Festival, LLC Fireworks	• Date: June 26, 2015. • Rain Date: June 28, 2015. • Time: 8:40 p.m. to 10:30 p.m. • Location: All waters of Bridgeport Harbor, Bridgeport CT within 800 feet of the land launch site located in approximate position 41°09′34″ N., 073°11′18″ W. (NAD 83).
2 Salute to Veterans Fireworks	• Date: June 27, 2015.

TABLE TO § 165.T01–0438—Continued

	• Rain Date: June 28, 2015. • Time: 9:00 p.m. to 10:45 p.m. • Location: All waters of Reynolds Channel off Hempstead, NY within 600 feet of the fireworks barge located in approximate position 40°35′36.87″ N., 073°35′20.72″ W. (NAD 83).
3 City of Stamford Fireworks	• Date: July 2, 2015. • Rain Date: July 3, 2015. • Time: 8:30 p.m. to 10:30 p.m. • Location: All waters of the Fisher's Westcott cove, Stamford, CT within 800 feet of the fireworks barge in approximate position 41°02′09.56″ N., 072°30′57.76″ W. (NAD 83).
4 Freeport Chamber of Commerce Fireworks	• Date: July 2, 2015. • Rain Date: July 9, 2015. • Time: 8:45 p.m. to 10:00 p.m. • Location: All waters of Guy Lombardo Marina, Freeport, NY within 300 feet of the land launch site located in approximate position 40°37′27.27″ N., 073°34′34.64″ W. (NAD 83).
5 City of Norwich Fireworks	• Date: July 2, 2015. • Rain Date: July 3, 2015. • Time: 9:00 p.m. to 11:00 p.m. • Location: All waters of the Thames River, Norwich, CT in approximate positions, 41°31′14.64″ N., 072°04′43.60″ W. (NAD 83).
6 Go 4th Connetquot Fireworks	• Date: July 2, 2015. • Rain Date: July 3, 2015. • Time: 8:45 p.m. to 10:00 p.m. • Location: All waters of Great South Bay within 600 feet of the fireworks barge at approximate position, 40°43′30.03″ N.; 073°08′40.25″ W. (NAD 83).
7 Madison Fireworks Organization Fireworks	• Date: July 3, 2015. • Rain Date: July 5, 2015. • Time: 9:00 p.m. to 10:30 p.m. • Location: All waters of Long Island Sound off Madison Beach, Madison, CT within 800 feet of the fireworks barge located in approximate position 41°16′09.04″ N., 072°36′18.30″ W. (NAD 83).
8 City of Middletown Fireworks	• Date: July 3, 2015. • Rain Date: July 5, 2015. • Time: 9:00 p.m. to 10:30 p.m. • Location: Waters of the Connecticut River, Middletown Harbor, Middletown, CT within 600 feet of the fireworks barge in approximate positions, 41°33′43″ N., 072°38′32″ W. (NAD 83).
9 Fairfield Independence Day Celebration Fireworks	• Date: July 3, 2015. • Rain Date: July 4, 2015. • Time: 8:45 p.m. to 10:45 p.m. • Location: All waters of Long Island Sound, Fairfield, CT within 800 feet of the fireworks barge at approximate position, 41°08′16.92″ N.; 073°14′01.02″ W. (NAD 83).
10 City of West Haven Fireworks	• Date: July 3, 2015. • Rain Date: July 5,2015. • Time: 8:45 p.m. to 10:30 p.m. • Location: All waters of New Haven Harbor off Bradley Point, West Haven, CT within 800 feet of the fireworks barge at approximate position, 41°15′07″ N.; 072°57′25″ W. (NAD 83).
11 Village of Port Jefferson Independence Day Celebration	• Date: July 4, 2015. • Rain Date: July 5, 2015. • Time: 8:30 p.m. to 10:30 p.m. • Location: All waters of Port Jefferson Harbor within 500 feet of the land launch at approximate position, 40°57′53.189″ N.; 073°03′09.72″ W. (NAD 83).
12 Shelter Island Fireworks	• Date: July 11, 2015. • Rain Date: July 12, 2015. • Time: 9:00 p.m. to 11:00 p.m. • Location: All waters of Gardiner's Bay, Shelter Island, NY in approximate position, 41°04′27.60″ N., 072°22′13.50″ W. (NAD 83).
13 Sebonack Golf Club Fireworks	• Date: July 31, 2015.

TABLE TO § 165.T01–0438—Continued

	• Rain Date: August 1, 2015. • Time: 8:30 p.m. to 10:30 p.m. • Location: All waters of Peconic Bay, Southampton, NY within 600 feet of the fireworks barge at approximate position, 40°54′49.92″ N.; 072°27′39.28″ W. (NAD 83).

Dated: June 17, 2015.

E.J. Cubanski, III,

Captain, U.S. Coast Guard, Captain of the Port Sector Long Island Sound.

[FR Doc. 2015–16748 Filed 7–7–15; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2015–0104 FRL–9926–48–Region 7]

Approval and Promulgation of Air Quality Implementation Plans; Kansas; Update to Materials Incorporated by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; notice of administrative change.

SUMMARY: Environmental Protection Agency (EPA) is updating the materials submitted by Kansas that are incorporated by reference (IBR) into the state implementation plan (SIP). EPA is also notifying the public of the correction of certain typographical errors within the IBR table. The regulations affected by this update have been previously submitted by the state agency and approved by EPA. This update affects the SIP materials that are available for public inspection at the National Archives and Records Administration (NARA), and the Regional Office.

DATES: This rule is effective on July 8, 2015.

ADDRESSES: SIP materials which are incorporated by reference into 40 CFR part 52 are available for inspection at the following locations: Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219; or at *http://www.epa.gov/region07/air/rules/fedapprv.htm;* and the National Archives and Records Administration. For information on the availability of this material at NARA, call (202) 741–6030, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jan Simpson at (913) 551–7089, or by email at *simpson.jan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The SIP is a living document which the state revises as necessary to address the unique air pollution problems in the state. Therefore, EPA from time to time must take action on SIP revisions containing new and/or revised regulations to make them part of the SIP. On May 22, 1997 (62 FR 27968), EPA revised the procedures for incorporating by reference Federally-approved SIPs, as a result of consultations between EPA and the Office of **Federal Register**. The description of the revised SIP document, IBR procedures and ''Identification of plan'' format are discussed in further detail in the May 22, 1997, **Federal Register** document.

On February 12, 1999, EPA published a document in the **Federal Register** (64 FR 7091) beginning the new IBR procedure for Kansas. On November 14, 2003 (68 FR 64532), and on April 8, 2009 (74 FR 15856), EPA published an update to the IBR material for Kansas.

In this document, EPA is publishing an updated set of tables listing the regulatory (*i.e.,* IBR) materials in the Kansas SIP taking into account the additions, deletions, and revisions to those materials previously submitted by the state agency and approved by EPA. We are removing the EPA Headquarters Library from paragraph (b)(3), as IBR materials are no longer available at this location. In addition, EPA has found errors in certain entries listed in 40 CFR 52.870(c) and (e), as amended in the published IBR update actions listed above, and is correcting them in this document. Table (c) revisions include:

• Updating state effective date, **Federal Register** citation and removing outdated text in explanation column for 28–19–200

• removing outdated text in explanation column for 28–19–201

• adding text in EPA approval date column and removing outdated text in explanation column for 28–19–650

Table (e) is being revised by:

• Adding text in the explanation column for (7)–(39).

II. EPA Action

In this action, EPA is doing the following:

A. Announcing the update to the IBR material as of December 31, 2014;

B. Revising the entry in paragraph 52.870(b) to reflect the update and corrections;

C. Revising certain entries in paragraphs 52.870(c) and (e) as described above;

D. Correcting the date format in the ''State effective date'' or ''State submittal date'' and ''EPA approval date'' columns in paragraphs 52.870(c), (d) and (e). Dates are numerical month/day/year without additional zeros;

E. Modifying the **Federal Register** citation in paragraphs 52.870(c), (d) and (e) to reflect the beginning page of the preamble as opposed to the page number of the regulatory text.

EPA has determined that this rule falls under the ''good cause'' exemption in section 553(b)(3)(B) of the Administrative Procedures Act (APA) which, upon finding ''good cause,'' authorizes agencies to dispense with public participation and section 553(d)(3), which allows an agency to make a rule effective immediately (thereby avoiding the 30-day delayed effective date otherwise provided for in the APA). This rule simply codifies provisions which are already in effect as a matter of law in Federal and approved State programs. Under section 553 of the APA, an agency may find good cause where procedures are ''impractical, unnecessary, or contrary to the public interest.'' Public comment is ''unnecessary'' and ''contrary to the public interest'' since the codification only reflects existing law. Immediate notice in the CFR benefits the public by providing notice of the updated Kansas SIP compilation.

Statutory and Executive Order Reviews

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Kansas regulations described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see

the **ADDRESSES** section of this preamble for more information).

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

- Is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

EPA has also determined that the provisions of section 307(b)(1) of the CAA pertaining to petitions for judicial review are not applicable to this action. Prior EPA rulemaking actions for each individual component of the Kansas SIP compilations previously afforded interested parties the opportunity to file a petition for judicial review in the United States Court of Appeals for the appropriate circuit within 60 days of such rulemaking action. Thus, EPA sees no need in this action to reopen the 60-day period for filing such petitions for judicial review for this ''Identification of plan'' reorganization update action for the State of Kansas.

List of Subjects in 40 CFR Part 52

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

Dated: April 7, 2015.

Mark Hague,

Acting Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as set forth below:

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart R—Kansas

■ 2. In § 52.870 paragraphs (b), (c), (d) and (e) are revised to read as follows:

§ 52.870 Identification of plan.

* * * * *

(b) *Incorporation by reference.* (1) Material listed in paragraphs (c) and (d) of this section with an EPA approval date prior to December 31, 2014, was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Material is incorporated as it exists on the date of the approval, and notice of any change in the material will be published in the **Federal Register**. Entries in paragraphs (c) and (d) of this section with EPA approval dates after December 31, 2014, will be incorporated by reference in the next update to the SIP compilation.

(2) EPA Region 7 certifies that the rules/regulations provided by EPA in the SIP compilation at the addresses in paragraph (b)(3) of this section are an exact duplicate of the officially promulgated state rules/regulations which have been approved as part of the SIP as of December 31, 2014.

(3) Copies of the materials incorporated by reference may be inspected at the Environmental Protection Agency, Region 7, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; at the EPA, Air and Radiation Docket and Information Center, and the National Archives and Records Administration (NARA). If you wish to obtain material from the EPA Regional Office, please call (913) 551–7089. For information on the availability of this material at NARA, call (202) 741–6030, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(c) *EPA-approved regulations.*

EPA-APPROVED KANSAS REGULATIONS

Kansas citation	Title	State effective date	EPA approval date	Explanation
Kansas Department of Health and Environment Ambient Air Quality Standards and Air Pollution Control				
General Regulations				
K.A.R. 28–19–6	Statement of Policy	1/1/72	5/31/72, 37 FR 10867	Kansas revoked this rule 5/1/82.
K.A.R. 28–19–8	Reporting Required	1/23/95	7/17/95, 60 FR 36361	
K.A.R. 28–19–9	Time Schedule for Compliance	5/1/84	12/21/87, 52 FR 48265.	
K.A.R. 28–19–10	Circumvention of Control Regulations.	1/1/71	5/31/72, 37 FR 10867.	
K.A.R. 28–19–11	Exceptions Due to Breakdowns or Scheduled Maintenance.	1/1/74	11/8/73, 38 FR 30876.	
K.A.R. 28–19–12	Measurement of Emissions	1/1/71	5/31/72, 37 FR 10867.	
K.A.R. 28–19–13	Interference with Enjoyment of Life and Property.	1/1/74	11/8/73, 38 FR 30876.	
K.A.R. 28–19–14	Permits Required	1/24/94	7/17/95, 60 FR 36361.	
K.A.R. 28–19–15	Severability	1/1/71	5/31/72, 37 FR 10867.	
Nonattainment Area Requirements				
K.A.R. 28–19–16	New Source Permit Requirements for Designated Nonattainment Areas.	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–16a	Definitions	10/10/97	1/11/00, 65 FR 1545.	
K.A.R. 28–19–16b	Permit Required	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–16c	Creditable Emission Reductions	10/16/89	1/16/90, 55 FR 1420	EPA deferred action on the state's current definition of the terms ''building, structure, facility, or installation''; ''installation''; and ''reconstruction.''
K.A.R. 28–19–16d	Fugitive Emission Exemption	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–16e	Relaxation of Existing Emission Limitations.	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–16f	New Source Emission Limits	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–16g	Attainment and Maintenance of National Ambient Air Quality Standards.	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–16h	Compliance of Other Sources	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–16i	Operating Requirements	10/16/89	1/16/90 55 FR 1420.	
K.A.R. 28–19–16j	Revocation and Suspension of Permit.	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–16k	Notification Requirements	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–16l	Failure to Construct	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–16m	Compliance with Provisions of Law Required.	10/16/89	1/16/90, 55 FR 1420.	
Attainment Area Requirements				
K.A.R. 28–19–17	Prevention of Significant Deterioration of Air Quality.	11/22/02	2/26/03, 68 FR 8845	K.A.R. 28–19–17a through 28–19–17q revoked. Provision moved to K.A.R. 28–19–350.
Stack Height Requirements				
K.A.R. 28–19–18	Stack Heights	5/1/88	4/20/89, 54 FR 15934	The state regulation has stack height credit. EPA has not approved that part.
K.A.R. 28–19–18b	Definitions	5/1/88	4/20/89, 54 FR 15934.	
K.A.R. 28–19–18c	Methods for Determining Good Engineering Practice Stack Height.	5/1/88	4/20/89, 54 FR 15934.	
K.A.R. 28–19–18d	Fluid Modeling	5/1/88	4/20/89, 54 FR 15934.	
K.A.R. 28–19–18e	Relaxation of Existing Emission Limitations.	5/1/88	4/20/89, 54 FR 15934.	
K.A.R. 28–19–18f	Notification Requirements	5/1/88	4/20/89, 54 FR 15934.	
Continuous Emission Monitoring				
K.A.R. 28–19–19	Continuous Emission Monitoring	6/8/92	1/12/93, 58 FR 3847.	

EPA-APPROVED KANSAS REGULATIONS—Continued

Kansas citation	Title	State effective date	EPA approval date	Explanation
	Processing Operation Emissions			
K.A.R. 28–19–20	Particulate Matter Emission Limitations.	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–21	Additional Emission Restrictions	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–23	Hydrocarbon Emissions—Stationary Sources.	12/27/72	11/8/73, 38 FR 30876.	
K.A.R. 28–19–24	Control of Carbon Monoxide Emissions..	1/1/72	11/8/73, 38 FR 30876.	
	Indirect Heating Equipment Emissions			
K.A.R. 28–19–30	General Provisions	1/1/72	5/31/72, 37 FR 10867.	
K.A.R. 28–19–31	Emission Limitations	11/8/93	10/18/94, 59 FR 52425.	
K.A.R. 28–19–32	Exemptions—Indirect Heating Equipment.	11/8/93	10/18/94, 59 FR 52425.	
	Incinerator Emissions			
K.A.R. 28–19–40	General Provisions	1/1/71	5/31/72, 37 FR 10867.	
K.A.R. 28–19–41	Restriction of Emission	12/27/72	11/8/73, 38 FR 30876.	
K.A.R. 28–19–42	Performance Testing	1/1/72	11/8/73, 38 FR 30876.	
K.A.R. 28–19–43	Exceptions	1/1/71	5/31/72, 37 FR 10867.	
	Air Pollution Emergencies			
K.A.R. 28–19–55	General Provisions	1/1/72	5/31/72, 37 FR 10867.	
K.A.R. 28–19–56	Episode Criteria	10/16/89	1/16/90, 55 FR 1420.	
K.A.R. 28–19–57	Emission Reduction Requirements	1/1/72	5/31/72, 37 FR 10867.	
K.A.R. 28–19–58	Emergency Episode Plans	1/1/72	5/31/72, 37 FR 10867.	
	Volatile Organic Compound Emissions			
K.A.R. 28–19–61	Definitions	10/7/91	6/23/92, 57 FR 27936.	
K.A.R. 28–19–62	Testing Procedures	10/7/71	6/23/92, 57 FR 27936.	
K.A.R. 28–19–63	Automobile and Light Duty Truck Surface Coating.	11/8/93	10/18/94, 59 FR 52425.	
K.A.R. 28–19–64	Bulk Gasoline Terminals	5/1/88	5/18/88, 53 FR 17700.	
K.A.R. 28–19–65	Volatile Organic Compounds (VOC) Liquid Storage in Permanent Fixed Roof Type Tanks.	5/1/88	5/18/88, 53 FR 17700.	
K.A.R. 28–19–66	Volatile Organic Compounds (VOC) Liquid Storage in External Floating Roof Tanks.	5/1/88	5/18/88, 53 FR 17700.	
K.A.R. 28–19–67	Petroleum Refineries	5/1/86	1/2/87, 52 FR 53.	
K.A.R. 28–19–68	Leaks from Petroleum Refinery Equipment.	5/1/86	1/2/87, 52 FR 53.	
K.A.R. 28–19–69	Cutback Asphalt	5/1/88	5/18/88, 53 FR 17700.	
K.A.R. 28–19–70	Leaks from Gasoline Delivery Vessels and Vapor Collection Systems.	5/15/98	1/11/00, 65 FR 1545.	
K.A.R. 28–19–71	Printing Operations	5/1/88	5/18/88, 53 FR 17700.	
K.A.R. 28–19–72	Gasoline Dispensing Facilities	5/1/88	5/18/88, 53 FR 17700.	
K.A.R. 28-19-73	Surface Coating of Miscellaneous Metal Parts and Products and Metal Furniture.	6/8/92	1/12/93, 58 FR 3847.	
K.A.R. 28–19–74	Wool Fiberglass Manufacturing	5/1/88	5/18/88, 53 FR 17700.	
K.A.R. 28–19–76	Lithography Printing Operations	10/7/91	6/23/92, 57 FR 27936.	
K.A.R. 28–19–77	Chemical Processing Facilities That Operate Alcohol Plants or Liquid Detergent Plants.	10/7/91	6/23/92, 57 FR 27936.	
	General Provisions			
K.A.R. 28–19–200	General Provisions; definitions	1/2/11	2/22/11, 76 FR 9658.	
K.A.R. 28–19–201	General Provisions; Regulated Compounds List.	10/10/97	1/11/00, 65 FR 1545.	
KAR 28–19–202	Annual Emissions Fee	11/15/10	1/27/14, 79 FR 4274	Paragraph (c), has not been approved as part of the SIP.
K.A.R. 28–19–204	Permit Issuance and Modification; Public Participation.	1/23/95	7/17/95, 60 FR 36361.	

EPA-APPROVED KANSAS REGULATIONS—Continued

Kansas citation	Title	State effective date	EPA approval date	Explanation
K.A.R. 28–19–210	Calculation of Actual Emissions	11/22/93	1/11/00, 65 FR 1545.	
K.A.R. 28–19–212	Approved Test Methods and Emission Compliance Determination Procedures.	1/23/95	7/17/95, 60 FR 36361.	
Construction Permits And Approvals				
K.A.R. 28–19–300	Applicability	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–301	Application and Issuance	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–302	Additional Provisions; Construction Permits.	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–303	Additional Provisions; Construction Approvals.	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–304	Fees	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–350	Prevention of Significant Deterioration (PSD) of Air Quality.	12/28/12	6/20/13, 78 FR 37126	Provisions of the 2010 $PM_{2.5}$ PSD-Increments, SILs and SMCs rule (75 FR 64865, October 20, 2010) relating to SILs and SMCs that were affected by the January 22, 2013, U.S. Court of Appeals decision are not SIP approved. Provisions of the 2002 NSR reform rule relating to the Clean Unit Exemption, Pollution Control Projects, and exemption from recordkeeping provisions for certain sources using the actual-to-projected-actual emissions projections test are not SIP approved. In addition, we have not approved Kansas rule incorporating EPA's 2007 revision of the definition of ''chemical processing plants'' (the ''Ethanol Rule,'' 72 FR 24060 (May 1, 2007) or EPA's 2008 ''fugitive emissions rule,'' 73 FR 77882 (December 19, 2008).
General Permits				
K.A.R. 28–19–400	General Requirements	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–401	Adoption by the Secretary	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–402	Availability of Copies; Lists of Sources to Which Permits Issued.	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–403	Application to Construct or Operate Pursuant to Terms of General Permits.	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–404	Modification, Revocation	1/23/95	7/17/95, 60 FR 36361.	
Operating Permits				
K.A.R. 28–19–500	Applicability	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–501	Emissions Limitations and Pollution Control Equipment for Class I and Class II Operating Permits; Conditions.	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–502	Identical Procedural Requirements	1/23/95	7/17/95, 60 FR 36361.	
Class II Operating Permits				
K.A.R. 28–19–540	Applicability	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–541	Application Timetable and Contents	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–542	Permit-by-Rule	9/23/05	2/8/08, 73 FR 7468.	
K.A.R. 28–19–543	Permit Term and Content; Operational Compliance.	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–544	Modification of Sources or Operations.	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–545	Application Fee	1/23/95	7/17/95, 60 FR 36361.	
K.A.R. 28–19–546	Annual Emission Inventory	9/23/05	2/8/08, 73 FR 7468.	

EPA-APPROVED KANSAS REGULATIONS—Continued

Kansas citation	Title	State effective date	EPA approval date	Explanation
K.A.R. 28–19–561	Permit-by-Rule; Reciprocating Engines.	9/23/05	2/8/08, 73 FR 7468.	
K.A.R. 28–19–562	Permit-by-Rule; Organic Solvent Evaporative Sources.	9/23/05	2/8/08, 73 FR 7468.	
K.A.R. 28–19–563	Permit-by-Rule; Hot Mix Asphalt Facilities.	9/23/05	2/8/08, 73 FR 7468.	
K.A.R. 28–19–564	Permit-by-Rule; Sources with Actual Emissions Less Than 50 Percent of Major Source Thresholds.	10/4/02	3/26/03, 68 FR 14540.	
Open Burning Restrictions				
K.A.R. 28–19–645	Open Burning Prohibited	3/1/96	10/2/96, 61 FR 51366.	
K.A.R. 28–19–646	Responsibility for Open Burning	3/1/96	10/2/96, 61 FR 51366.	
K.A.R. 28–19–647	Exceptions to Prohibition on Open Burning.	3/1/96	10/2/96, 61 FR 51366.	
K.A.R. 28–19–648	Agricultural Open Burning	3/1/96	10/2/96, 61 FR 51366.	
K.A.R. 28–19–650	Emissions Opacity Limits	1/29/99	12/12/01, 66 FR 64148 (correction). 1/11/00, 65 FR 1545.	
Nitrogen Oxide Emissions				
K.A.R. 28–19–712	Definitions	6/25/10	2/20/13, 78 FR 11751.	
K.A.R. 28–19–712a ..	Applicability	6/25/10	2/20/13, 78 FR 11751.	
K.A.R. 28–19–712b ..	General requirement for heavy-duty diesel vehicles.	6/25/10	2/20/13, 78 FR 11751.	
K.A.R. 28–19–712c ..	General requirement for load and unload locations.	6/25/10	2/20/13, 78 FR 11751.	
K.A.R. 28–19–712d ..	Exemptions	6/25/10	2/20/13, 78 FR 11751.	
K.A.R. 28–19–713	Applicability	6/25/10	2/20/13, 78 FR 11751.	
K.A.R. 28–19–713a ..	Emission limitation requirements	6/25/10	2/20/13, 78 FR 11751.	
K.A.R. 28–19–713b ..	Alternate emissions limit	6/25/10	2/20/13, 78 FR 11751.	
K.A.R. 28–19–713c ..	Control measures and equipment ...	6/25/10	2/20/13, 78 FR 11751.	
K.A.R. 28–19–713d ..	Compliance demonstration, monitoring, and reporting requirements.	6/25/10	2/20/13, 78 FR 11751.	
Volatile Organic Compound Emissions				
K.A.R. 28–19–714	Control of Emissions from Solvent Metal Cleaning.	9/1/02	10/30/02, 67 FR 66058.	
K.A.R. 28–19–717	Control of Volatile Organic Compound (VOC) Emissions from Commercial Bakery Ovens in Johnson and Wyandotte Counties.	12/22/00	12/12/01, 66 FR 64148.	
K.A.R. 28–19–719	Fuel Volatility	4/27/01	2/13/02, 67 FR 6655.	
Conformity				
K.A.R. 28–19–800	General Conformity of Federal Actions.	3/15/96	10/2/96, 61 FR 51366.	

(d) *EPA-approved State source-specific permits.*

EPA-APPROVED KANSAS SOURCE-SPECIFIC PERMITS

Name of source	Permit or case No.	State effective date	EPA approval date	Explanation
(1) Board of Public Utilities, Quindaro Power Station.	2090048	10/20/93	10/18/94, 59 FR 52425.	
(2) Board of Public Utilities, Kaw Power Station.	2090049	10/20/93	10/18/94, 59 FR 52425.	
(3) Kansas City Power and Light Company.	.....	12/5/07	12/27/11, 76 FR 80754	Certain provisions withdrawn from plan as identified in letter dated 12/1/11 from Kansas.

EPA-APPROVED KANSAS SOURCE-SPECIFIC PERMITS—Continued

Name of source	Permit or case No.	State effective date	EPA approval date	Explanation
(4) Westar Energy, Inc.	.....	2/29/08	12/27/11, 76 FR 80759	Certain provisions withdrawn from plan as identified in letter dated 12/1/11 from Kansas.

(e) *EPA-approved nonregulatory provisions and quasi-regulatory measures.*

EPA-APPROVED KANSAS NONREGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
(1) Implementation Plan for Attainment and Maintenance of the National Air Quality Standards.	Statewide	1/31/72	5/31/72, 37 FR 10867.	
(2) Comments on the Plan in Response to EPA Review.	Kansas City	3/24/72	6/22/73, 38 FR 16550	Correction notice published 3/2/76.
(3) Emergency Episode Operations/Communications Manual.	Kansas City	4/6/72	11/8/73, 38 FR 30876	Correction notice published 3/2/76.
(4) Emergency Episode Operations/Communications Manual.	Statewide except Kansas City.	2/15/73	11/8/73, 38 FR 30876	Correction notice published 3/2/76.
(5) Letter Concerning Attainment of CO Standards.	Kansas City	5/29/73	11/8/73, 38 FR 30876	Correction notice published 3/2/76.
(6) Amendment to State Air Quality Control Law Dealing with Public Access to Emissions Data.	Statewide	7/27/73	11/8/73, 38 FR 30876	Correction notice published 3/2/76.
(7) Analysis and Recommendations Concerning Designation of Air Quality Maintenance Areas.	Statewide	2/28/74	3/2/76, 41 FR 8956	[FRL 484–4].
(8) Ozone Nonattainment Plan	Kansas City	9/17/79	4/3/81, 46 FR 20164	[A–7–FRL 1788–5].
(9) Ozone Nonattainment Plan	Douglas County	10/22/79	4/3/81, 46 FR 20164	[A–7–FRL 1788–5].
(10) TSP Nonattainment Plan	Kansas City	3/10/80	4/3/81, 46 FR 20164	[A–7–FRL 1788–5].
(11) Lead Plan	Statewide	2/17/81	10/22/81, 46 FR 51742	[A–7–FRL–1938–8].
(12) CO Nonattainment Plan	Wichita	4/16/81	12/15/81, 46 FR 61117	[A–7–FRL–1990–3].
(13) Air Monitoring Plan	Statewide	10/16/81	1/22/82, 47 FR 3112	[A–7–FRL–2024–8].
(14) Letter and Supporting Documentation Relating to Reasonably Available Control Technology for Certain Particulate Matter Sources.	Kansas City	9/15/81	6/18/82, 47 FR 26387	[EPA Action KS 276; FRL 2137–6]. Correction notice published 1/12/84.
(15) Letter Agreeing to Follow EPA Interim Stack Height Policy for Each PSD Permit Issued Until EPA Revises the Stack Height Regulations.	Statewide	6/20/84	12/11/84, 49 FR 48185	[A–7–FRL–2734–4; EPA No 1163].
(16) Letters Pertaining to Permit Fees.	Statewide	3/27/86, 9/15/87	12/21/87, 52 FR 48265	[FRL 3299–4].
(17) Revisions to the Ozone Attainment Plan.	Kansas City	7/2/86, 4/16/87, 8/18/87, 8/19/87, 1/6/88.	5/18/88, 53 FR 17700	[3375–5].
(18) Revised CO Plan	Wichita	3/1/85, 9/3/87	10/28/88, 53 FR 43691	[FRL–3449–1].
(19) Letter Pertaining to the Effective Date of Continuous Emission Monitoring Regulations.	Statewide	1/6/88	11/25/88, 53 FR 47690	[FRL–3473–9].
(20) Letters Pertaining to New Source Permit Regulations, Stack Height Regulations, and Stack Height Analysis and Negative Declarations.	Statewide	3/27/86, 12/7/87 1/6/88.	4/20/89, 54 FR 15934	[FRL–3558–5].
(21) PM_{10} Plan	Statewide	10/5/89, 10/16/89	1/16/90, 55 FR 1420	[FRL–3704–3].
(22) Ozone Maintenance Plan	Kansas City	10/23/91	6/23/92, 57 FR 27936	[KS1–1–5439; FRL 4126–6].
(23) Letter Pertaining to PSD NO_X Requirements.	Statewide	9/15/92	1/12/93, 58 FR 3847	[KS–2–1–5640; FRL–4552–3].
(24) Small Business Assistance Plan.	Statewide	1/25/94	5/12/94, 59 FR 24644	[KS–3–1–8332; FRL–4882–4].

EPA-APPROVED KANSAS NONREGULATORY PROVISIONS—Continued

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
(25) Letter Regarding Compliance Verification Methods and Schedules Pertaining to the Board of Public Utilities Power Plants.	Kansas City	12/11/92	10/18/94, 59 FR 52425	[KS–4–1–6508a; FRL–5079–2].
(26) Emissions Inventory Update Including a Motor Vehicle Emissions Budget.	Kansas City	5/11/95	4/25/96, 61 FR 18251	[KS–6–1–6985, MO–31–1–7153; FRL 5448–9].
(27) Air monitoring plan	Statewide	1/6/02	8/30/02, 67 FR 55726	[KS 162–1162a; FRL–7270–4].
(28) Maintenance Plan for the 1-hour ozone standard in the Kansas portion of the Kansas City maintenance area for the second ten-year period.	Kansas City	1/9/03	1/13/04, 69 FR 1919	[KS 202–1202; FRL–7608–9].
(29) Revision to Maintenance Plan for the 1-hour ozone standard in the Kansas portion of the Kansas City maintenance area for the second ten-year period.	Kansas City	2/10/06	6/26/06, 71 FR 36213	[EPA–R07–OAR–2006–0365; FRL–8188–4].
(30) CAA 110(a)(2)(D)(i) SIP—Interstate Transport.	Statewide	1/7/07	3/9/07, 72 FR 10608	[EPA–R07–OAR–2007–0141; FRL–8286–3].
(31) Maintenance Plan for the 8-hour ozone standard in the Kansas portion of the Kansas City area.	Kansas City	5/23/07	8/9/07, 72 FR 44781	[EPA–R07–OAR–2007–0620; FRL–8450–5] This plan replaces numbers (28) and (29).
(32) Section 110(a)(2) Infrastructure Requirements for the 1997 8-Hour Ozone NAAQS.	Statewide	1/8/08 7/20/09	7/11/11, 76 FR 40624	[EPA–R07–OAR–2011–0304; FRL–9434–3]. This action addresses the following CAA elements as applicable: 111(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L) and (M).
(33) Regional Haze Plan for the first implementation period.	Statewide	11/9/09	12/27/11, 76 FR 80754	[EPA–R07–OAR–2011–0675; FRL–9611–3]. Certain provisions withdrawn from plan as identified in letter dated 12/1/11 from Kansas.
(34) Section 110(a)(2) Infrastructure Requirements for the 1997 $PM_{2.5}$ NAAQS.	Statewide	1/08/08	6/20/13, 78 FR 37126	[EPA–R07–OAR–2013–0233; FRL–9825–6]. This action addresses the following CAA elements: 110(a)(2)(A), (B), (C), (D)(i)(II) (prongs 3 and 4), D(ii), (E), (F), (G), (H), (J), (K), (L), and (M), except as noted.
(35) Section 110(a)(2) Infrastructure Requirements for the 2006 $PM_{2.5}$ NAAQS.	Statewide	4/12/10	6/20/13, 78 FR 37126	[EPA–R07–OAR–2013–0233; FRL–9825–6]. This action addresses the following CAA elements: 110(a)(2)(A), (B), (C), (D)(i)(II) (prongs 3 and 4), D(ii), (E), (F), (G), (H), (J), (K), (L) and (M), except as noted.
(36) Section 128 Declaration: Kansas Department of Health and Environment Representation and Conflicts of Interest Provisions, Kansas Revised Statutes (KSA). KSA 46–221, KSA 46–229, KSA 46–247(c).	Statewide	3/19/13	6/20/13, 78 FR 37126	[EPA–R07–OAR–2013–0233; FRL–9825–6].
(37) Section 110(a)(2) infrastructure Requirements for the 2008 Pb NAAQS.	Statewide	1/13/12	9/15/14, 79 FR 54908	[EPA–R07–OAR–2014–0271; FRL–9916–50–Region 7]. This action addresses the following CAA elements: 110(a)(2)(A), (B), (C), (D), (E), (F), (G), (H), (J), (K), (L) and (M).

EPA-APPROVED KANSAS NONREGULATORY PROVISIONS—Continued

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
(38) Section 110(a)(2) Infrastructure Requirements for the 2008 O_3 NAAQS.	Statewide	3/19/13	10/21/14, 79 FR 62861	[EPA–R07–OAR–2014–0401; FRL–9918–19–Region 7]. This action addresses the following CAA elements: 110(a)(2)(A), (B), (C), (D)(i)(II) (prongs 3 and 4), (D)(ii), (E), (F), (G), (H), (J), (K), (L) and (M) except as noted.
(39) Section 110(a)(2) Infrastructure Requirements for the 2010 NO_2 NAAQS.	Statewide	3/19/13	10/22/14, 79 FR 63044	[EPA–R07–OAR–2014–0500; FRL–9918–11–Region 7]. This action addresses the following CAA elements: 110 (a)(2)(A), (B), (C), (D), (E), (F), (G), (H), (J), (K), (L) and (M).

[FR Doc. 2015–16626 Filed 7–7–15; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0164; FRL–9927–76–Region 9]

Revisions to the California State Implementation Plan, Feather River Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the Feather River Air Quality Management District (FRAQMD or the District) portion of the California State Implementation Plan (SIP). Included in this approval are the following three SIP demonstrations from FRAQMD: 2006 Reasonably Available Control Technology (RACT) Analysis for State Implementation Plan (SIP), November 2006; Reasonably Available Control Technology State Implementation Plan Revision Negative Declaration for Control Techniques Guidelines Issued 2006–2008, June 1, 2009 and; Reasonably Available Control Technology Analysis and Negative Declarations, July 3, 2014. The first two demonstrations address the 1997 8-hour National Ambient Air Quality Standards (NAAQS) for ozone, and the third demonstration addresses the 2008 8-hour NAAQS for ozone. These submitted SIP revisions contain FRAQMD's negative declarations for volatile organic compound (VOC) source categories. We are approving the submitted SIP revisions under the Clean Air Act as amended in 1990 (CAA or the Act). We are also approving a local rule to regulate VOC emissions from gasoline dispensing facilities.

DATES: This rule is effective on September 8, 2015 without further notice, unless EPA receives adverse comments by August 7, 2015. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2015–0164, by one of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.
2. *Email: steckel.andrew@epa.gov.*
3. *Mail or deliver:* Andrew Steckel (Air–4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *www.regulations.gov* or email. *www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

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

FOR FURTHER INFORMATION CONTACT: James Shears, EPA Region IX, (213) 244–1810, *shears.james@epa.gov.*

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

Table of Contents

I. The State's Submittal.

A. What documents and what rule did the state submit?

Table 1 lists the RACT SIP documents addressed by this action with the date that each one was adopted by the local air agency and submitted to EPA by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED DOCUMENTS

Local agency	Document	Adopted	Submitted
FRAQMD	2006 Reasonably Available Control Technology (RACT) Analysis for State Implementation Plan (SIP) (''2006 RACT SIP'').	12/4/06	7/11/07
FRAQMD	Reasonably Available Control Technology State Implementation Plan Revision, Negative Declaration for Control Techniques Guidelines Issued 2006–2008 (''2009 RACT SIP'').	6/1/09	10/27/09
FRAQMD	Reasonably Available Control Technology Analysis and Negative Declarations (''2014 RACT SIP'').	8/4/14	9/29/14

The FRAQMD 2006 RACT SIP submittal became complete by operation of law on January 11, 2008, and the FRAQMD 2009 RACT SIP submittal became complete by operation of law on April 27, 2010, each pursuant to CAA section 110(k)(1)(B). On January 23, 2015, EPA determined that the submittal for the FRAQMD 2014 RACT SIP met the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

For the rule submitted by the state, Table 2 lists the rule we are approving with the dates it was adopted by the local air agency and submitted to EPA by CARB.

TABLE 2—SUBMITTED RULE

Local agency	Rule No.	Document	Amended	Submitted
FRAQMD	3.8	Gasoline Dispensing Facilities	6/2/14	11/6/14

B. Are there other versions of these documents and the rule?

There are no previous submitted versions of FRAQMD's 2006, 2009, and 2014 RACT SIPs. For Rule 3.8, we approved an early version: The Sutter County Rule 3.08(3.8), ''Storage and Transfer of Gasoline'', on May 3, 1982 (47 FR 18856). With the formation of FRAQMD in 1991, this rule was adopted with identical language in June 1991 to apply beyond just Sutter County to the entire larger FRAQMD area.

C. What is the purpose of the RACT SIP submissions and the submitted rule revision?

VOCs and nitrogen oxides (NO_X) help produce ground-level ozone and smog, which harm human health and the environment. Section 110(a) of the CAA requires states to submit enforceable regulations that control VOC and NO_X emissions. Sections 182(b)(2) and (f) require that SIPs for ozone nonattainment areas classified as moderate or above require implementation of RACT for any source covered by an EPA Control Techniques Guidance (CTG) document and any other major stationary source of VOCs or NO_X. FRAQMD is subject to this requirement as the southern part of Sutter County in FRAQMD is designated and classified as a severe ozone nonattainment area for the 1997 and 2008 8-hour NAAQS for ozone (see 40 CFR 81.305). Therefore, FRAQMD must, at a minimum, adopt RACT-level controls for all sources covered by a CTG document and for all major non-CTG stationary sources of VOCs or NO_X in south Sutter County. The District adopted its 2006 RACT SIP, with negative declarations, on December 4, 2006. FRAQMD adopted its 2009 RACT SIP revision, which included negative declarations for 11 new or updated CTGs issued from 2006 to 2008, on June 1, 2009. FRAQMD adopted its 2014 RACT SIP, with negative declarations, on August 2014. No comments were received on any of the three RACT SIP demonstrations. Along with the 2014 RACT SIP adoption, FRAQMD adopted Rule 3.8 which is designed to limit VOC emissions from displaced gasoline vapors while transferring gasoline into storage tanks and transport vessels. This rule is intended to fully satisfy the CTG design criteria for Stage I vapor control systems.

II. EPA's Evaluation and Action

A. How is EPA evaluating the RACT SIP submissions and the submitted rule revision?

FRAQMD regulates the Yuba County and Sutter County portions of the Sacramento Valley Air Basin. The southern part of Sutter County is designated and classified as a severe ozone nonattainment area for the 1997 and 2008 8-hour national ambient air quality standards (NAAQS) for ozone (40 CFR 81.305). CAA Section 182(b)(2) and (f), as well as 40 CFR 51.912(a)(1) require that SIPs for ozone nonattainment areas classified as moderate or above require implementation of RACT for any source covered by a CTG document and any other major stationary source of VOCs or NO_X. Any stationary source that emits or has a potential to emit at least 25 tons per year (tpy) of VOCs or NO_X in a severe ozone nonattainment area is considered a major stationary source (see CAA sections 182(b(2)) and (f) and 302(j)). Where there are no existing sources covered by a particular CTG document or no other major stationary sources of VOCs or NO_X, states may, in lieu of adopting RACT requirements, adopt negative declarations certifying that there are no such sources in the relevant nonattainment area (see Memorandum from William T. Harnett to Regional Air Division Directors, (May 18, 2006), ''RACT Qs & As—Reasonably Available Control Technology (RACT) Questions and Answers'' page 7).

SIP rules must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)),

and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193).

Guidance and policy documents that we used to evaluate CAA section 182 RACT SIPs for FRAQMD include the following:

1. ''Final Rule to Implement the 8-Hour Ozone National Ambient Air Quality Standard—Phase 2'' (70 FR 71612; November 29, 2005).

2. ''Air Quality Designations and Classifications for the 8-Hour Ozone National Ambient Air Quality Standards; Early Action Compact Areas With Deferred Dates''—Final Rule (69 FR 23858; April 30, 2004).

3. ''State Implementation Plans, General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990'' (57 FR 13498; April 16, 1992).

4. Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations: Clarification to Appendix D of November 24, 1987 **Federal Register**, May 25, 1988, Revised January 11, 1990, U.S. EPA, Air Quality Management Division, Office of Air Quality Planning and Standards (''The Blue Book'').

5. Guidance Document for Correcting Common VOC and Other Rule Deficiencies, August 21, 2001, U.S. EPA Region IX (the ''Little Bluebook'').

6. ''State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990'' (57 FR 55620, November 25, 1992) (''the NO_X Supplement'').

7. Memorandum from William T. Harnett to Regional Air Division Directors, (May 18, 2006), ''RACT Qs & As—Reasonably Available Control Technology (RACT) Questions and Answers.''

8. RACT SIPs, Letter dated March 9, 2006 from EPA Region IX (Andrew Steckel) to CARB (Kurt Karperos) describing Region IX's understanding of what constitutes a minimally acceptable RACT SIP.

9. ''Final Rule to Implement the 1997 8-Hour Ozone National Ambient Air Quality Standard: Classification of Areas That Were Initially Classified Under Subpart 1; Revision of the Anti-Backsliding Provisions To Address 1-Hour Contingency Measure Requirements; Deletion of Obsolete 1-Hour Standard Provision''—Final Rule (77 FR 28424; May 14, 2012).

10. ''Model Volatile Organic Compound Rules for Reasonably Available Control Technology'', EPA (June 1992).

11. Beyond VOC RACT Requirements'', EPA (April 1995).

12. EPA's CTGs *http://www.epa.gov/glo/SIPToolkit/ctgs.html*.

13. CARB's emissions inventory database *http://www.arb.ca.gov/app/emsinv/facinfo/facinfo.php*

14. FRAQMD, CARB and EPA Region IX databases of FRAQMD rules—
FRAQMD: *http://myairdistrict.com/index.php?Itemid=71*
CARB: *http://www.arb.ca.gov/ridb.htm*
EPA: *http://epa.gov/region09/air/sips/index.html*

15. Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements''—Final Rule (80 FR 12264; March 6, 2015).

B. Does the RACT SIP submission meet the evaluation criteria?

The 2006, 2009 and 2014 RACT SIPs each includes three elements, as described further below:

1. Evaluations of VOC and NO_X rules for sources subject to a CTG.

2. Negative declarations where there are no facilities subject to a CTG.

3. Negative declaration for major non-CTG sources of VOC or NO_X.

A summary of our evaluation of each element is provided below. For additional information concerning our evaluation, please refer to the Technical Support Documents (TSDs) concerning the 2006, 2009 and 2014 RACT SIPs and FRAQMD Rule 3.8, which are available in the docket for this action.

1. Evaluations of VOC and NO_X Rules for Sources Subject to a CTG

We believe that Rule 3.8 is consistent with the relevant requirements, as well as policy and guidance regarding enforceability, RACT, and SIP relaxations. We are not aware of information suggesting that additional controls are needed to fulfill RACT.

2. Negative Declarations Where There are no Facilities Subject to a CTG

Negative declarations are only required for CTG source categories for which the District has no sources covered by the CTG. A negative declaration is not required for non-CTG source categories. Table 3 below lists the CTG source categories for the 2006, 2009 and 2014 RACT SIPs. The District indicated it does not currently have, nor does it anticipate sources subject to the CTGs in these categories in the future. We searched CARB's emissions inventory database to verify there are no facilities in FRAQMD that might be subject to the CTGs listed below. We concur with the District's negative declarations.

TABLE 3—NEGATIVE DECLARATIONS FOR THE 2006, 2009 AND 2014 RACT SIPS

CTG source category	Negative declaration CTG reference document	2006 RACT SIP	2009 RACT SIP	2014 RACT SIP
Aerospace	EPA–453/R–97–004—Control of VOC Emissions from Coating Operations at Aerospace Manufacturing and Rework.	X	.....	X
Automobile Coating; Metal Coil Container, & Closure; Paper & Fabric.	EPA–450/2–77–008—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks.	X	.....	X
Automobile and Light-Duty Truck Assembly Coatings.	EPA–453/R–08–006—Control Techniques Guidelines for Automobile and Light-Duty Assembly Coatings.	.....	X	X
Cutback Asphalt	EPA–450/2–77–037—Control of Volatile Organic Emissions from Use of Cutback Asphalt.	X	.....	X
Dry Cleaning	EPA–450/3–82–009—Control of Volatile Organic Compound Emissions from Large Petroleum Dry Cleaners.	X	.....	X
Flat Wood Paneling Coatings	EPA–453/R–06–004—Control Techniques Guidelines for Flat Wood Paneling Coatings.	.....	X	X
Fiberglass Boat Manufacturing Materials.	EPA–453/R–08–004—Control Techniques Guidelines for Fiberglass Boat Manufacturing Materials.	.....	X	X
Flexible Package Printing	EPA–453/R06–003—Control Techniques Guidelines for Flexible Package Printing.	.....	X	X

TABLE 3—NEGATIVE DECLARATIONS FOR THE 2006, 2009 AND 2014 RACT SIPS—Continued

CTG source category	Negative declaration CTG reference document	2006 RACT SIP	2009 RACT SIP	2014 RACT SIP
Gasoline Loading Terminal	EPA–450/2–77–026—Control of Hydrocarbons from Tank Truck Gasoline Loading Terminals.	X	.....	X
Gasoline Trucks	EPA–450/2–78–051—Control of Volatile Organic Compound Leaks from Gasoline Tank Trucks and Vapor Collection Systems.	X	.....	X
Gasoline Bulk Plants	EPA–450/2–77–035—Control of Volatile Organic Emissions from Gasoline Bulk Plants.	X	.....	X
Graphic Arts Rotogravure and Flexography.	EPA–450/2–78–033—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume VIII: Rotogravure and Flexography.	X	.....	X
Industrial Cleaning Solvents	EPA–453/R–06–001—Control Techniques Guidelines for Industrial Cleaning Solvents.	X	X	X
Large Appliance Coating	EPA–450/2–77–034—Control of Volatile Organic Emissions from Existing Stationary Sources, Volume V: Surface Coating of Large Appliances.	X	.....	X
Large Appliance Coating	EPA–453/R–07–004—Control Techniques for Large Appliance Coatings.	.....	X	X
Magnet Wire Coating	EPA–450/2–77–033—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume IV: Surface Coating of Insulation of Magnet Wire.	X	.....	X
Metal Can Coating; Metal Coil Coating.	EPA–450/2–77–008—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks.	X	.....	X
Metal Furniture	EPA–450/2–77–032—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume III: Surface Coating of Metal Furniture.	X	.....	X
Metal Furniture Coatings	EPA–453/R–07–005—Control Techniques Guidelines for Metal Furniture Coatings.	.....	X	X
Metal Parts and Products	EPA–450/2–78–015—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume VI: Surface Coating of Miscellaneous Parts and Products.	X	.....	X
Miscellaneous Industrial Adhesives	EPA–453/R–08–005—Control Techniques Guidelines for Miscellaneous Industrial Adhesives.	X	X	X
Miscellaneous Metal and Plastic Parts Coatings.	EPA–453/R–08–003—Control Techniques Guidelines for Miscellaneous Metal and Plastic Parts Coatings.	.....	X	X
Natural Gas/Gasoline	EPA–450/2–83–007—Control of VOC Equipment Leaks from Natural Gas/Gasoline Processing Plants.	X	.....	X
Offset Lithographic Printing and Letterpress Printing.	EPA–453/R–06–002—Control Techniques Guidelines for Offset Lithographic Printing and Letterpress Printing.	.....	X	X
Paper and Fabric Coating	EPA–450/2–77–008—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks.	X	.....	X
Paper, Film, and Foil Coatings	EPA–453/R–07–003—Control Techniques Guidelines for Paper, Film, and Foil Coatings.	.....	X	X
Perchloroethylene Dry Cleaning Systems[1].	EPA–450/2–78–050—Control of Volatile Organic Emissions from Perchloroethylene Dry Cleaning Systems.	.....	.....	X
Petroleum Liquid Storage Tanks	EPA–450/2–77–036—Control of VOC Emissions from Storage of Petroleum Liquids in Fixed Roof Tanks.	X	.....	X
Petroleum Liquid Storage Tanks	EPA–450/2–78–047—Control of VOC Emissions from Petroleum Liquid Storage in External Floating Roof Tanks.	X	.....	X
Pharmaceutical Products	EPA–450/2–78–029—Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products.	X	.....	X
Resin Manufacturing	EPA–450/3–83–008—Control of VOC Emissions from Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.	X	.....	X
Resin Manufacturing	EPA–450/3–83–006—Control of VOC Fugitive Emissions from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.	X	.....	X
Refineries	EPA–450/2–77–025—Control of Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.	X	.....	X
Refineries	EPA–450/2–78–036—Control of VOC Leaks from Petroleum Refinery Equipment.	X	.....	X
Rubber Tire Manufacturing	EPA–450/2–78–030—Control of Volatile Organic Emissions from Manufacture of Pneumatic Rubber Tires.	X	.....	X
Ship Coatings	61 FR 44050 Shipbuilding and Ship Repair Operations (Surface Coating).	X	.....	X
Ship Coatings	EPA–453/R–94–032—Alternative Control Technology Document—Surface Coating Operations at Shipbuilding and Ship Repair Operations (Surface Coating).	.....	.....	X
Solvent Cleaning Degreasers	EPA–450/2–77–022—Control of Volatile Organic Emissions from Solvent Metal Cleaning.	X	.....	X

TABLE 3—NEGATIVE DECLARATIONS FOR THE 2006, 2009 AND 2014 RACT SIPS—Continued

CTG source category	Negative declaration CTG reference document	2006 RACT SIP	2009 RACT SIP	2014 RACT SIP
Synthetic Organic Chemical Manufacturing.	EPA–450/3–84–015—Control of VOC Emissions from Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry.	X	.....	X
Synthetic Organic Chemical Manufacturing.	EPA–450/4–91–031—Control of VOC Emissions from Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry.	X	.....	X
Wood Coating Factory Surface of Flat Wood Paneling.	EPA–450/2–78–032—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume VII: Factory Surface of Flat Wood Paneling.	X	.....	X
Wood Furniture Coating	EPA–453/R–96–007—Control of VOC Emissions from Wood Furniture Manufacturing Operations.	X	.....	X

[1] This item is not a CTG because EPA exempted perchloroethylene as a VOC for purposes of ozone SIPs. 61 FR 4588 (February 7, 1996) (codified at 40 CFR 51.100(s)(1)).

3. Negative Declaration for Major Non-CTG Sources of VOC or NO_X

The 2006, 2009 and 2014 RACT SIPs each included a negative declaration for major non-CTG sources of VOC and NO_X. EPA agrees that there are no major non-CTG sources of NO_X or VOCs in the south Sutter County nonattainment area.

4. Conclusion

We find that FRAQMD's 2006, 2009, and 2014 RACT SIPs including the negative declarations and the Rule 3.8 revisions, adequately demonstrate that they satisfy RACT for the 1997 and 2008 8-hour ozone NAAQS. Our TSDs have more information on our evaluation of the three RACT SIP submissions and Rule 3.8.

C. EPA Recommendations To Strengthen the RACT SIPs and the Rule

Our TSD for Rule 3.8 describes additional revisions that we recommend for the next time FRAQMD modifies the rule.

D. Public Comment and Final Action

As authorized in section 110(k)(3) of the Act, EPA is fully approving the submitted SIP revisions because we believe they fulfill all relevant requirements. We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same SIP revisions. If we receive adverse comments by August 7, 2015, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on September 8, 2015. This will incorporate these documents and rule into the federally enforceable SIP.

Please note that if EPA receives adverse comment on a specific provision of this SIP revision and if that provision may be severed from the remainder of the SIP revision, EPA may adopt as final those provisions of the SIP revision that are not the subject of an adverse comment.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the FRAQMD rule described in the amendments to 40 CFR 52 set forth below. EPA has made, and will continue to make, this document available electronically through *www.regulations.gov* and in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

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

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

In addition, the SIPs and the rule are not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as

specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 8, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

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

Dated: April 30, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(382)(ii)(B), (c)(457)(i)(A)(3), (c)(459) and (c)(460) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(382) * * *

(ii) * * *

(B) Feather River Air Quality Management District.

(*1*) 2006 Reasonably Available Control Technology (RACT) Analysis for State Implementation Plan (SIP) (''2006 RACT SIP'') as adopted on December 4, 2006.

* * * * *

(457) * * *

(i) * * *

(A) * * *

(*3*) Rule 3.8, ''Gasoline Dispensing Facilities,'' amended on June 2, 2014.

* * * * *

(459) The following plan revision was submitted on September 29, 2014, by the Governor's designee.

(i) [Reserved]

(ii) Additional Material.

(A) Feather River Air Quality Management District.

(*1*) Reasonably Available Control Technology Analysis and Negative Declarations (''2014 RACT SIP''), as adopted on August 4, 2014.

(460) New and amended regulations for the following AQMDs were submitted on November 5, 2014 by the Governor's designee.

(i) Incorporation by Reference.

(A) Feather River Air Quality Management District.

(*1*) Rule 3.8, ''Gasoline Dispensing Facilities,'' amended on June 2, 2014.

■ 3. Section 52.222 is amended by adding paragraph (a)(11) to read as follows:

§ 52.222 Negative declarations.

(a) * * *

(11) Feather River Air Quality Management District.

CTG source category	Negative declaration CTG reference document	2006 RACT SIP submitted 7/11/07	2009 RACT SIP submitted 10/27/09	2014 RACT SIP submitted 9/29/14
Aerospace	EPA–453/R–97–004—Control of VOC Emissions from Coating Operations at Aerospace Manufacturing and Rework.	X	.....	X
Automobile Coating; Metal Coil Container, & Closure; Paper & Fabric.	EPA–450/2–77–008—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks.	X	.....	X
Automobile and Light-Duty Truck Assembly Coatings.	EPA–453/R–08–006—Control Techniques Guidelines for Automobile and Light-Duty Assembly Coatings.	.....	X	X
Cutback Asphalt	EPA–450/2–77–037—Control of Volatile Organic Emissions from Use of Cutback Asphalt.	X	.....	X
Dry Cleaning	EPA–450/3–82–009—Control of Volatile Organic Compound Emissions from Large Petroleum Dry Cleaners.	X	.....	X
Flat Wood Paneling Coatings	EPA–453/R–06–004—Control Techniques Guidelines for Flat Wood Paneling Coatings.	.....	X	X
Fiberglass Boat Manufacturing Materials.	EPA–453/R–08–004—Control Techniques Guidelines for Fiberglass Boat Manufacturing Materials.	.....	X	X
Flexible Package Printing	EPA–453/R06–003—Control Techniques Guidelines for Flexible Package Printing.	.....	X	X
Gasoline Loading Terminal	EPA–450/2–77–026—Control of Hydrocarbons from Tank Truck Gasoline Loading Terminals.	X	.....	X
Gasoline Trucks	EPA–450/2–78–051—Control of Volatile Organic Compound Leaks from Gasoline Tank Trucks and Vapor Collection Systems.	X	.....	X
Gasoline Bulk Plants	EPA–450/2–77–035—Control of Volatile Organic Emissions from Gasoline Bulk Plants.	X	.....	X

CTG source category	Negative declaration CTG reference document	2006 RACT SIP submitted 7/11/07	2009 RACT SIP submitted 10/27/09	2014 RACT SIP submitted 9/29/14
Graphic Arts Rotogravure and Flexography.	EPA–450/2–78–033—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume VIII: Rotogravure and Flexography.	X	.....	X
Industrial Cleaning Solvents	EPA–453/R–06–001—Control Techniques Guidelines for Industrial Cleaning Solvents.	X	X	X
Large Appliance Coating	EPA–450/2–77–034—Control of Volatile Organic Emissions from Existing Stationary Sources, Volume V: Surface Coating of Large Appliances.	X	.....	X
Large Appliance Coating	EPA–453/R–07–004—Control Techniques for Large Appliance Coatings.	.....	X	X
Magnet Wire Coating	EPA–450/2–77–033—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume IV: Surface Coating of Insulation of Magnet Wire.	X	.....	X
Metal Can Coating; Metal Coil Coating.	EPA–450/2–77–008—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks.	X	.....	X
Metal Furniture	EPA–450/2–77–032—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume III: Surface Coating of Metal Furniture.	X	.....	X
Metal Furniture Coatings	EPA–453/R–07–005—Control Techniques Guidelines for Metal Furniture Coatings.	.....	X	X
Metal Parts and Products	EPA–450/2–78–015—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume VI: Surface Coating of Miscellaneous Parts and Products.	X	.....	X
Miscellaneous Industrial Adhesives	EPA–453/R–08–005—Control Techniques Guidelines for Miscellaneous Industrial Adhesives.	X	X	X
Miscellaneous Metal and Plastic Parts Coatings.	EPA–453/R–08–003—Control Techniques Guidelines for Miscellaneous Metal and Plastic Parts Coatings.	.....	X	X
Natural Gas/Gasoline	EPA–450/2–83–007—Control of VOC Equipment Leaks from Natural Gas/Gasoline Processing Plants.	X	.....	X
Offset Lithographic Printing and Letterpress Printing.	EPA–453/R–06–002—Control Techniques Guidelines for Offset Lithographic Printing and Letterpress Printing.	.....	X	X
Paper and Fabric Coating	EPA–450/2–77–008—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks.	X	.....	X
Paper, Film, and Foil Coatings	EPA–453/R–07–003—Control Techniques Guidelines for Paper, Film, and Foil Coatings.	.....	X	X
Petroleum Liquid Storage Tanks	EPA–450/2–77–036—Control of VOC Emissions from Storage of Petroleum Liquids in Fixed Roof Tanks.	X	.....	X
Petroleum Liquid Storage Tanks	EPA–450/2–78–047—Control of VOC Emissions from Petroleum Liquid Storage in External Floating Roof Tanks.	X	.....	X
Pharmaceutical Products	EPA–450/2–78–029—Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products.	X	.....	X
Resin Manufacturing	EPA–450/3–83–008—Control of VOC Emissions from Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.	X	.....	X
Resin Manufacturing	EPA–450/3–83–006—Control of VOC Fugitive Emissions from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.	X	.....	X
Refineries	EPA–450/2–77–025—Control of Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.	X	.....	X
Refineries	EPA–450/2–78–036—Control of VOC Leaks from Petroleum Refinery Equipment.	X	.....	X
Rubber Tire Manufacturing	EPA–450/2–78–030—Control of Volatile Organic Emissions from Manufacture of Pneumatic Rubber Tires.	X	.....	X
Ship Coatings	61 FR 44050 Shipbuilding and Ship Repair Operations (Surface Coating).	X	.....	X
Ship Coatings	EPA–453/R–94–032—Alternative Control Technology Document—Surface Coating Operations at Shipbuilding and Ship Repair Operations (Surface Coating).	.....	.....	X
Solvent Cleaning Degreasers	EPA–450/2–77–022—Control of Volatile Organic Emissions from Solvent Metal Cleaning.	X	.....	X
Synthetic Organic Chemical Manufacturing.	EPA–450/3–84–015—Control of VOC Emissions from Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry.	X	.....	X
Synthetic Organic Chemical Manufacturing.	EPA–450/4–91–031—Control of VOC Emissions from Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry.	X	.....	X
Wood Coating Factory Surface of Flat Wood Paneling.	EPA–450/2–78–032—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume VII: Factory Surface of Flat Wood Paneling.	X	.....	X

CTG source category	Negative declaration CTG reference document	2006 RACT SIP submitted 7/11/07	2009 RACT SIP submitted 10/27/09	2014 RACT SIP submitted 9/29/14
Wood Furniture Coating	EPA–453/R–96–007—Control of VOC Emissions from Wood Furniture Manufacturing Operations.	X	.....	X

[FR Doc. 2015–16627 Filed 7–7–15; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0037; FRL–9928–50–Region 9]

Revisions to the California State Implementation Plan, Butte County Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing a limited approval and limited disapproval of revisions to the Butte County Air Quality Management District (BCAQMD) portion of the California State Implementation Plan (SIP). These revisions concern volatile organic compound (VOC), oxides of nitrogen (NO_X) and particulate matter (PM) emissions from open burning. Under authority of the Clean Air Act (CAA or the Act), this action simultaneously approves a local rule that regulates these emission sources and directs BCAQMD to correct rule deficiencies.

DATES: This rule is effective on August 7, 2015.

ADDRESSES: The EPA has established docket number EPA–R09–OAR–2015–0037 for this action. Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps, multi-volume reports), and some may not be available in either location (*e.g.,* confidential business information (CBI)). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Kevin Gong, EPA Region IX, (415) 972–3073, *Gong.Kevin@epa.gov.*

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

Table of Contents

I. Proposed Action

On February 11, 2015, in 80 FR 7555, the EPA proposed a limited approval and limited disapproval of the following rule that was submitted for incorporation into the California SIP.

TABLE 1—SUBMITTED RULE

Local agency	Rule No.	Rule title	Amended	Submitted
BCAQMD	300	Open Burning Requirements, Prohibitions and Exemptions.	02/24/11	09/21/12

This rule supersedes the BCAQMD rules currently in the California SIP as listed below.

TABLE 2—RULES TO BE SUPERSEDED

Rule	Title	SIP approval date	FR citation
301	Prohibitions on Open Burning	February 3, 1987	52 FR 3226.
302	Exemptions to Rule 301	February 3, 1987	52 FR 3226.
303	Burn Permits	February 3, 1987	52 FR 3226.
304	Exemptions to Rule 303	February 3, 1987	52 FR 3226.
306	Information Furnished by Permit Applicant	February 3, 1987	52 FR 3226.
307	Ignition Hours	February 3, 1987	52 FR 3226.
308	Notice of Intent to Ignite	February 3, 1987	52 FR 3226.
309	Freedom from Debris and Moisture	February 3, 1987	52 FR 3226.
310	Arrangement of Agricultural and Wood Waste	February 3, 1987	52 FR 3226.
311	Drying Period	February 3, 1987	52 FR 3226.
312	Wind Direction	February 3, 1987	52 FR 3226.
313	Ignition Devices	February 3, 1987	52 FR 3226.
314	Burning of Vines or Bushes Treated with Herbicides.	February 3, 1987	52 FR 3226.
315	Rice Straw Burning	February 3, 1987	52 FR 3226.
316	Field Crop Ignition	February 3, 1987	52 FR 3226.
317	Field Crops Harvested Prior to September 10	February 3, 1987	52 FR 3226.

TABLE 2—RULES TO BE SUPERSEDED—Continued

Rule	Title	SIP approval date	FR citation
318	Restriction of Burning During Poor Air Quality Conditions.	February 3, 1987	52 FR 3226.
320	Certificate from Department of Fish and Game	February 3, 1987	52 FR 3226.
322	Special Permit	February 3, 1987	52 FR 3226.
323	Range Improvement Burning	February 3, 1987	52 FR 3226.
324	Burning at Disposal Sites	February 3, 1987	52 FR 3226.
325	Exemption to Rule 324	February 3, 1987	52 FR 3226.

We proposed a limited approval because we determined that Rule 300 improves the SIP and is largely consistent with the relevant CAA requirements. We simultaneously proposed a limited disapproval because some rule provisions conflict with section 110 and part D of the Act. These provisions include the following:

1. Allowing the burning of rubbish under variance approved by hearing board in paragraphs 5.53 and 6.5.

2. Air Pollution Control Officer discretion to waive drying time requirements in paragraph 8.2.4.

Our proposed action contains more information on the basis for this rulemaking and on our evaluation of the submittal.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received no comments.

III. EPA Action

No comments were submitted. Therefore, as authorized in sections 110(k)(3) and 301(a) of the Act, the EPA is finalizing a limited approval of the submitted rule. This action incorporates the submitted rule into the California SIP, including those provisions identified as deficient. As authorized under section 110(k)(3), EPA is simultaneously finalizing a limited disapproval of the rule. As a result, sanctions will be imposed unless the EPA approves subsequent SIP revisions that correct the rule deficiencies within 18 months of the effective date of this action. These sanctions will be imposed under section 179 of the Act according to 40 CFR 52.31. In addition, the EPA must promulgate a federal implementation plan (FIP) under section 110(c) unless we approve subsequent SIP revisions that correct the rule deficiencies within 24 months. Note that the submitted rule has been adopted by the BCAQMD, and the EPA's final limited disapproval does not prevent the local agency from enforcing it. The limited disapproval also does not prevent any portion of the rule from being incorporated by reference into the federally enforceable SIP as discussed in a July 9, 1992 EPA memo found at: *http://www.epa.gov/nsr/ttnnsr01/gen/pdf/memo-s.pdf.*

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the BCAQMD rules described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available electronically through *www.regulations.gov* and in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

V. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled ''Regulatory Planning and Review.''

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) 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. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This rule will not have a significant impact on a substantial number of small entities because SIP limited approvals/limited disapprovals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because this limited approval/limited disapproval action does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The Clean Air Act forbids the EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.,* v. *U.S. EPA,* 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

D. Unfunded Mandates Reform Act

Under sections 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, the EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, the EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires the EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

The EPA has determined that the limited approval/limited disapproval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal

governments, or to the private sector, result from this action.

E. Executive Order 13132, Federalism

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (Federalism) and 12875 (Enhancing the Intergovernmental Partnership). Executive Order 13132 requires the EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, the EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or the EPA consults with State and local officials early in the process of developing the proposed regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

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, as specified in Executive Order 13132, because it merely approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

F. Executive Order 13175, Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires the EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This final rule does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, 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. Thus, Executive Order 13175 does not apply to this rule.

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

The EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045, because it approves a State rule implementing a Federal standard.

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

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, the EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. This action does not require the public to perform activities conducive to the use of VCS.

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

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

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective on August 7, 2015.

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 8, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

Dated: May 18, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

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

PART 52—[AMENDED]

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(168)(i)(A)(*7*) and (c)(423)(i)(G)(*1*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(168) * * *

(i) * * *

(A) * * *

(*7*) Previously approved on February 3, 1987 in paragraph (c)(168)(i)(A)(*1*) of this section and now deleted with replacement in paragraph (c)(423)(i)(G)(*1*) by Butte County APCD, Rule 300, as amended on February 24, 2011, Rules 301, 302, 303, 304, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 322, 323, 324 and 325.

* * * * *

(423) * * *

(i) * * *

(G) Butte County Air Quality Management District.

(*1*) Rule 300, ''Open Burning Requirements, Prohibitions and Exemptions,'' amended on February 24, 2011.

* * * * *

[FR Doc. 2015–16715 Filed 7–7–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2015–0106 FRL–9926–49–Region 7]

Approval and Promulgation of Air Quality Implementation Plans; Nebraska; Update to Materials Incorporated by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; notice of administrative change.

SUMMARY: The Environmental Protection Agency (EPA) is updating the materials submitted by Nebraska that are incorporated by reference (IBR) into the state implementation plan (SIP). EPA is also notifying the public of the correction of certain typographical errors within the IBR table. The regulations affected by this update have been previously submitted by the state agency and approved by EPA. This update affects the SIP materials that are available for public inspection at the National Archives and Records Administration (NARA), and the Regional Office.

DATES: This rule is effective on July 8, 2015.

ADDRESSES: SIP materials which are incorporated by reference into 40 CFR part 52 are available for inspection at the following locations: Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219; or at *http://www.epa.gov/region07/air/rules/fedapprv.htm;* and the National Archives and Records Administration. For information on the availability of this material at NARA, call (202) 741–6030, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jan Simpson at (913) 551–7089, or by email at *simpson.jan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The SIP is a living document which the state revises as necessary to address the unique air pollution problems in the state. Therefore, EPA from time to time must take action on SIP revisions containing new and/or revised regulations to make them part of the SIP. On May 22, 1997 (62 FR 27968), EPA revised the procedures for incorporating by reference Federally-approved SIPs, as a result of consultations between EPA and the Office of Federal Register (OFR). The description of the revised SIP document, IBR procedures and ''Identification of plan'' format are discussed in further detail in the May 22, 1997, **Federal Register** document.

On February 12, 1999, EPA published a document in the **Federal Register** (64 FR 7091) beginning the new IBR procedure for Nebraska. On December 1, 2003, (68 FR 67045) and on July 30, 2009 (74 FR 37939), EPA published updates to the IBR material for Nebraska.

In this document, EPA is publishing an updated set of tables listing the regulatory (*i.e.,* IBR) materials in the Nebraska SIP taking into account the additions, deletions, and revisions to those materials previously submitted by the state agency and approved by EPA. We are removing the EPA Headquarters Library from paragraph (b)(3), as IBR materials are no longer available at this location. Table (e) revisions include:

- Adding text in the explanation column for (6)–(27).

II. EPA Action

In this action, EPA is doing the following:

A. Announcing the update to the IBR material as of December 31, 2014.

B. Revising the entry in § 52.1420(b) to reflect the update and corrections.

C. Revising certain entries in § 52.1420(e) as described above;

D. Correcting the date format in the ''State effective date'' or ''State submittal date'' and ''EPA approval date'' columns in § 52.1420(c), (d) and (e). Dates are numerical month/day/year without additional zeros;

E. Modifying the **Federal Register** citation in § 52.1420(c), (d) and (e) to reflect the beginning page of the preamble as opposed to the page number of the regulatory text.

EPA has determined that this rule falls under the ''good cause'' exemption in section 553(b)(3)(B) of the Administrative Procedures Act (APA) which, upon finding ''good cause,'' authorizes agencies to dispense with public participation and section 553(d)(3), which allows an agency to make a rule effective immediately (thereby avoiding the 30-day delayed effective date otherwise provided for in the APA). This rule simply codifies provisions which are already in effect as a matter of law in Federal and approved State programs. Under section 553 of the APA, an agency may find good cause where procedures are ''impractical, unnecessary, or contrary to the public interest.'' Public comment is ''unnecessary'' and ''contrary to the public interest'' since the codification only reflects existing law. Immediate notice in the CFR benefits the public by providing notice of the updated Nebraska SIP compilation.

Statutory and Executive Order Reviews

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Nebraska regulations described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions,

EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

EPA has also determined that the provisions of section 307(b)(1) of the CAA pertaining to petitions for judicial review are not applicable to this action. Prior EPA rulemaking actions for each individual component of the Nebraska SIP compilations previously afforded interested parties the opportunity to file a petition for judicial review in the United States Court of Appeals for the appropriate circuit within 60 days of such rulemaking action. Thus, EPA sees no need in this action to reopen the 60-day period for filing such petitions for judicial review for this ''Identification of plan'' reorganization update action for the State of Nebraska.

List of Subjects in 40 CFR Part 52

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

Dated: March 13, 2015.

Mark Hague,

Acting Regional Administrator, Region 7.

Editorial Note: This document was received for publication by the Office of the Federal Register on July 1, 2015.

For the reasons stated in the preamble, the EPA amends 40 CFR part 52 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart CC—Nebraska

■ 2. In § 52.1420, paragraphs (b), (c), (d) and (e) are revised to read as follows:

§ 52.1420 Identification of Plan.

* * * * *

(b) *Incorporation by reference.* (1) Material listed in paragraphs (c) and (d) of this section with an EPA approval date prior to December 31, 2014, was approved for incorporation by reference by the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Material is incorporated as it exists on the date of the approval, and notice of any change in the material will be published in the **Federal Register**. Entries in paragraphs (c) and (d) of this section with EPA approval dates after December 31, 2014, will be incorporated by reference in the next update to the SIP compilation.

(2) EPA Region 7 certifies that the rules/regulations provided by EPA in the SIP compilation at the addresses in paragraph (b)(3) of this section are an exact duplicate of the officially promulgated state rules/regulations which have been approved as part of the SIP as of December 31, 2014.

(3) Copies of the materials incorporated by reference may be inspected at the Environmental Protection Agency, Region 7, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; at the EPA, Air and Radiation Docket and Information Center, and the National Archives and Records Administration (NARA). If you wish to obtain material from the EPA Regional Office, please call (913) 551–7089. For information on the availability of this material at NARA, call (202) 741–6030, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(c) *EPA-approved regulations.*

EPA-APPROVED NEBRASKA REGULATIONS

Nebraska citation	Title	State effective date	EPA approval date	Explanation
STATE OF NEBRASKA				
Department of Environmental Quality				
Title 129—Nebraska Air Quality Regulations				
129–1	Definitions	4/1/12	8/4/14, 79 FR 45108	
129–2	Definition of Major Source	3/14/06	3/22/11, 76 FR 15852	
129–3	Region and Subregions: How Classified.	6/26/94	1/4/95, 60 FR 372	
129–4	Ambient Air Quality Standards	4/1/02, 7/10/02	7/8/03, 68 FR 40528	
129–5	Operating Permit—When Required.	11/20/02	9/5/03, 68 FR 52691	Section 001.02 is not SIP approved.
129–6	Emissions Reporting; When Required.	11/20/02	9/5/03, 68 FR 52691	
129–7	Operating Permits—Application	8/22/00	5/29/02, 67 FR 37325	
129–8	Operating Permit Content	8/22/00	5/29/02, 67 FR 37325	
129–9	General Operating Permits for Class I and II Sources.	6/26/94	1/4/95, 60 FR 372	
129–10	Operating Permits for Temporary Sources.	9/7/97	1/20/00, 65 FR 3130	
129–11	Operating Permits—Emergency; Defense.	6/26/94	1/4/95, 60 FR 372	
129–12	Operating Permit Renewal and Expiration.	5/29/95	2/9/96, 61 FR 4899	
129–13	Class I Operating Permit—EPA Review; Affected States Review; Class II Permit.	6/26/94	1/4/95, 60 FR 372	
129–14	Permits—Public Participation	2/6/08	3/22/11, 76 FR 15852	
129–15	Operating Permit Modification; Reopening for Cause.	2/6/08	3/22/11, 76 FR 15852	
129–16	Stack Heights; Good Engineering Practice (GEP).	12/15/98	5/29/02, 67 FR 37325	
129–17	Construction Permits—When Required.	4/1/12	8/4/14, 79 FR 45108	Approval does not include Nebraska's revisions to sections 001.02T and 013.04T pertaining to ethanol production facilities, which were not submitted by the State.
129–19	Prevention of Significant Deterioration of Air Quality.	4/1/12	8/4/14, 79 FR 45108	Provisions of the 2010 $PM_{2.5}$ PSD-Increments, SILs and SMCs rule (75 FR 64865, October 20, 2010) relating to SILs and SMCs that were affected by the January 22, 2013, U.S. Court of Appeals decision are not SIP approved.
129–20	Particulate Emissions; Limitations and Standards (Exceptions Due to Breakdowns or Scheduled Maintenance: See Chapter 35).	2/7/04	3/31/05, 70 FR 16426	
129–21	Controls for Transferring, Conveying, Railcar and Truck Loading at Rock Processing Operations in Cass County.	7/10/02	7/8/03, 68 FR 40528	
129–22	Incinerators; Emission Standards	9/7/97	1/20/00, 65 FR 3130	
129–24	Sulfur Compound Emissions; Existing Sources Emission Standards.	6/26/94	1/4/95, 60 FR 372	
129–25	Nitrogen Oxides (Calculated as Nitrogen Dioxide); Emissions Standards for Existing Stationary Sources.	9/7/97	1/20/00, 65 FR 3130	
129–30	Open Fires, Prohibited; Exceptions.	9/25/05	8/11/10, 75 FR 48582	
129–32	Dust; Duty to Prevent Escape of	6/26/94	1/4/95, 60 FR 372	
129–33	Compliance; Time Schedule for	6/26/94	1/4/95, 60 FR 372	
129–34	Emission Sources; Testing; Monitoring.	5/7/05	7/10/06, 71 FR 38776	

EPA-APPROVED NEBRASKA REGULATIONS—Continued

Nebraska citation	Title	State effective date	EPA approval date	Explanation
129–35	Compliance; Exceptions Due to Startup, Shutdown, or Malfunction.	9/7/97	1/20/00, 65 FR 3130	
129–36	Control Regulations; Circumvention, When Excepted.	6/26/94	1/4/95, 60 FR 372	
129–37	Compliance; Responsibility	6/26/94	1/4/95, 60 FR 372	
129–38	Emergency Episodes; Occurrence and Control, Contingency Plans.	6/26/94	1/4/95, 60 FR 372	
129–39	Visible Emissions from Diesel-powered Motor Vehicles.	6/26/94	1/4/95, 60 FR 372	
129–40	General Conformity	5/29/95	2/12/96, 61 FR 5297	
129–41	General Provisions	12/15/98	5/29/02, 67 FR 37325	
129–42	Permits-By-Rule	11/20/02, 4/8/03, 5/7/05.	7/10/06, 71 FR 38776	
129–43	Consolidated with Chapter 41	5/29/95	2/9/96, 61 FR 4899	
129–44	Consolidated with Chapter 41	5/29/95	2/9/96, 61 FR 4899	
Appendix I	Emergency Emission Reductions	6/26/94	1/4/95, 60 FR 372	
Appendix II	Hazardous Air Pollutants (HAPS)	5/7/05	7/10/06, 71 FR 38776	
Title 115—Rules of Practice and Procedure				
115–1	Definitions of Terms	8/8/93	1/4/95, 60 FR 372	
115–2	Filing and Correspondence	8/8/93	1/4/95, 60 FR 372	
115–3	Public Records Availability	8/8/93	1/4/95, 60 FR 372	
115–4	Public Records Confidentiality	8/8/93	1/4/95, 60 FR 372	
115–5	Public Hearings	8/8/93	1/4/95, 60 FR 372	
115–6	Voluntary Compliance	8/8/93	1/4/95, 60 FR 372	
115–7	Contested Cases	8/8/93	1/4/95, 60 FR 372	
115–8	Emergency Proceeding Hearings	8/8/93	1/4/95, 60 FR 372	
115–9	Declaratory Rulings	8/8/93	1/4/95, 60 FR 372	
115–10	Rulemaking	8/8/93	1/4/95, 60 FR 372	
115–11	Variances	8/8/93	1/4/95, 60 FR 372	
Lincoln-Lancaster County Air Pollution Control Program				
Article 1—Administration and Enforcement				
Section 1	Intent	5/16/95	2/14/96, 61 FR 56991	
Section 2	Unlawful Acts—Permits Required	5/16/95	2/14/96, 61 FR 5699	
Section 3	Violations—Hearings—Orders	5/16/95	2/14/96, 61 FR 5699	
Section 4	Appeal Procedure	5/16/95	2/14/96, 61 FR 5699	
Section 5	Variance	5/16/95	2/14/96, 61 FR 5699	
Section 7	Compliance—Actions to Enforce—Penalties for Non-Compliance.	5/16/95	2/14/96, 61 FR 5699	
Section 8	Procedure for Abatement	5/16/95	2/14/96, 61 FR 5699	
Section 9	Severability	5/16/95	2/14/96, 61 FR 5699	
Article 2—Regulations and Standards				
Section 1	Definitions	8/11/98	1/20/00, 65 FR 3130	
Section 2	Major Sources—Defined	8/11/98	1/20/00, 65 FR 3130	
Section 4	Ambient Air Quality Standards	5/16/95	2/14/96, 61 FR 5699	
Section 5	Operating Permits—When Required.	8/11/98	1/20/00, 65 FR 3130	
Section 6	Emissions Reporting—When Required.	8/11/98	1/20/00, 65 FR 3130	
Section 7	Operating Permit—Application	8/11/98	1/20/00, 65 FR 3130	
Section 8	Operating Permit—Content	8/11/98	1/20/00, 65 FR 3130	
Section 9	General Operating Permits for Class I and II Sources.	5/16/95	2/14/96, 61 FR 5699	
Section 10	Operating Permits for Temporary Services.	5/16/95	2/14/96, 61 FR 5699	
Section 11	Emergency Operating Permits—Defense.	5/16/95	2/14/96, 61 FR 5699	
Section 12	Operating Permit Renewal and Expiration.	5/16/95	2/14/96, 61 FR 5699	
Section 14	Permits—Public Participation	5/16/95	2/14/96, 61 FR 5699	
Section 15	Operating Permit Modifications—Reopening for Cause.	8/11/98	1/20/00, 65 FR 3130	
Section 16	Stack—Heights—Good Engineering Practice (GEP).	5/16/95	2/14/96, 61 FR 5699	

EPA-APPROVED NEBRASKA REGULATIONS—Continued

Nebraska citation	Title	State effective date	EPA approval date	Explanation
Section 17	Construction Permits—When Required.	8/11/98	1/20/00, 65 FR 3130	
Section 19	Prevention of Significant Deterioration of Air Quality.	5/16/95	2/14/96, 61 FR 5699	
Section 20	Particulate Emissions—Limitations and Standards.	3/31/97	1/20/00, 65 FR 3130	
Section 22	Incinerator Emissions	5/16/95	2/14/96, 61 FR 5699	
Section 24	Sulfur Compound Emissions—Existing Sources—Emission Standards.	5/16/95	2/14/96, 61 FR 5699	
Section 25	Nitrogen Oxides (Calculated as Nitrogen Dioxide)—Emissions Standards for Existing Stationary Sources.	5/16/95	2/14/96, 61 FR 5699	
Section 32	Dust—Duty to Prevent Escape of	3/31/97	1/20/00, 65 FR 3130	
Section 33	Compliance—Time Schedule for ..	5/16/95	2/14/96, 61 FR 5699	
Section 34	Emission Sources—Testing—Monitoring.	5/16/95	2/14/96, 61 FR 5699	
Section 35	Compliance—Exceptions Due to Startup Shutdown or Malfunction.	5/16/95	2/14/96, 61 FR 5699	
Section 36	Control Regulations—Circumvention—When Expected.	5/16/95	2/14/96, 61 FR 5699	
Section 37	Compliance—Responsibility of Owner/Operator Pending Review by Director.	5/16/95	2/14/96, 61 FR 5699	
Section 38	Emergency Episodes—Occurrence and Control—Contingency Plans.	5/16/95	2/14/96, 61 FR 5699	
Appendix I	Emergency Emission Reduction Regulations.	5/16/95	2/14/96, 61 FR 5699	
City of Omaha				
Chapter 41—Air Quality Control				
Article I—In General				
41–2	Adoption of State Regulations with Exceptions.	4/1/98	1/20/00, 65 FR 3130	
41–4	Enforcement—Generally	5/29/95	2/14/96, 61 FR 5699	
41–5	Same Health Department	5/29/95	2/14/96, 61 FR 5699	
41–6	Residential Exemptions	5/29/95	2/14/96, 61 FR 5699	
41–9	Penalties	5/29/95	2/14/96, 61 FR 5699	
41–10	Civil Enforcement	5/29/95	2/14/96, 61 FR 5699	
Article II—Permitting of Air Contaminant Sources				
41–23	Prerequisite to Approval	5/29/95	2/14/96, 61 FR 5699	
41–27	Signature Required; Guarantee ...	5/29/95	2/14/96, 61 FR 5699	
41–38	Funds	5/29/95	2/14/96, 61 FR 5699	
41–40	Fees—When Delinquent	5/29/95	2/14/96, 61 FR 5699	
Article IV—Waste Incinerators—Division 1. Generally				
41–60	Definitions	5/29/95	2/14/96, 61 FR 5699	
41–61	Violations	5/29/95	2/14/96, 61 FR 5699	
Article IV—Waste Incinerators—Division 2. Emissions				
41–70	New or Modified Facilities	5/29/95	2/14/96, 61 FR 5699	
41–71	Existing Facilities	5/29/95	2/14/96, 61 FR 5699	
41–72	Emission Testing	5/29/95	2/14/96, 61 FR 5699	
Article IV—Waste Incinerators—Division 3. Design				
41–80	New or Modified Waste Incinerators.	5/29/95	2/14/96, 61 FR 5699	
41–81	Existing Incinerators	5/29/95	2/14/96, 61 FR 5699	

(d) *EPA-approved state source-specific permits.*

EPA-APPROVED NEBRASKA SOURCE-SPECIFIC PERMITS

Name of source	Permit No.	State effective date	EPA approval date	Explanation
(1) Gould, Inc	677	11/9/83	1/31/85, 50 FR 4510	
(2) Asarco, Inc.	1520	6/6/96	3/20/97, 62 FR 13329	The EPA did not approve paragraph 19.
(3) Nebraska Public Power District, Gerald Gentleman Station.	CP07–0050	5/11/10	7/6/12, 78 FR 40140	EPA has only approved the elements of the permit pertaining to NO_X requirements.
(4) Omaha Public Power District, Nebraska City Station.	CP07–0049	2/26/09	7/6/12, 78 FR 40140	

(e) *EPA-approved nonregulatory provisions and quasi-regulatory measures.*

EPA-APPROVED NEBRASKA NONREGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
(1) Air Quality Implementation Plan.	Statewide	1/28/72	5/31/72, 37 FR 10842	
(2) Confirmation That the State Does Not Have Air Quality Control Standards Based on Attorney General's Disapproval.	Statewide	4/25/72	5/31/72, 37 FR 10842	
(3) Request for Two-Year Extension to Meet the Primary NO_X Standard.	Omaha	1/24/72	7/27/72, 37 FR 15080	
(4) Clarification of Section 11 of the State's Plan.	Statewide	2/16/72	7/27/72, 37 FR 15080	
(5) Letters Clarifying the Application of the State's Emergency Episode Rule.	Omaha	10/2/72	5/14/73, 38 FR 12696	
(6) Analysis of Ambient Air Quality in Standard Metropolitan Statistical Areas and Recommendations for Air Quality Maintenance Areas.	Omaha, Lincoln, Sioux City.	5/9/74	6/2/75, 40 FR 23746	[FRL 369–8].
(7) Amended State Law (LB1029) Giving the Department of Environmental Quality Authority to Require Monitoring of Emissions, Reporting of Emissions and Release of Emissions Data.	Statewide	2/10/76	6/23/76, 41 FR 25898	[FRL 564–5].
(8) Air Monitoring Plan	Statewide	6/19/81	10/6/81, 46 FR 49122	[A–7–FRL–1933–1].
(9) TSP Nonattainment Plan	Douglas and Cass Counties.	9/25/80 ..... 8/9/82	3/28/83, 48 FR 12715	[EPA Action NE 129; A–7–FRL 2302–8].
(10) Plan for Intergovernmental Consultation and Coordination and for Public Notification.	Statewide	8/9/82	7/5/83, 48 FR 30631	[EPA Action NE 1123; A–7–FRL 2353–7].
(11) Lead Plan	Statewide except Omaha	1/9/81, 8/5/81, 1/11/83.	11/29/83, 48 FR 53697.	[AD–FRL 2479–3; EPA Action NE 1122] The plan was approved except that portion pertaining to Omaha.
(12) Lead Nonattainment Plan	Omaha	7/24/84, 11/17/83, 8/1/84.	1/31/85, 50 FR 4510	[NE 1418; A–7–FRL–2768–3].
(13) CO Nonattainment Plan	Omaha	4/3/85	9/15/86, 51 FR 32640	[A–7–FRL–3065–7].
(14) CO Nonattainment Plan	Lincoln	4/3/85	9/19/86, 51 FR 33264	[A–7–FRL–3082–8].
(15) Revised Lead Nonattainment Plan.	Omaha	2/2/87	8/3/87, 52 FR 28694	[A–7–FRL–3238–2].

EPA-APPROVED NEBRASKA NONREGULATORY PROVISIONS—Continued

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
(16) Letter Pertaining to NO_X Rules and Analysis Which Certifies the Material Became Effective on February 20, 1991.	Statewide	3/8/91	7/2/91, 56 FR 30335	[FRL–3968–7] State submittal date is date of the letter.
(17) Small Business Assistance Program.	Statewide	11/12/92	8/30/93, 58 FR 45452	[NE–4–1–5861; FRL–4694–6].
(18) Class II Operating Permit Program Including Letter Committing to Submit Information to RACT/BACT/LAER Clearinghouse, Letter Regarding Availability of State Operating Permits to the EPA and Specified Emissions Limits in Permits, and Letter Regarding the Increase in New Source Review Thresholds.	Statewide	2/16/94	1/4/95, 60 FR 372	[NE–6–1–6445a; FRL–5115–3].
(19) Letter from City of Omaha Regarding Authority to Implement Section 112(l) and Letter from the State Regarding Rule Omissions and PSD Program Implementation.	Omaha, Lincoln	9/13/95, 11/9/95.	2/14/96, 61 FR 5725	[NE–9–1–7220b, FRL–5409–8]. State submittal dates are dates of letters.
(20) Lincoln Municipal Code, Chapter 8.06.140 and 8.06.145.	City of Lincoln	2/5/99	1/20/00, 65 FR 3130	[NE 071–1071a, FRL–6521–6].
(21) Lancaster Co. Resolution 5069, Sections 12 and 13.	Lancaster County	2/5/99	1/20/00, 65 FR 3130	[NE 071–1071a, FRL–6521–6].
(22) Nebraska Lead Maintenance SIP.	Omaha	1/18/01	4/20/01, 66 FR 20196	[Region 7 Tracking No. 0124–1124(b), FRL–6968–5].
(23) CAA 110(1)(2)(D)(i) SIP—Interstate Transport.	Statewide	5/18/07	12/17/07, 72 FR 71245.	[EPA–R07–OAR–2007–1128, FRL–8507–1].
(24) Section 110(a)(2) Infrastructure Requirements for the 1997 8-Hour Ozone NAAQS.	Statewide	12/7/07	7/8/11, 76 FR 40258	[EPA–R07–OAR–2011–0310, FRL–9434–4]. This action addresses the following CAA elements as applicable: 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M).
(25) Regional haze plan for the first implementation period.	Statewide	6/30/11	7/6/12, 78 FR 40150	[EPA–R07–OAR–2012–0158; FRL–9689–2]. The plan was approved except for that portion pertaining to SO_2 BART for Nebraska Public Power District, Gerald Gentleman Units 1 and 2, and the portion of the long- term strategy addressing the SO_2 BART measures for these Units.
(26) Section 110(a)(2) Infrastructure Requirements for the 2008 Pb NAAQS.	Statewide	10/18/11	10/21/14, 79 FR 62832.	[EPA–R07–OAR–2014–0685; FRL–9918–13–Region 7]. This action addresses the following CAA elements: 110(a)(2)(A), (B), (C), (D), (E), (F), (G), (H), (J), (K), (L), and (M).
(27) Section 128 Declaration: Nebraska Department of Environmental Quality Representation and Conflicts of Interest Provisions, Section 49–1493(13) of the NE Political Accountability and Disclosure Act and Chapter 2 of Title 4, NE Accountability and Disclosure Commission.	Statewide	8/22/13	10/21/14, 79 FR 62832.	[EPA–R07–OAR–2014–0685; FRL–9918–13–Region 7]. This declaration is contained within Nebraska's 2010 Sulfur Dioxide NAAQS Infrastructure SIP submission concerning Section 110(a)(2)(E) of the CAA.

[FR Doc. 2015–16632 Filed 7–7–15; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0346; FRL–9927–25]

Prohexadione Calcium; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of prohexadione calcium in or on strawberry and watercress. Inter-Regional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 8, 2015. Objections and requests for hearings must be received on or before September 8, 2015, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0346, 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.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2014–0346 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 8, 2015. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2014–0346, 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 CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 1, 2014 (79 FR 44729) (FRL–9911–67), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8264) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08450. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide prohexadione calcium, calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate, in or on strawberry at 0.3 parts per million (ppm) and watercress at 2.0 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has amended the tolerance for watercress from what the petitioner requested. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a

reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for prohexadione calcium including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with prohexadione calcium follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The most sensitive effect in the prohexadione toxicity database by oral exposure is kidney toxicity in dogs both for subchronic and chronic durations. Minor hematological changes (decreased white blood cell counts in males), and fore-stomach hyperplasia were seen only at very high doses in rodents. No dermal toxicity was observed up to the limit dose of 1,000 milligram/kilogram/day (mg/kg/day). There was no evidence of neurotoxicity in either of the neurotoxicity screening batteries up to or exceeding the limit dose.

In rats and rabbits, no increased quantitative or qualitative pre- or postnatal susceptibility was observed. In rats, no maternal or developmental toxicity was observed up to the limit dose (1,000 mg/kg/day). Three developmental studies in rabbits are available in the toxicological database for prohexadione calcium. In one study, late abortions occurred during GD 24–29 at 200 mg/kg/day, with increased mortality in maternal animals (GD 15–24) also noted at this dose. In another rabbit developmental study, two premature deliveries (on GD 24 and 26) were noted at the highest dose tested (350 mg/kg/day) with no developmental effects observed. No maternal or developmental effects were seen in a third rabbit developmental study up to 150 mg/kg/day. In the 2-generation reproductive toxicity study with rats, parental toxicity (minimal mortality) occurred at a dose well below the dose that caused decreases in offspring body weight (3, 850 mg/kg/day).

Prohexadione calcium is classified as not likely to be carcinogenic to humans based on lack of evidence of carcinogenicity in rats and mice.

Specific information on the studies received and the nature of the adverse effects caused by prohexadione calcium as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document Prohexadione Calcium. Section 3 Registration for Use on Strawberry and Watercress. Human Health Risk Assessment on pages 11–14 in docket ID number EPA–HQ–OPP–2014–0346.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors (U/SF) are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for prohexadione calcium used for human risk assessment is shown in the Table of this unit. Since the assessment in 2011, (November 18, 2011) (76 FR 71459) (FRL–9326–4), the Agency has reevaluated the endpoints and determined that the previously identified dermal endpoints are no longer appropriate.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PROHEXADIONE CALCIUM FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations).	No endpoint attributable to a single dose and appropriate for the U.S. general population was seen in the prohexadione calcium toxicological database; therefore, an acute dietary point of departure for the general U.S. population was not established.		
Chronic dietary (All populations).	NOAEL = 20 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = cPAD = 0.20 mg/kg/day.	Chronic toxicity—Dog. LOAEL = 200 mg/kg/day based on histopathological changes in the kidneys (dilated basophilic tubules) and increased urinary volume and sodium concentration.
Incidental oral short-term (1 to 30 days) and intermediate-term. (1 to 6 months)	NOAEL= 80 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-Day oral toxicity—Dog. LOAEL = 400 mg/kg/day based on moderate cortical areas of dilated basophilic tubules in the kidneys and decreased potassium levels.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PROHEXADIONE CALCIUM FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).	Short-term and intermediate-term dermal endpoints were not selected since there were no adverse dermal or systemic effects observed in the 28-day dermal study in rats. There was also no evidence of increased quantitative or qualitative pre- or postnatal sensitivity in the prohexadione calcium database. Therefore no concern for any duration of dermal exposure and no dermal endpoints are required		
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL= 40 mg/kg/day ..... UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x ..... Inhalation assumed equivalent to oral.	LOC for MOE = 100	Prenatal Developmental Toxicity—Rabbit. Maternal LOAEL = 200 mg/kg/day based on increased mortality, and abortions.
Cancer (Oral, dermal, inhalation).	''Not likely to be carcinogenic to humans'' based upon lack of evidence of carcinogenicity in rats and mice. No evidence of carcinogenic potential, therefore, cancer risk assessment is not required.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to prohexadione calcium, EPA considered exposure under the petitioned-for tolerances as well as all existing prohexadione calcium tolerances in 40 CFR 180.547. EPA assessed dietary exposures from prohexadione calcium in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for prohexadione calcium; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA Nationwide Health and Nutrition Examination Survey, What We Eat In America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, the chronic dietary analysis assumed Dietary Exposure Evaluation Model (DEEM) (ver. 7.81) default processing factors, 100 percent crop treated (PCT) and tolerance-level residues for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that prohexadione calcium does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for prohexadione calcium. Tolerance-level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for prohexadione calcium in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of prohexadione calcium. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Tier 1 Rice Model and Screening Concentration in Ground Water (SCI–GROW) model, the estimated drinking water concentrations (EDWCs) of prohexadione calcium for chronic exposures for non-cancer assessments are estimated to be 170 parts per billion (ppb) for surface water and 0.137 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 170 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Prohexadione calcium is currently registered for the following uses that could result in residential exposures: Residential lawns, ornamentals, athletic fields, parks, and golf courses. EPA assessed residential exposure using the following assumptions: Short-term residential handler exposures may result from adults applying prohexadione calcium to residential lawns and ornamentals. The Agency assessed inhalation exposures for adult handlers applying manually-pressurized handwand applications to bedding plants. Short-term exposure is also possible for post-application incidental oral exposures of children 1–<2 years old. The Agency assessed hand-to-mouth exposures and incidental soil ingestions from applications to turf for children. Intermediate- and long-term exposures are not expected since there are no registered or proposed uses of prohexadione calcium that result in intermediate- or long-term residential exposures. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/science/residential-exposure-sop.html.*

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

EPA has not found prohexadione calcium to share a common mechanism

of toxicity with any other substances, and prohexadione calcium does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that prohexadione calcium does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data are available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There are no residual uncertainties for prenatal and postnatal toxicity and there is no evidence of increased qualitative or quantitative susceptibility of any kind for fetuses and offspring in both rats and rabbits.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for prohexadione calcium is complete.

ii. There is no indication that prohexadione calcium is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that prohexadione calcium results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT, tolerance-level residues, and DEEM (Ver 7.81) default processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to prohexadione calcium in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by prohexadione calcium.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, prohexadione calcium is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to prohexadione calcium from food and water will utilize 19% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of prohexadione calcium is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Prohexadione calcium is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to prohexadione calcium.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 14,000 for adults and 2,100 for children. Because EPA's level of concern for prohexadione calcium is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, prohexadione calcium is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for prohexadione calcium.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, prohexadione calcium is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to prohexadione calcium residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (BASF Analytical Method D9601 and 564/0) is available to enforce the tolerance expression for residues of prohexadione calcium in watercress and strawberry samples.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural

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

The Codex has not established a MRL for prohexadione calcium in/on strawberries and watercress.

C. Response to Comments

One comment was received in response to the notice of filing of IR–4's petition. The commenter stated this use should be denied due to toxicity to bees and that all use of chemicals should be stopped. The comment primarily appears directed to the registration of the pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), but to the extent the comment is directed at the present tolerance action, the Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework. As to bees the EPA will consider impacts to the environment and non-target species under the authority of FIFRA.

D. Revisions to Petitioned-For Tolerances

The tolerance on watercress has been revised from what was proposed in the initial petition. EPA is increasing the proposed tolerance for residues in/on watercress from 2 ppm to 4.0 ppm based on the available watercress field trial data and the OECD tolerance calculation procedure.

V. Conclusion

Therefore, tolerances are established for residues of prohexadione calcium, calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate, in or on strawberry at 0.30 ppm and watercress at 4.0 ppm.

VI. Statutory and Executive Order Reviews

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

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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 180

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

Dated: June 22, 2015.

Daniel J. Rosenblatt,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.547, add alphabetically the following commodities to the table in paragraph (a) to read as follows:

§ 180.547 Prohexadione calcium; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Strawberry	0.30
Watercress	4.0

* * * * *

[FR Doc. 2015–16419 Filed 7–7–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0284; FRL–9927–85]

S-metolachlor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of S-metolachlor in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 8, 2015. Objections and requests for hearings must be received on or before September 8, 2015, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0284, 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.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2014–0284 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 8, 2015. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2014–0284, 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 CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 17, 2014 (79 FR 75107) (FRL–9918–90), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8248) by IR–4 500 College Road East, Suite 201 W, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of S-metolachlor in or on the raw agricultural commodity lettuce at 1.5 parts per million (ppm); vegetable, cucurbit group 9 at 0.50 ppm; vegetable, fruiting, group 8–10, except tabasco pepper at 0.10 ppm; low growing berry subgroup 13–07G except cranberry at 0.40 ppm; and sunflower subgroup 20B at 0.50 ppm and the concurrent deletion of the existing tolerances for okra; vegetable, fruiting, group 8 except tabasco pepper; cucumber; melon subgroup 9A; pumpkin; squash, winter; and sunflower, seed. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which some of the tolerances are being established. The reason for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure

of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for S-metolachlor including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with S-metolachlor follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The existing toxicological database is primarily comprised of studies conducted with metolachlor. However, bridging studies indicate that the metolachlor toxicology database can be used to assess toxicity for S-metolachlor. In subchronic (metolachlor and S-metolachlor) and chronic (metolachlor) toxicity studies in dogs and rats decreased body weight and body weight (bw) gain were the most commonly observed effects. No systemic toxicity was observed in rabbits when metolachlor was administered dermally. There was no evidence of neurotoxic effects in the available toxicity studies, and there is no evidence of Immunotoxicity in the submitted mouse Immunotoxicity study.

Prenatal developmental studies in the rat and rabbit with both metolachlor and S-metolachlor revealed no evidence of a qualitative or quantitative susceptibility in fetal animals. A 2-generation reproduction study with metolachlor in rats showed no evidence of parental or reproductive toxicity. There are no residual uncertainties with regard to pre- and/or postnatal toxicity.

Metolachlor has been evaluated for carcinogenic effects in the mouse and the rat. Metolachlor did not cause an increase in tumors of any kind in mice. In rats, metolachlor caused an increase in benign liver tumors in rats, but this increase was seen only at the highest dose tested and was statistically significant compared to controls only in females. There was no evidence of mutagenic or cytogenetic effects *in vivo* or *in vitro.* Based on this evidence, EPA has concluded that metolachlor does not have a common mechanism of carcinogenicity with acetochlor and alachlor, compounds that are structurally similar to metolachlor. Metolachlor has been classified as a Group C, possible human carcinogen, based on liver tumors in rats at the highest dose tested (HDT).

Taking into account the qualitatively weak evidence on carcinogenic effects and the fact that the increase in benign tumors in female rats occurs at a dose 1,500 times the chronic reference dose (cRfD), EPA has concluded that the cRfD is protective of any potential cancer effect.

Specific information on the studies received and the nature of the adverse effects caused by S-metolachlor as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document ''S-metolachlor—Risk Assessment for Establishment of Tolerances for New Uses on Lettuce, Low Growing Berry Subgroup 13–07G, except Cranberry; Vegetable, Cucurbit, Group 9; Sunflower subgroup 20B; Vegetable, Fruiting, Group 8–10; except Tabasco Pepper and Okra'' on pp. 40 in docket ID number EPA–HQ–OPP–2014–0284.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for S-metolachlor used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR S-METOLACHLOR FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	NOAEL = 300 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x.	Acute RfD = 3.0 mg/kg/day. aPAD = 3.0 mg/kg/day	Developmental Toxicity Study—Rat (metolachlor). LOAEL = 1,000 mg/kg/day based increased incidence of death, clinical signs (clonic and/or tonic convulsions, excessive salivation, urine-stained abdominal fur and/or excessive lacrimation), and decreased body weight gain.
Chronic dietary (All populations)	NOAEL= 9.7 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x.	Chronic RfD = 0.097 mg/kg/day. cPAD = 0.097 mg/kg/day.	One Year Chronic Toxicity—Dog (metolachlor). LOAEL = 33 mg/kg/day based decreased body weight gain in females.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR S-METOLACHLOR FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Incidental oral short-term (1 to 30 days)	NOAEL= 50 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x.	LOC for MOE = 100	Developmental Toxicity Study—Rat (S-metolachlor). LOAEL = 500 mg/kg/day based on increased incidence of clinical signs, decreased body weight/body weight gain, food consumption and food efficiency seen in maternal animals.
Inhalation short-term (1 to 30 days)	Inhalation (or oral) study NOAEL= 50 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 10x UF_{DB}.	LOC for MOE = 1,000	Developmental Toxicity Study—Rat (S-metolachlor). LOAEL = 500 mg/kg/day based on increased incidence of clinical signs, decreased body weight/body weight gain, food consumption and food efficiency seen at the LOAEL in maternal animals.
Cancer (all routes)	Metolachlor has been classified as a Group C carcinogen with risk quantitated using a non-linear RfD approach.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. Mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to S-metolachlor, EPA considered exposure under the petitioned-for tolerances as well as all existing S-metolachlor tolerances in 40 CFR 180.368. EPA assessed dietary exposures from S-metolachlor in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for S-metolachlor. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey/What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA assumed tolerance level residues and 100 PCT.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to S-metolachlor. Therefore, a separate quantitative cancer exposure assessment is unnecessary since the chronic dietary risk estimate will be protective of potential cancer risk.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for S-metolachlor. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for S-metolachlor in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of S-metolachlor. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

The Agency assessed parent metolachlor, and the metabolites CGA–51202 (metolachlor-OA), CGA–40172, and CGA–50720 together in the drinking water assessment using a total toxic residues (TTR) approach where half-lives were recalculated to collectively account for the parent and the combined residues of concern.

Based on the Surface Water Concentration Calculator (SWCC), the Pesticide Root Zone Model Ground Water (PRZM GW), and the Screening Concentration in Ground Water (SCI–GROW), the estimated drinking water concentrations (EDWCs) of S-metolachlor and its metabolites for acute exposures are estimated to be 371 parts per billion (ppb) for surface water and 1,060 ppb for ground water, and for chronic exposures are estimated to be 43.70 ppb for surface water and 14.3 ppb in ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 1,060 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 43.70 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticide, and flea and tick control on pets).

S-metolachlor is currently registered for the following uses that could result in residential exposures: On commercial (sod farm) and residential warm-season turf grasses and other non-crop land including golf courses, sports fields, and ornamental gardens. EPA assessed residential exposure using the following assumptions: For residential handlers, short-term inhalation exposure is

expected. The following scenarios were evaluated:

- Mixing/loading/applying gardens/trees with manually-pressurized hand wand, hose-end sprayer, backpack, and sprinkler can equipment.
- Mixing/loading/applying lawns/turf with manually-pressurized hand wand, hose-end sprayer, backpack, and sprinkler can equipment.

For residential post-application, there is the potential for short-term incidental oral exposure for individuals exposed as a result of being in an environment that has been previously treated with S-metolachlor. The quantitative exposure/risk assessment for residential post-application exposures is based on the following scenario:

- Hand-to-mouth incidental oral exposure of children 1–2 years old playing on turf treated with S-metolachlor.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/science/residential-exposure-sop.html.*

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

EPA has not found S-metolachlor to share a common mechanism of toxicity with any other substances, and S-metolachlor does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that S-metolachlor does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10×) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10×, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased quantitative or qualitative fetal susceptibility in the prenatal developmental studies in rats and rabbits or in the reproductive toxicity study in rats, with either metolachlor or S-metolachlor. In general, significant developmental toxicity was not seen in rats or rabbits with either compound. The only effects observed in fetal animals were in the rat prenatal developmental study and included slightly decreased number of implantations per dam, decreased number of live fetuses/dam, increased number of resorptions/dam and significant decrease in mean fetal bw. These effects occurred at maternally toxic doses (1,000 milligram/kilogram/day (mg/kg/day)).

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1× for all scenarios except inhalation. For inhalation scenarios a 10× database uncertainty factor (UF) still applies. This decision is based on the following findings:

i. The toxicology database for metolachlor and S-metolachlor is complete, with the exception of a required subchronic inhalation study for metolachlor. As noted above, a 10× data base UF will be applied only for assessing risk for inhalation exposure scenarios.

ii. There is no indication that S-metolachlor is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that S-metolachlor results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to S-metolachlor in drinking water. EPA used similarly conservative assumptions to assess post-application incidental oral exposure of children 1<2 years old. These assessments will not underestimate the exposure and risks posed by S-metolachlor.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to S-metolachlor will occupy 6.1% of the aPAD for all infants (less than 1 year old), the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to S-metolachlor from food and water will utilize 6.8% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of S-metolachlor is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

S-metolachlor is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to S-metolachlor. Potential short-term residential risk scenarios anticipated include adult inhalation handler exposure to turf via backpack sprayer and post-application incidental oral exposure of children playing on treated lawns.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 10,400 for adults and 1,100 for children 1–2 years old. Because EPA's levels of concern for S-metolachlor is a

MOE of 1,000 or below for inhalation scenarios (adults) and 100 or below for incidental oral scenarios (children 1–2 years old), these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, S-metolachlor is not registered for any use patterns that would result in intermediate-term residential exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for S-metolachlor.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A, the chronic dietary risk assessment is protective of any potential cancer effects. Based on the results of that assessment, EPA concludes that S-metolachlor is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to S-metolachlor residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methodology is available for enforcing the established and recommended tolerances. PAM Vol. II, Pesticide Regulation Section 180.368, lists a gas chromatography with nitrogen-phosphorus detector (GC/NPD) method (Method I) for determining residues in/on plant commodities and a gas chromatography with mass selective detector (GC/MSD) method (Method II) for determining residues in livestock commodities. These methods determine residues of metolachlor and its metabolites as either CGA–37913 or CGA–49751 following acid hydrolysis. Adequate data are also available on the recovery of metolachlor through FDA's Multiresidue Method Testing Protocols which indicate that metolachlor is completely recovered through Method 302.

B. International Residue Limits

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

The Codex has not established a MRL for S-metolachlor.

C. Revisions to Petitioned-For Tolerances

The tolerance being established for the sunflower subgroup 20B is 1.0 ppm, not 0.50 ppm as proposed. This is due to the Agency using the Organization for Economic Cooperation and Development (OECD) Tolerance Calculation procedures, which determined that a tolerance of 1.0 ppm is appropriate based on entry of the 4 field trials for pre-emergence application.

V. Conclusion

Therefore, tolerances are established for residues of S-metolachlor in or on lettuce at 1.5 ppm; the low growing berry subgroup 13–07G, except cranberry at 0.40 ppm; the sunflower subgroup 20B at 1.0 ppm; the vegetable, cucurbit group 9 at 0.50 ppm; and the vegetable, fruiting, group 8–10, except tabasco pepper at 0.10 ppm. Additionally, due to the establishment of the tolerances listed above, the existing tolerances for vegetable, fruiting, group 8, except tabasco pepper; cucumber; melon subgroup 9A; okra; pumpkin; squash, winter; and sunflower, seed are removed as they are unnecessary.

VI. Statutory and Executive Order Reviews

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

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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 180

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

Dated: June 26, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.368:

■ a. Remove the entries ''Cucumber,'' ''Melon subgroup 9A,'' ''Okra,'' ''Pumpkin,'' ''Squash, winter,'' ''Sunflower, seed,'' and ''Vegetable, fruiting, group 8, except tabasco pepper,'' in paragraph (a)(2).

■ b. Add alphabetically the following commodities to the table in paragraph (a)(2).

The amendments read as follows:

§ 180.368 Metolachlor; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
* * * * *	
Lettuce	1.5
Low growing berry subgroup 13–07G, except cranberry	0.40
* * * * *	
Sunflower subgroup 20B	1.0
* * * * *	
Vegetable, cucurbit group 9	0.50
* * * * *	
Vegetable, fruiting, group 8–10, except tabasco pepper	0.10
* * * * *	

* * * * *

[FR Doc. 2015–16523 Filed 7–7–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 141222999–5561–02]

RIN 0648–BE71

International Fisheries; Pacific Tuna Fisheries; 2015 and 2016 Commercial Fishing Restrictions for Pacific Bluefin Tuna in the Eastern Pacific Ocean

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

ACTION: Final rule.

SUMMARY: The National Marine Fisheries Service (NMFS) is issuing regulations under the Tuna Conventions Act to implement Resolution C–14–06 of the Inter-American Tropical Tuna Commission (IATTC or the Commission) by establishing limits on U.S. commercial catch of Pacific bluefin tuna from waters of the IATTC Convention Area for 2015 and 2016. This action is necessary for the United States to satisfy its obligations as a member of the IATTC.

DATES: The final rule is effective July 9, 2015.

ADDRESSES: Copies of the Regulatory Impact Review (RIR), Environmental Assessment, and other supporting documents are available via the Federal eRulemaking Portal: *http://www.regulations.gov,* docket NOAA–NMFS–2014–0151, or contact with the Regional Administrator, William W. Stelle, Jr., NMFS West Coast Region, 7600 Sand Point Way NE., Bldg 1, Seattle, WA 98115–0070, or *RegionalAdministrator.WCRHMS@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Celia Barroso, NMFS, *Celia.Barroso@noaa.gov,* 562–432–1850.

SUPPLEMENTARY INFORMATION:

Background

On March 9, 2015, NMFS published a proposed rule in the **Federal Register** (80 FR 12375) to revise regulations at 50 CFR part 300, subpart C, to implement Resolution C–14–06, ''Measures for the Conservation and Management of Bluefin Tuna in the Eastern Pacific Ocean, 2015–2016.'' This resolution was adopted by the IATTC at its 88th meeting in October 2014. The public comment period was open until April 8, 2015, and NMFS accepted public comment at a hearing held at the NMFS West Coast Region Long Beach office on March 26, 2015. Additionally, NMFS solicited public comment on the proposed trip limits, which are a new management tool in U.S. West Coast management of fisheries for Pacific bluefin tuna. The proposed trip limits were based on a recommendation from the Pacific Fishery Management Council (Council) at its November 2014 meeting.

The final rule is implemented under the authority of the Tuna Conventions Act (16 U.S.C. 951 *et seq.*), which directs the Secretary of Commerce, after approval by the Secretary of State, to promulgate regulations as may be necessary to implement resolutions adopted by the IATTC. This authority has been delegated to NMFS.

The proposed rule contains additional background information, including information on the IATTC, the international obligations of the United States as an IATTC member, and the need for regulations. Additional information on changes since the proposed rule is included below.

New Regulations

This final rule establishes catch limits for U.S. commercial vessels that catch Pacific bluefin tuna in the Convention Area (defined as the waters of the eastern Pacific Ocean (EPO)) for 2015 and 2016. Since 1998, conservation resolutions adopted by the IATTC have further defined the Convention Area as the area bounded by the coast of the Americas, the 50° N. and 50° S. parallels, and the 150° W. meridian. In 2015, the catch limit for the entire U.S. fleet is 425 metric tons (mt) with an initial trip limit [1] of 25 mt per vessel. When NMFS anticipates that the total catch for the fleet has reached 375 mt, NMFS will impose a 2-mt trip limit for each vessel that will be in effect until the total catch for 2015 reaches 425 mt. For calendar year 2016, NMFS will announce the catch limit in a **Federal Register** notice; NMFS will calculate the 2016 catch limit to ensure compliance with Resolution C–14–06 (*i.e.,* not to exceed 425 mt in either year and if catch exceeds 300 mt in 2015, then catch will be limited to 200 mt in 2016). The 2016 catch limit will be calculated as the remainder from the 2015 catch limit (*i.e.,* how much of 425 mt was not

[1] This rule defines ''trip limit'' as the total allowable amount of a species by weight of fish that may be retained on board, transshipped, or landed during a single fishing trip.

caught) added to 175 mt, except as follows: (1) If 175 mt or less is caught in 2015, then the 2016 catch limit is 425 mt; (2) if greater than 300 mt and up to 400 mt are caught in 2015, then the catch limit in 2016 will be 200 mt; or (3) if greater than 425 mt is caught in 2015, then the catch limit in 2016 will be further reduced by the amount in excess of 425 mt (*i.e.,* the remainder of the 600 mt limit for 2015–2016). The fishery in 2016 will also be subject to an initial 25-mt trip limit until catch is within 50 mt of the 2016 catch limit, after which a 2-mt trip limit will be imposed.

When NMFS determines that the catch limit is expected to be reached in 2015 or 2016 (based on landings receipts, data submitted in logbooks, and other available fishery information), NMFS will prohibit commercial fishing for, or retention of, Pacific bluefin tuna for the remainder of the calendar year. NMFS will publish a notice in the **Federal Register** announcing that the targeting, retaining, transshipping or landing for Pacific bluefin tuna will be prohibited on a specified effective date through the end of that calendar year. Upon that effective date, a commercial fishing vessel of the United States may not be used to target, retain on board, transship, or land Pacific bluefin tuna captured in the Convention Area during the period specified in the announcement, with the exception that any Pacific bluefin tuna already on board a fishing vessel on the effective date may be retained on board, transshipped, and/or landed, to the extent authorized by applicable laws and regulations, provided that they are landed within 14 days after the effective date.

Catch Monitoring, Catch Limit Announcements

NMFS will provide updates on Pacific bluefin tuna catches in the Convention Area to the public via the IATTC listserv and the West Coast Region Web site: *http://www.westcoast.fisheries.noaa.gov/fisheries/migratory_species/bluefin_tuna_harvest_status.html.* Additionally, NMFS will report preliminary estimates of Pacific bluefin tuna catch between monthly intervals if and when commercial catches approach the limits to help participants in the U.S. commercial fishery plan for the possibility of catch limits being reached. NMFS will notify industry when catch approaches 250 mt in 2015.

In 2015, NMFS will publish up to two **Federal Register** notices after the final rule is issued, imposing inseason management measures. First, NMFS will publish a notice when the commercial 2-mt trip limit is imposed (*i.e.,* catch is expected to reach 375 mt). Second, NMFS will publish a notice closing the entire commercial fishery when NMFS determines that the catch limit is expected to be met.

In 2016, NMFS will publish up to three notices in the **Federal Register**. The first notice will announce the 2016 catch limit. A second notice will announce the 2-mt trip limit, when NMFS determines that the commercial catch is expected to be within 50 mt of the catch limit. NMFS will publish a third notice in the **Federal Register** when NMFS determines that the catch limit is expected to be reached.

Public Comments and Responses

NMFS received eight written public comments and additional comments from attendees to a public hearing held on March 26, 2015, at the NMFS West Coast Region Long Beach office. Comments received were in regard to more than one aspect of the rule and some comments were very similar; therefore, NMFS is responding to the common themes/topics. The responses are summarized below. NMFS did not receive any comments objecting to the 2-mt trip limit when catch is within 50 mt of the catch limit in either 2015 or 2016. One commenter generally supported restrictions on commercial fishing and did not express support or objections to specific measures of the proposed rule.

Comments that were beyond the scope of this rulemaking are not addressed here. Nonetheless, some of those comments are valuable and NMFS will consider them for future management planning.

Comment 1: The rule should not include a trip limit (*e.g.,* an initial 20-mt trip limit proposed), or should have a higher trip limit (*e.g.,* up to 50 mt), because it will lead to discards. In support for this point, a commenter noted that a recent record of per trip catches from one vessel exceeded the proposed trip limit. The commenter also stated that fish in excess of the trip limit that are encircled and then released would not survive; therefore, the trip limits do not promote management measures to reduce fishing mortality. Additionally, the ability of vessel operators to catch a small quantity is uncertain. If only large schools are present, the vessel operators may have to forgo catching Pacific bluefin tuna. A comment received at the public hearing also recommended a higher trip limit.

Response: NMFS agrees that an increase in the trip limit from 20 mt to 25 mt is warranted (for an explanation of the rationale, please see the next section, Changes from the Proposed Rule). NMFS anticipates that increasing the trip limit from the proposed 20 mt to 25 mt will reduce the potential for discards while still sufficiently reducing the rate of harvest to meet the management objectives of providing access to, without exceeding, the full catch limit. Increasing the trip limit beyond 25 mt would make monitoring and timely closure more difficult. Regarding mortality of released fish, other comments received suggest vessel operators could target smaller schools and fish could survive brailing operations. NMFS is unaware of any studies that refute this anecdotal information.

Comment 2: NMFS should adopt an initial trip limit (*e.g.,* 20-mt trip limit) as proposed because it may alleviate derby-style fishing pressures and the potential for excess supply of Pacific bluefin tuna, and therefore, could make fishery more profitable. In particular, slowing the harvest rate could support development of a local fresh-frozen market for Pacific bluefin tuna in California, whereas large sets are only suitable for canning. Commenters also specifically supported 20 mt as the initial trip limit. The 20-mt trip limit is a good an inseason management tool to ensure that catch limits are not exceeded and reduce the potential for a fishery closure that could require discarding of incidentally caught PBF. A skilled purse seine captain can estimate the size of a set, and release fish alive during the brailing operation, if needed. One commenter suggested trip limits should only be imposed for the short-term, while the overall catch limit is so low.

Response: NMFS agrees that the initial trip limit (*e.g.,* 20 mt) is a useful management tool in this situation. As explained in the Response to Comment 1, NMFS is implementing an initial trip limit of 25 mt, rather than 20 mt as originally proposed, to address concerns about discards; the higher trip limit is expected to meet the management objectives, including alleviating derby-style fishing pressure. Further, the 2-mt trip limit when catch is within 50 mt of the 2015 or 2016 limit is intended to prevent discards of incidentally caught PBF in non-directed fisheries (*e.g.* troll and line, drift gillnet). Additionally, the catch and trip limits in this rule are only applicable to 2015 and 2016. If the IATTC adopts subsequent resolutions on the conservation and management of Pacific bluefin tuna, NMFS will evaluate whether trip limits are appropriate management measures at that time.

Comment 3: Current monitoring and enforcement is inadequate to enforce catch and trip limits, and ensure the biennial catch limits are not exceeded. The proposed trip limit—NMFS assumes this refers to the 20-mt trip limit and not the 2-mt trip limit—incentivizes discards. Further, misreporting could undermine accurate estimates of fishing mortality. Vessel operators should be required to record discards to ensure that the United States does not exceed the catch limits. Without observer coverage, NMFS should estimate the portion of catch discarded dead and include it in the estimate of total U.S. catch of Pacific bluefin tuna. The fishery should be closely monitored to ensure the catch limit is not exceeded.

Response: NMFS acknowledges that monitoring and enforcement of trip limits can be a problem for fisheries management, but has determined that an initial trip limit of 25 mt can be adequately monitored and enforced. Vessel operators are required to fill out logbooks, which includes all catch, whether kept or returned to sea, and to submit the logbooks to NMFS within 30 days of each landing or transshipment (see 50 CFR 660.708). All catch, including discards, will count toward the catch limits. NMFS intends to work closely with California Department of Fish and Wildlife (CDFW) and vessel operators, as it did in 2014, to monitor catches and landings to ensure limits are not exceeded. In 2014, NMFS received near real-time landings data from CDFW and vessel operators.

Comment 4: The proposed rule fails to address an objective in Resolution C–14–06 that only 50 percent of the total catch be comprised of fish less than 30 kilograms (kg). Furthermore, the United States should limit catches even further to 250 mt per year, a level comparable to the 30 percent reduction considered for the recreational fishery.

Response: Regarding size limits, C–14–06 establishes a goal, but not a requirement. NMFS is promulgating this rule in accordance with the requirements of Resolution C–14–06 with additional provisions (*e.g.,* trip limits) to be able to effectively meet the requirements of the resolution (*i.e.,* not exceeding catch limits). Resolution C–14–06 and this rule represent commercial catch reductions consistent with recommendations of the IATTC scientific staff (*i.e.,* 20 to 45 percent) to aid in the rebuilding of the stock. More specifically, the catch limits in Resolution C–14–06 (*i.e.,* an average of 300 mt per year) represent a 40 percent reduction from U.S. commercial catch limits in previous resolutions (*i.e.,* 500 mt per year) on the conservation and management of Pacific bluefin tuna. Lastly, requiring that fishermen target and land larger fish (*i.e.,* greater than 30 kg) could lead to discards, as well as additional harvest costs (*e.g.,* search time for schools of larger fish).

General Comments not Within the Scope of the Rule: NMFS received several comments outside the scope of the proposed rule regarding: Future negotiations tactics by the United States on Pacific bluefin tuna conservation and management measures in the Convention Area, recommendations for additional science needs, improvement of catch monitoring by requiring daily communication between NMFS and vessel owners, requiring full retention of Pacific bluefin tuna, objections to the current catch limit as agreed to in Resolution C–14–06, and the effects of the current fishery conditions for other species targeted by the coastal purse seiners (*i.e.,* sardines and market squid).

Response to General Comments not Within the Scope of the Rule: NMFS will take these comments and concerns into consideration when developing future positions at upcoming IATTC meetings, as well as developing scientific partnerships to address gaps in knowledge. Regarding daily communication between vessel operators and NMFS, there would be value in increased communication to more closely monitor the fishery. NMFS is considering developing a rule to require vessel operators to notify NMFS upon landing Pacific bluefin tuna. Nonetheless, NMFS will endeavor to promote better cooperation and communication with vessel operators to receive catch data at the time of landing. NMFS views the requirement to log all catches and a requirement to land all catch (*i.e.,* full retention) as having the same goal: To account for all Pacific bluefin tuna caught by U.S. vessels. Vessel operators are currently required to log all catch, which would be counted toward the catch limit. As described in responses above, NMFS is implementing a higher than originally proposed trip limit to address concerns about discards. Regarding other target fisheries (*e.g.,* sardines, market squid), at the time Resolution C–14–06 was adopted (October 2014), the U.S. delegation was unaware of the drastic reductions in the fishery for Pacific sardine that are being imposed because of the reduced biomass estimates. However, the United States would have nonetheless endeavored to make cuts consistent with IATTC scientific staff recommendations to aid in rebuilding of Pacific bluefin tuna.

Changes From the Proposed Rule

NMFS received a number of comments expressing concern about the potential for discards resulting from the proposal to set the initial trip limit each year at 20 mt. NMFS has concluded that a higher trip limit of 25 mt is warranted to reduce the potential for discards while still meeting the management objectives (*e.g.,* inseason management). NMFS found that the average landing by a vessel from a trip targeting PBF during 2005 to 2014 was 30.6 mt (ranging from 0.04 mt to 75.8 mt; median is 29.2); 36 percent of these trips included landings up to 25 mt, whereas only 23 percent of the trips included landings up to 20 mt. NMFS concludes that increasing the trip limit to 25 mt will tend to reduce discards while still sufficiently reducing the rate of harvest to meet the objective of providing access to, without exceeding, the full catch limit. Consequently, NMFS is implementing trip limits as recommended by the Council, but increasing the level of the initial trip limit from 20 mt to 25 mt.

Classification

The NMFS Assistant Administrator has determined that this rule is consistent with the Tuna Conventions Act and other applicable laws.

This rule was determined to be not significant for purposes of Executive Order 12866.

Although there are no new collection-of-information requirements associated with this action that are subject to the Paperwork Reduction Act, existing collection-of-information requirements associated with the Fishery Management Plan for U.S. West Coast Fisheries for Highly Migratory Species (HMS FMP) still apply. These requirements have been approved by the Office of Management and Budget under Control Number 0648–0204. Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection-of-information subject to the requirements of the PRA, unless that collection-of-information displays a currently valid OMB control number.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. This final rule contains a change in the trip limit that was published in the

proposed action. As a result of public comments, the trip limit was increased from 20 mt to 25 mt. This change is anticipated to result in a minor economic benefit for impacted business entities. No comments were received regarding the certification. Therefore, the certification published with the proposed rule, that this rule is not expected to have a significant economic impact on a substantial number of small entities, is still valid. As a result, a regulatory flexibility analysis was not required and none was prepared.

The Assistant Administrator for Fisheries has determined that the need to conserve Pacific bluefin tuna and comply with our international obligations constitutes good cause, under 5 U.S.C. 553(d)(3), to waive the requirement for a 30-day delay in effectiveness. Pacific bluefin tuna have migrated in significant numbers into waters off of southern California and commercial purse seine vessels have begun fishing for Pacific bluefin tuna off of the U.S West Coast. If the trip limits implemented by this rule were subject to the 30-day delay in effectiveness, and taking into account that a single trip could catch up to 75 mt, there is potential for a derby-style fishery that would result in exceeding the 425-mt catch limit for 2015 before this rule goes into effect. Although justification exists to waive the 30-day delay in effectiveness, NMFS is implementing a 7-day delay in effectiveness to provide sufficient time for any vessels currently operating to comply with the new regulations; vessels that target Pacific bluefin tuna typically complete their fishing trips within one to two days. As soon as the rule is filed, notice will be sent to inform members of the tuna-fishing industry.

Therefore, to conserve Pacific bluefin tuna, which are overfished, and to remain in compliance with IATTC Resolution C–14–06, NMFS has determined that implementing these measures 7 days after filing with the Office of Federal Register is in the public's interest.

List of Subjects in 50 CFR Part 300

Administrative practice and procedure, Fish, Fisheries, Fishing, Marine resources, Reporting and recordkeeping requirements, Treaties.

Dated: July 1, 2015.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 300 is amended as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

Subpart C—Eastern Pacific Tuna Fisheries

■ 1. The authority citation for part 300, subpart C, continues to read as follows:

Authority: 16 U.S.C. 951 *et seq.*

■ 2. In § 300.21, add the definition for ''Trip limit'' in alphabetical order to read as follows:

§ 300.21 Definitions.

* * * * *

Trip limit means the total allowable amount of a species by weight of fish that may be retained on board, transshipped, or landed from a single fishing trip by a vessel that harvests tuna or tuna-like species.

* * * * *

■ 3. In § 300.24, revise paragraph (u) to read as follows:

§ 300.24 Prohibitions.

* * * * *

(u) Use a United States commercial fishing vessel in the Convention Area to target, retain on board, transship or land Pacific bluefin tuna in contravention of § 300.25(h)(3) and (5).

* * * * *

■ 4. In § 300.25, revise paragraph (h) to read as follows:

§ 300.25 Eastern Pacific fisheries management.

* * * * *

(h) *Pacific bluefin tuna commercial catch limits in the eastern Pacific Ocean for 2015–2016.* The following is applicable to the U.S. commercial fishery for Pacific bluefin tuna in the Convention Area in the years 2015 and 2016.

(1) For the calendar year 2015, all commercial fishing vessels of the United States combined may capture, retain, transship, or land no more than 425 metric tons in the Convention Area.

(2) In 2016, NMFS will publish a notice in the **Federal Register** announcing the 2016 catch limit. For the calendar year 2016, all commercial fishing vessels of the United States combined may capture, retain on board, transship, or land no more than the 2016 catch limit. The 2016 catch limit is calculated by adding any amount of the 425 metric ton catch limit that was not caught in 2015, as determined by NMFS, to 175 metric tons, except as follows:

(i) If 175 metric tons or less are caught in 2015, as determined by NMFS, then the 2016 catch limit is 425 metric tons;

(ii) If in 2015, greater than 300 metric tons and up to 400 metric tons are caught, as determined by NMFS, then the 2016 catch limit is 200 metric tons; or

(iii) If greater than 425 metric tons are caught in 2015, as determined by NMFS, then the 2016 catch limit is calculated by subtracting the amount caught in 2015 from 600 metric tons.

(3) In 2015 and 2016, a 25 metric ton trip limit will be in effect until NMFS anticipates that catch will be within 50 metric tons of the catch limits, after which a 2 metric ton trip limit will be in effect upon publication of a notice in the **Federal Register** by NMFS.

(4) After NMFS determines that the catch limits under paragraphs (h)(1) and (2) of this section are expected to be reached by a future date, NMFS will publish a fishing closure notice in the **Federal Register** announcing the effective date that additional targeting, retaining on board, transshipping or landing Pacific bluefin tuna in the Convention Area shall be prohibited as described in paragraph (h)(5) of this section.

(5) Beginning on the date announced in the fishing closure notice published under paragraph (h)(4) of this section through the end of the calendar year, a commercial fishing vessel of the United States may not be used to target, retain on board, transship, or land Pacific bluefin tuna captured in the Convention Area, with the exception that any Pacific bluefin tuna already on board a fishing vessel on the effective date of the notice may be retained on board, transshipped, and/or landed, to the extent authorized by applicable laws and regulations, provided such Pacific bluefin tuna is landed within 14 days after the effective date published in the fishing closure notice.

[FR Doc. 2015–16720 Filed 7–2–15; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 80, No. 130
Wednesday, July 8, 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 39

[Docket No. FAA–2015–1383; Directorate Identifier 2015–NE–15–AD]

RIN 2120–AA64

Airworthiness Directives; Technify Motors GmbH Reciprocating Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Technify Motors GmbH TAE 125–02 reciprocating engines with a dual mass flywheel installed. This proposed AD was prompted by reports of a gearbox drive shaft breaking during starting or restarting of the engine. This proposed AD would require installation of a start phase monitoring system and associated specified software. We are proposing this AD to prevent overload and failure of the gearbox drive shaft, which could lead to failure of the engine, in-flight shutdown, and loss of control of the airplane.

DATES: We must receive comments on this proposed AD by September 8, 2015.

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

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

For service information identified in this proposed AD, contact Technify Motors GmbH, Platanenstrasse 14, D–09356 Sankt Egidien, Germany; phone: +49 37204 696 0; fax: +49 37204 696 29125; email: *info@centurion-engines.com;* and Diamond Aircraft Industries GmbH, N. A. Otto-Strasse 5, 2700 Wiener Neustadt, Austria; phone: +43 2622 26700; fax: +43 2622 26700 1369; email: *airworthiness@diamond-air.at.* You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–1383.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–1383; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–1383; Directorate Identifier 2015–NE–15–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2015–0055, dated March 31, 2015 (referred to hereinafter as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> Cases of a broken gearbox drive shaft have been reported on aeroplanes equipped with TAE 125–02 engines that have a Dual Mass Flywheel installed.
>
> Investigations results showed a possible overload of the gearbox drive shaft during starting of the engine or during restarting of the engine in-flight.
>
> This condition, if not corrected, could lead to engine power loss during flight, possibly resulting in loss of control of the aeroplane.

You may obtain further information by examining the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–1383.

Related Service Information Under 1 CFR Part 51

Technify Motors GmbH (type certificate previously held by Thielert Aircraft Engines GmbH) issued Technify Motors Service Bulletin (SB) No. SB TMG 125–1018 P1, Revision 1, dated February 5, 2015. The service information describes procedures for installing a start phase monitoring system and associated specified software mapping on particular airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

Other Related Service Information

Technify Motors GmbH has also issued Technify Motors SB No. TM TAE 000–0007, Revision 28, dated February 5, 2015; Technify Motors Installation Manual No. IM–02–02, Issue 4, Revision 2, dated January 30, 2015, with Chapter 02–IM–13–02, section 13.8.16, Revision 1, dated November 28, 2014; Technify

Motors SB No. SB TMG 601–1007 P1, Revision 3, dated February 5, 2015; and Technify Motors SB No. SB TMG 651–1004 P1, Revision 2, dated February 5, 2015.

Diamond Aircraft Industries GmbH (DAI) has issued DAI Mandatory Service Bulletin (MSB) No. 42–109/1, dated February 4, 2015; and DAI MSB No. 42–007/16, dated February 4, 2015.

The service information describes procedures for installing a start phase monitoring system and associated specified software mapping.

FAA's Determination and Requirements of This Proposed AD

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

Costs of Compliance

We estimate that this proposed AD affects 97 engines installed on airplanes of U.S. registry. We also estimate that it would take about 3 hours per engine to comply with this proposed AD. The average labor rate is $85 per hour. For 13 of the engines, required parts cost about $285 per engine. For 84 of the engines, required parts cost about $206 per engine. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $45,744.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Technify Motors GmbH (Type Certificate Previously Held by Thielert Aircraft Engines GmbH): Docket No. FAA–2015–1383; Directorate Identifier 2015–NE–15–AD.

(a) Comments Due Date

We must receive comments by September 8, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Technify Motors GmbH TAE 125–02–99 (commercial designation CD–135, formerly Centurion 2.0) and TAE 125–02–114 (commercial designation CD–155, formerly Centurion 2.0S) reciprocating engines, with a dual mass flywheel installed.

(d) Reason

This AD was prompted by reports of a gearbox drive shaft breaking during starting or restarting of the engine. We are issuing this AD to prevent overload and failure of the gearbox drive shaft, which could lead to failure of the engine, in-flight shutdown, and loss of control of the airplane.

(e) Actions and Compliance

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

Within 110 flight hours or at the next scheduled inspection after the effective date of this AD, whichever occurs first, install a start phase monitoring system and software mapping. Use Technify Motors Service Bulletin (SB) No. SB TM 125–1018 P1, Revision 1, dated February 5, 2015, to do the installation.

(f) Installation Prohibition

After the effective date of this AD, do not install onto any airplane any Technify Motors TAE 125–02–99 or TAE 125–02–114 reciprocating engine that is not equipped with a start phase monitoring system and software mapping.

(g) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(h) Related Information

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

(2) Refer to MCAI European Aviation Safety Agency AD 2015–0055, dated March 31, 2015, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2015–1383.

(3) Technify Motors SB No. SB TMG 125–1018 P1, Revision 1, dated February 5, 2015; Technify Motors SB No. TM TAE 000–0007, Revision 28, dated February 5, 2015; Technify Motors Installation Manual No. IM–02–02, Issue 4, Revision 2, dated January 30, 2015, with Chapter 02–IM–13–02, section 13.8.16, Revision 1, dated November 28, 2014; Technify Motors SB No. SB TMG 601–1007 P1, Revision 3, dated February 5, 2015; and Technify Motors SB No. SB TMG 651–1004 P1, Revision 2, dated February 5, 2015, can be obtained from Technify Motors GmbH, using the contact information in paragraph (h)(5) of this proposed AD.

(4) Diamond Aircraft Industries GmbH MSB No. 42–109/1, dated February 4, 2015; and DAI MSB No. 42–007/16, dated February 4, 2015, can be obtained from Diamond

Aircraft Industries GmbH, using the contact information in paragraph (h)(5) of this proposed AD.

(5) For Technify Motors service information identified in this proposed AD, contact Technify Motors GmbH, Platanenstrasse 14, D–09356 Sankt Egidien, Germany; phone: +49–37204–696–0; fax: +49–37204–696–55; email: *info@centurion-engines.com.* For DAI service information identified in this proposed AD, contact Diamond Aircraft Industries GmbH, N. A. Otto-Strasse 5, 2700 Wiener Neustadt, Austria; phone: +43 2622 26700; fax: +43 2622 26700 1369; email: *airworthiness@diamond-air.at.*

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

Issued in Burlington, Massachusetts, on June 26, 2015.

Ann C. Mollica,

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

[FR Doc. 2015–16586 Filed 7–7–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–2458; Directorate Identifier 2014–NM–122–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Airbus Model A318, A319, and A321 series airplanes. This proposed AD was prompted by reports of in-flight loss of fixed and hinged main landing gear (MLG) fairings, and reports of post-modification MLG fixed fairing assemblies that have wear and corrosion. This proposed AD would require, for certain airplanes, repetitive replacements of the fixed fairing upper and lower attachment studs of both the right-hand (RH) and left-hand (LH) MLG; and repetitive inspections for corrosion, wear, fatigue, cracking, and loose studs of each forward stud assembly of the fixed fairing door upper and lower forward attachment of both RH and LH MLG; and replacement if necessary. This proposed AD also provides an optional terminating modification for the repetitive replacements of the fixed fairing upper and lower attachment studs. We are proposing this AD to prevent in-flight detachment of an MLG fixed fairing and consequent damage to the airplane.

DATES: We must receive comments on this proposed AD by August 24, 2015.

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

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

For service information identified in this proposed AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–2458; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–2458; Directorate Identifier 2014–NM–122–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2015–0001R1, dated January 15, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Model A318, A319, A320, and Model A321 series airplanes. The MCAI states:

> Several occurrences of in-flight loss of main landing gear (MLG) fixed and hinged fairings were reported. The majority of reported events occurred following scheduled maintenance activities. One result of the investigation was that a discrepancy between the drawing and the maintenance manuals was discovered. The maintenance documents were corrected to prevent mis-rigging of the MLG fixed and hinged fairings, which could induce fatigue cracking.
>
> Airbus issued Service Bulletin (SB) A320–52–1083, providing instructions for a one-time inspection of the MLG fixed fairing composite insert and the surrounding area, replacement of the adjustment studs at the lower forward position and adjustment to the new clearance tolerances. That SB was replaced by Airbus SB A320–52–1100 (mod 27716) introducing a re-designed location stud, rod end and location plate at the forward upper and lower leg fixed-fairing positions. Subsequently, reports were received of post-mod 27716/post-SB A320–52–1100 MLG fixed fairing assemblies with corrosion, which could also induce cracking.
>
> This condition, if not detected and corrected, could lead to further cases of in-flight detachment of a MLG fixed fairing, possibly resulting in injury to persons on the ground and/or damage to the aeroplane.
>
> To address this potential unsafe condition, EASA issued AD 2014-0096 [*http://ad.easa.europa.eu/blob/easa_ad_2014_0096_superseded.pdf/AD_2014-0096_1*] to require [for certain airplanes] repetitive detailed inspections (DET) of the MLG fixed fairings,

and, depending on findings, accomplishment of applicable corrective actions. That [EASA] AD also prohibited installation of certain MLG fixed fairing rod end assemblies and studs as replacement parts on aeroplanes incorporating Airbus mod 27716 in production, or modified in accordance with Airbus SB A320–52–1100 (any revision) in service.

Since EASA AD 2014–0096 was issued, Airbus developed an alternative inspection programme to meet the AD requirements. In addition, a terminating action (mod 155648) was developed, which is to be made available for in service aeroplanes through Airbus SB A320–52–1165.

For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2014–0096, which is superseded, and adds an optional terminating action for the repetitive inspections. For post-mod aeroplanes, *i.e.* incorporating Airbus mod 155648 in production, or modified by Airbus SB A320–52–1165 in service, the only remaining requirement is to ensure that pre-mod components are no longer installed.

Prompted by these developments, EASA issued AD 2015–0001, retaining the requirements of EASA AD 2014–0096, which was superseded, and adding an optional terminating action for the repetitive inspections. For post-mod aeroplanes, *i.e.* incorporating Airbus mod 155648 in production, or modified by Airbus SB A320–52–1165 in service, the only remaining requirement is to ensure that pre-mod components are no longer installed.

Since that [EASA] AD was issued, it was discovered that a certain plate support, Part Number (P/N) D5285600620000 as listed in Table 3 of the [EASA] AD, remains part of the post SB A320–52–1165 configuration and is therefore not affected by any prohibition of installation—paragraph (11) of the [EASA] AD. In addition, an error was detected in Table 1 of the [EASA] AD (missing P/N plate support) and paragraph (9) was found to be incorrectly worded.

For the reasons described above, this [EASA] AD is revised to introduce the necessary corrections.

Required actions also include, for airplanes in Airbus pre-modification 27716 and pre-Airbus Service Bulletin A320–52–1100 configuration on which certain components have been installed, repetitive replacements of the fixed fairing upper and lower attachment studs of both the RH and LH MLG. An optional terminating modification also is provided for the repetitive replacements of the fixed fairing upper and lower attachment studs. The optional terminating modification includes a resonance frequency inspection for debonding of the composite insert and delamination of the honeycomb area around the insert, and applicable corrective actions if necessary; and installation of new studs, rod ends, and location plates at the forward upper and lower leg fixed-fairing positions. An additional optional terminating modification, for airplanes in pre-modification 27716 and pre-Airbus Service Bulletin A320–52–1100 configuration, includes installation of a locking device, new studs, rod ends, and location plates at the forward upper and lower leg fixed-fairing positions.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–2458.

Related Service Information Under 1 CFR Part 51

- Airbus has issued Service Bulletin A320–52–1100, Revision 01, dated March 12, 1999. This service information describes procedures for modification of the airplane to post-modification 27716 configuration (by replacing the location stud, rod end, and location plate at the forward upper and lower leg fixed-fairing positions of the MLG door assemblies). The modification includes a resonance frequency inspection for debonding of the composite insert and delamination of the honeycomb area around the insert, and applicable corrective actions. Corrective actions include repairing the insert. The actions in this service information are an optional terminating modification.
- Airbus has also issued Service Bulletin A320–52–1163, dated February 4, 2014. This service information describes procedures for inspection of the fixed fairing forward attachments of the MLG door assemblies, and replacement of the fixed fairing upper and lower attachment studs of the RH and LH MLG door assemblies.
- Airbus has issued Service Bulletin A320–52–1165, dated November 3, 2014. This service information describes procedures for replacing the fairing attachment stud assemblies of the MLG door assembly with new assemblies. The actions in this service information are an optional terminating modification.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this AD.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Costs of Compliance

We estimate that this proposed AD affects 851 airplanes of U.S. registry.

We also estimate that it would take about 18 work-hours per product to comply with the basic inspection requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $4,110 per product. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $4,799,640, or $5,640 per product.

We estimate that the optional terminating modification would take about 18 work-hours and require parts costing $4,110, for a cost of $5,640 per product.

In addition, we estimate that any necessary follow-on actions would take about 18 work-hours and require parts costing $4,110, for a cost of $5,640 per product. We have no way of determining the number of aircraft that might need these actions.

According to the manufacturer, some of the costs of this proposed AD might be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

We determined that this proposed AD would not have federalism implications

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;

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

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus: Docket No. FAA–2015–2458; Directorate Identifier 2014–NM–122–AD.

(a) Comments Due Date

We must receive comments by August 24, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Airbus airplanes identified in paragraphs (c)(1) through (c)(4) of this AD, certificated in any category, all manufacturer serial numbers.

(1) Airbus Model A318–111, –112, –121, and –122 airplanes.

(2) Airbus Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Airbus Model A320–211, –212, –214, –231, –232, and –233 airplanes.

(4) Airbus Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 52, Doors.

(e) Reason

This AD was prompted by reports of in-flight loss of fixed and hinged main landing gear (MLG) fairings, and reports of post-modification MLG fixed fairing assemblies that have wear and corrosion. We are issuing this AD to prevent in-flight detachment of an MLG fixed fairing and consequent damage to the airplane.

(f) Compliance

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

(g) Repetitive Replacements

For airplanes in pre-modification 27716 and pre-Airbus Service Bulletin A320–52–1100 configuration, with any of the components installed that are identified in paragraphs (g)(1) through (g)(5) of this AD: At the applicable compliance time specified in paragraph (h) of this AD, replace fixed fairing upper and lower attachment studs of both right-hand (RH) and left-hand (LH) MLG, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1163, dated February 4, 2014. Repeat the replacements thereafter at intervals not to exceed 6,500 flight cycles.

(1) Plate—support having part number (P/N) D5284024820000.

(2) Plate—support having part number (P/N) D5284024820200.

(3) Stud—adjustment having P/N D5284024420000.

(4) Rod end assembly (lower) having P/N D5284000500000.

(5) Rod end assembly (upper) having P/N D5284000600000.

(h) Compliance Times for the Requirements of Paragraph (g) of this AD

Do the initial replacement required by paragraph (g) of this AD at the latest of the times specified in paragraphs (h)(1) through (h)(4) of this AD.

(1) Before the accumulation of 6,500 total flight cycles since the airplane's first flight.

(2) Within 6,500 flight cycles since the last installation of a pre-modification 27716 stud on the airplane.

(3) Within 1,500 flight cycles after the effective date of this AD.

(4) Within 8 months after the effective date of this AD.

(i) Repetitive Inspections

For airplanes in post-modification 27716 or post-Airbus Service Bulletin A320–52–1100 configuration, with any of the components installed that are identified in paragraphs (i)(1), (i)(2), and (i)(3) of this AD: At the applicable compliance time specified in paragraph (j) of this AD, do a detailed inspection of the LH and RH stud assemblies of the fixed fairing door upper and lower forward attachments of both RH and LH MLG for indications of corrosion, wear, fatigue, cracking, and loose studs, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1163, dated February 4, 2014. Repeat the inspection thereafter at intervals not to exceed 12 months. Replacement of both RH and LH MLG forward stud assemblies on an airplane, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1163, dated February 4, 2014, extends the interval for the next detailed inspection to 72 months; and the inspection must be repeated thereafter at intervals not to exceed 12 months.

(1) Stud—adjustment having P/N D5285600720000.

(2) Rod end assembly (lower) having P/N D5285600400000.

(3) Rod end assembly (upper) having P/N D5285600500000.

(j) Compliance Times for the Requirements of Paragraph (i) of This AD

Do the initial inspection required by paragraph (i) of this AD at the latest of the times specified in paragraphs (j)(1) through (j)(4) of this AD.

(1) Before the accumulation of 72 months since the airplane's first flight.

(2) Within 72 months since the last installation of a post-modification 27716 assembly or since accomplishment of the actions specified in Airbus Service Bulletin A320–52–1100.

(3) Within 1,500 flight cycles after the effective date of this AD.

(4) Within 8 months after the effective date of this AD.

(k) Corrective Action

If any indication of corrosion, wear, fatigue, cracking, or loose studs of any forward stud assembly is found during any inspection required by paragraph (i) of this AD, except as specified in paragraph (l) of this AD: Before further flight, replace the upper and lower fixed fairing forward attachment assemblies of the RH and LH MLG, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1163, dated February 4, 2014; or Airbus Service Bulletin A320–52–1165, dated November 3, 2014.

(l) Corrective Action or Repetitive Inspections for Certain Corrosion Findings

If any corrosion is found during any inspection required by paragraph (i) of this AD on any MLG fixed fairing forward attachment stud assembly (upper, lower, LH or RH), but the corroded stud is not loose: Do the action specified in paragraph (l)(1) or (l)(2) of this AD.

(1) Before further flight, replace the affected assembly, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1163, dated February 4, 2014; or Airbus Service Bulletin A320–52–1165, dated November 3, 2014.

(2) Within 4 months after finding corrosion, and thereafter at intervals not to exceed 4 months, do a detailed inspection for indications of corrosion, wear, fatigue, cracking, and loose studs of the forward stud assembly of the affected (RH or LH) MLG, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1163, dated February 4, 2014.

(m) Corrective Action for Inspections Specified in Paragraph (l)(2) of This AD

If any indication of wear, fatigue, cracking, or loose studs of any forward stud assembly is found during any inspection required by

paragraph (l)(2) of this AD: Before further flight, replace the affected (RH or LH) MLG fixed fairing forward attachment assembly, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1163, dated February 4, 2014; or Airbus Service Bulletin A320–52–1165, dated November 3, 2014.

(n) Terminating Action

(1) Replacement of parts on an airplane, as required by paragraph (g), (k), or (l)(1) of this AD, does not constitute terminating action for the repetitive inspections required by paragraph (i) of this AD, except as specified in paragraph (n)(3) of this AD.

(2) The repetitive replacements required by paragraph (g) of this AD may be terminated by modification of the airplane to post-modification 27716 configuration, including a resonance frequency inspection for debonding of the composite insert and delamination of the honeycomb area around the insert, and all applicable corrective actions, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1100, Revision 01, dated March 12, 1999, provided all applicable corrective actions are done before further flight. Thereafter, refer to paragraph (i) of this AD to determine the compliance time for the next detailed inspection required by this AD.

(3) Modification of an airplane, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1165, dated November 3, 2014, constitutes terminating action for actions required by paragraphs (g) through (m) of this AD for the airplane on which the modification is done.

(o) Exception to Certain AD Actions

An airplane on which Airbus Modification 155648 has been embodied in production is not affected by the requirements of paragraphs (g) and (i) of this AD, provided that no affected component, identified by part number as listed paragraphs (g)(1) through (g)(5) and (i)(1) through (i)(3) of this AD, has been installed on that airplane since first flight of the airplane.

(p) Parts Installation Prohibition

(1) For airplanes in pre-Airbus-Modification 27716 and pre-Airbus-Service-Bulletin A320–52–1100 configuration: No person may install a component identified in paragraphs (g)(1) through (g)(5) of this AD on any airplane after doing the actions provided in paragraph (n)(2) of this AD.

(2) For airplanes in post-Airbus-Modification 27716 and post Airbus Service Bulletin A320–52–1100 configuration: As of the effective date of this AD, no person may install a component identified in paragraphs (g)(1) through (g)(5) of this AD on any airplane.

(3) For airplanes in pre-Airbus-Modification 155648 and pre-Airbus-Service-Bulletin A320–52–1165 configuration: No person may install a component identified in paragraphs (g)(1) through (g)(5) and (i)(1) through (i)(3) of this AD on any airplane after doing the actions provided in paragraph (n)(3) of this AD.

(4) For airplanes in post-Airbus-Modification 155648 and post-Airbus-Service-Bulletin A320–52–1165 configuration: As of the effective date of this AD, no person may install a component identified in (g)(1) through (g)(5) and (i)(1) through (i)(3) of this AD on any airplane.

(q) Credit for Previous Actions

This paragraph provides credit for optional actions provided by paragraph (n)(2) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–52–1100, dated December 7, 1998, which is not incorporated by reference in this AD.

(r) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(s) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2015–0001R1, dated January 15, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–2458.

(2) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on June 30, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–16583 Filed 7–7–15; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 33–9862; 34–75344 File No. S7–13–15]

RIN 3235–AL70

Possible Revisions To Audit Committee Disclosures

AGENCY: Securities and Exchange Commission.

ACTION: Concept release; request for comments.

SUMMARY: The Commission is publishing this concept release to seek public comment regarding audit committee reporting requirements, with a focus on the audit committee's reporting of its responsibilities with respect to its oversight of the independent auditor. Some have expressed a view that the Commission's disclosure rules for this area may not result in disclosures about audit committees and their activities that are sufficient to help investors understand and evaluate audit committee performance, which may in turn inform those investors' investment or voting decisions. The majority of these disclosure requirements, which exist in their current form principally in Item 407 of Regulation S–K, were adopted in 1999. Since then, there have been significant changes in the role and responsibilities of audit committees arising out of, among other things, the Sarbanes-Oxley Act of 2002, enhanced listing requirements for audit committees, enhanced requirements for auditor communications with the audit committee arising out of the rules of the Public Company Accounting Oversight Board, and changes in practice, both domestically and internationally.

DATES: Comments should be received on or before September 8, 2015.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/concept.shtml*); or

• Send an email to *rule-comments@sec.gov.* Please include File Number S7–13–15 on the subject line; or

• Use the Federal eRulemaking Portal (*http://www.regulations.gov*). Follow the instructions for submitting comments.

Paper Comments

• Send paper comments to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number S7–13–15. This file number should be included on the subject line if email is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Web site (*http://www.sec.gov/rules/concept.shtml*). Comments also are 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. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Duc Dang, Special Counsel at (202) 551–3386; Jennifer McGowan, Professional Accounting Fellow, at (202) 551–8736; Kevin Stout, Senior Associate Chief Accountant, at (202) 551–5930, Office of the Chief Accountant; or Lindsay McCord, Associate Chief Accountant, at (202) 551–3417, Division of Corporation Finance, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

Table of Contents

I. Introduction

The Commission has a long history of promoting effective and independent audit committees. The role and responsibilities of audit committees related to oversight of the independent auditor have evolved due to changes in both the securities laws and the national securities exchanges' listing requirements related to audit committees. Today, the audit committee of a listed issuer is directly responsible for the appointment, compensation, retention and oversight of the work of any registered public accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the issuer, and the independent auditor reports directly to the audit committee.[1] In addition, in connection with these oversight responsibilities, the audit committee has ultimate authority to approve all audit engagement fees and terms [2] and is responsible for resolving disagreements between management and the auditor regarding financial reporting.[3]

Requirements for the audit committee's reporting to shareholders are principally contained in Item 407 of Regulation S–K,[4] which have not changed substantively since 1999. As a result, some have expressed a view that the Commission's disclosure rules do not provide investors with sufficient useful information regarding the role of and responsibilities carried out by the audit committee in public companies.[5] The audit committee has a vital role in oversight of auditors, and the independent audits performed by those auditors have long been recognized as important to credible and reliable financial reporting and the functioning of our capital markets.[6] The reporting of additional information by the audit committee with respect to its oversight of the auditor may provide useful information to investors as they evaluate the audit committee's performance in

[1] *See* Section 10A(m) of the Securities Exchange Act of 1934 (the ''Exchange Act'') [15 U.S.C. 78j–1(m)]. As noted in Section II.B., audit committees of listed issuers also have responsibilities with respect to the receipt, retention, and treatment of complaints regarding accounting, internal accounting controls, or auditing matters, including procedures for the confidential, anonymous submission by employees of the issuer of concerns regarding questionable accounting or auditing matters.

[2] *See* Release No. 34–47654, *Standards Relating to Listed Company Audit Committees* (Apr. 9, 2003) [68 FR 18788].

[3] *See* Section 10A(m)(2) of the Exchange Act.

[4] 17 CFR 229.407

[5] *See* Audit Committee Collaboration, ''Enhancing the Audit Committee Report, A Call to Action,'' (Nov. 20, 2013), available at *http://www.thecaq.org/reports-and-publications/enhancing-the-audit-committee-report-a-call-to-action* (''A Call to Action''). This collaboration consisted of the following organizations: The National Association of Corporate Directors, Corporate Board Member/NYSE Euronext, Tapestry Networks, the Directors' Council, the Association of Audit Committee Members, Inc., and the Center for Audit Quality (''CAQ'').

[6] *See* Release No. 33–8177, *Disclosure Required by Sections 406 and 407 of the Sarbanes-Oxley Act of 2002* (Jan. 23, 2003) [68 FR 5110] (acknowledging the audit committee's vital role in financial reporting, public disclosure, and corporate governance); and Release No. 34–14970, *Proposed Rules Relating to Shareholder Communications, Shareholder Participation in the Corporate Electoral Process and Corporate Governance Generally,* (Jul. 18, 1978) [43FR 31945] (citing Report to Congress on the Accounting Profession and the Commission's Oversight Role, Jul. 5, 1978).

connection with, among other things, their vote for or against directors who are members of the audit committee, the ratification of the auditor, or their investment decisions.

Through this Concept Release, the Commission seeks public comment regarding the audit committee's reporting requirements, with a focus on the audit committee's reporting of its responsibilities and activities with respect to its oversight of the independent auditor. This concept release is focused on the audit committee and auditor relationship, but commenters may also provide views on other aspects of audit committee disclosures, such as those related to roles and responsibilities, audit committee qualifications, oversight of financial reporting, or oversight of internal control over financial reporting.

II. Background

A. The Importance of Audit Committees

The audit committee plays an important role in protecting the interests of investors by assisting the board of directors in fulfilling its responsibility to oversee the integrity of a company's accounting and financial reporting processes and both internal and external audits. Since as early as 1940, the Commission, along with the auditing and corporate communities, has had a continuing interest in promoting effective and independent audit committees.[7] Largely with the Commission's encouragement,[8] the national securities exchanges and national securities associations (self-regulatory organizations or ''SROs'') first adopted audit committee requirements in the 1970s.[9] Since that time, there has been support for strong, independent audit committees, including from the National Commission on Fraudulent Financial Reporting, also known as the Treadway Commission,[10] the General Accounting Office,[11] and others.[12]

In 1998, the New York Stock Exchange (the ''NYSE'') and the National Association of Securities Dealers (the ''NASD'') sponsored the Blue Ribbon Committee on Improving the Effectiveness of Corporate Audit Committees (the ''Blue Ribbon Committee''). In its 1999 report, the Blue Ribbon Committee recognized the importance of audit committees and issued ten recommendations to improve their effectiveness.[13] In response to these recommendations, the NYSE and the NASD, among others, revised their listing standards relating to audit committees,[14] and the Commission adopted new rules requiring disclosure relating to the functioning, governance and independence of corporate audit committees.[15]

Academic literature suggests that strong corporate governance, including the composition and actions of the audit committee, has a positive effect on the quality of the audit.[16] For example, some studies note that audit committee independence is associated with lower incidences of earnings management [17] and internal control problems at those issuers benefitting from independent audit committees,[18] while also shielding the external auditor from management's influence.[19]

B. The Impact of the Sarbanes-Oxley Act of 2002 and SRO Listing Standards on Audit Committees

In the early 2000's, multiple incidences of serious misconduct by corporate executives and independent auditors occurred in the financial markets raising concerns about the integrity and reliability of financial disclosures, and the adequacy of regulation and oversight of the accounting profession. This highlighted the need for strong, competent, and vigilant audit committees. In response, the Sarbanes-Oxley Act of 2002 (the ''Sarbanes-Oxley Act'') was enacted.[20] Among other things, the Sarbanes-Oxley Act mandated a number of reforms to enhance corporate responsibility, enhance financial disclosures, and combat corporate and accounting fraud. The Sarbanes-Oxley Act also created a new regulatory and oversight regime for auditors of public companies, including the creation of the Public Company Accounting Oversight Board (the ''PCAOB''), a nonprofit corporation, to oversee the audits of public companies in order to protect the interests of investors and further the public interest in the preparation of informative, accurate, and independent audit

[7] In 1940, the Commission investigated the auditing practices followed by the auditors of McKesson & Robbins, Inc., and the Commission's ensuing report prompted action on auditing procedures by the auditing community. *In the Matter of McKesson & Robbins,* Accounting Series Release (ASR) No. 19, Exchange Act Release No. 2707 (Dec. 5, 1940).

[8] For example, in 1972, the Commission recommended that companies establish audit committees composed of outside directors. *See* ASR No. 123 (Mar. 23, 1972). In 1974 and 1978, the Commission adopted rules requiring disclosures about audit committees. *See* Release No. 34–11147, *Notice of Amendments to Require Increased Disclosure of Relationships Between Registrants and Their Independent Public Accountants* (Dec. 20, 1974) and Release No. 34–15384, *Shareholder Communications, Shareholder Participation in Corporate Electoral Process and Corporate Governance Generally* (Dec. 6, 1978).

[9] *See, e.g.,* Release No. 34–13346, *In the Matter of New York Stock Exchange, Inc.* (Mar. 9, 1977) [42 FR 14793] (Commission order approving NYSE rule change related to the audit committee).

[10] The Treadway Commission was sponsored by the American Institute of Certified Public Accountants, the American Accounting Association, the Financial Executives Institute (now Financial Executives International), the Institute of Internal Auditors and the National Association of Accountants (now Institute of Management Accountants). Collectively, these groups were known as the Committee of Sponsoring Organizations, or COSO. The Treadway Commission's report, the Report of the National Commission on Fraudulent Financial Reporting (October 1987), is available at *www.coso.org.*

[11] *See e.g.,* U.S. General Accounting Office (now Government Accountability Office), ''CPA Audit Quality: Status of Actions Taken to Improve Auditing and Financial Reporting of Public Companies,'' at 5 (GAO/AFMD–89–38, March 1989). The report is available at *http://www.gao.gov/products/AFMD-89-38.*

[12] *See, e.g.,* Preliminary Report of the American Bar Association Task Force on Corporate Responsibility (July 16, 2002) reprinted in 58 Bus. Law. 189 (2002).

[13] *See* Blue Ribbon Committee on Improving the Effectiveness of Corporate Audit Committees, *Report and Recommendations of the Blue Ribbon Committee on Improving the Effectiveness of Corporate Audit Committees,* 54 **The Business Lawyer**, 1067 (1999).

[14] *See, e.g.,* Release No. 34–42231, *Order Approving Proposed Rule Change by the National Association of Securities Dealers, Inc. Amending Its Audit Committee Requirements* (Dec. 14, 1999) [64 FR 71523]; Release No. 34–42233, *Order Approving Proposed Rule Change by the New York Stock Exchange, Inc. Amending the Exchange's Audit Committee Requirements* (Dec. 14, 1999) [64 FR 71529]; Release No. 34–42232, *Order Approving Proposed Rule Change by the American Stock Exchange LLC Amending the Exchange's Audit Committee Requirements* (Dec. 14, 1999) [64 FR 71518]; and Release No. 34–43941, *Order Approving a Proposed Rule Change by the Pacific Exchange, Inc. Relating to Audit Committee Requirements for Listed Companies* (Feb. 7, 2001) [66 FR 10545].

[15] *See* Release No. 34–42266, *Audit Committee Disclosure* (Dec. 22, 1999) [64 FR 73389].

[16] Goh, B.W., *Audit Committees, Boards of Directors, and Remediation of Material Weaknesses in Internal Control,* 26 **Contemporary Accounting Research** 549 (2009); and Hoitash and Hoitash, *The Role of Audit Committees in Managing Relationships with External Auditors After SOX: Evidence from the USA,* 24 **Managerial Auditing Journal** 368 (2009). The positive effects of audit committee oversight are also illustrated in studies using data taken prior to the enactment of the Sarbanes-Oxley Act of 2002 when important characteristics such as the composition and actions of the audit committee were less uniform among companies. *See* Klein, A., *Audit Committee, Board of Director Characteristics, and Earnings Management,* 33 **Journal of Accounting and Economics**, 375 (2002); Krishnan, J., *Audit Committee Quality and Internal Control: An Empirical Analysis,* 80 **The Accounting Review**, 649 (2005); and Carcello, J and Neal. T., *Audit Committee Composition and Auditor Reporting,* 75 **The Accounting Review**, 453 (2000).

[17] Klein, A., *Audit Committee, Board of Director Characteristics, and Earnings Management.*

[18] Krishnan, J., *Audit Committee Quality and Internal Control: An Empirical Analysis.*

[19] Carcello, J. and Neal, T., *Audit Committee Composition and Auditor Reporting.*

[20] Pub. L. 107–204, 116 Stat. 745 (2002); 15 U.S.C. 7201 *et seq.*

reports.[21] During this time, the Commission also adopted significant corporate disclosure and financial reporting rules designed to improve the oversight and review processes of public companies related to their financial and other disclosures.[22]

The Sarbanes-Oxley Act amended the Exchange Act to define an audit committee as ''(A) a committee (or equivalent body) established by and amongst the board of directors of an issuer for the purpose of overseeing the accounting and financial reporting processes of the issuer and audits of the financial statements of the issuer; and (B) if no such committee exists with respect to an issuer, the entire board of directors of the issuer.'' [23] The Sarbanes-Oxley Act and the Commission's related implementation rules strengthened and expanded the role of the audit committee in overseeing a company's financial reporting process and independent auditor.

For example, Exchange Act Rule 10A–3,[24] which implemented Section 10A(m) of the Exchange Act, mandated that SROs prohibit the listing of any security of an issuer that does not comply with certain requirements, including:

- Each member of the audit committee of the issuer must be independent according to specified criteria;
- the audit committee of each issuer must be directly responsible for the appointment, compensation, retention, and oversight of the work of any registered public accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review, or attest services for the issuer, and each such registered public accounting firm must report directly to the audit committee;
- each audit committee must establish procedures for the receipt, retention, and treatment of complaints regarding accounting, internal accounting controls, or auditing matters, including procedures for the confidential, anonymous submission by employees of the issuer of concerns regarding questionable accounting or auditing matters;
- each audit committee must have the authority to engage independent counsel and other advisors, as it determines necessary to carry out its duties; and
- each issuer must provide appropriate funding for the audit committee.

The SROs also adopted additional listing requirements related to audit committees and strengthened the independence requirements for audit committee members.[25]

Also, Item 407(d)(5) of Regulation S–K, which was adopted to implement Section 407 of the Sarbanes-Oxley Act, defines the term ''audit committee financial expert.'' This item requires issuers to disclose whether they have at least one audit committee member that satisfies that definition. The Commission defines an audit committee financial expert as a person who has:

- An understanding of generally accepted accounting principles and financial statements;
- the ability to assess the general application of such principles in connection with the accounting for estimates, accruals and reserves;
- experience preparing, auditing, analyzing or evaluating financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the registrant's financial statements, or experience actively supervising one or more persons engaged in such activities;
- an understanding of internal control over financial reporting; and
- an understanding of audit committee functions.[26]

In addition to the listing requirements related to audit committees, Rule 2–07 of Regulation S–X was adopted to identify specific matters that auditors are required to report to audit committees.[27] Rule 2–07 requires public company auditors to report all critical accounting policies and practices, all alternative accounting treatments that have been discussed with management, and any other material written communications between the auditor and management.[28]

In the adopting release for Rule 2–07, the Commission referred to cautionary advice it issued in December 2001 regarding the disclosure of those accounting policies that management believes are most critical to the preparation of the issuer's financial statements.[29] These are often a subset of the accounting policies described in the issuer's financial statements. The cautionary advice indicated that ''critical'' accounting policies are those that are both most important to the portrayal of the issuer's financial condition and results and require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.[30] As part of that release, the Commission also advised:

Prior to finalizing and filing annual reports, audit committees should review the selection, application and disclosure of critical accounting policies. Consistent with auditing standards, audit committees should be apprised of the evaluative criteria used by management in their selection of the accounting principles and methods. Proactive discussions between the audit committee and the company's senior

[21] Section 101 of the Sarbanes-Oxley Act.

[22] *See, e.g.,* Release No. 33–8124, *Certification of Disclosure in Companies' Quarterly and Annual Reports* (Aug. 28, 2002) [67 FR 57276]; Release No. 34–47890, *Improper Influence on Conduct of Audits* (May, 20, 2003) [68 FR 31820]; Release No. 33–8177, *Disclosure Required by Sections 406 and 407 of the Sarbanes-Oxley Act of 2002* (Jan. 23, 2003) [68 FR 5110]; Release No. 33–8182, *Disclosure in Management's Discussion and Analysis About Off-Balance Sheet Arrangements and Aggregate Contractual Obligations* (Jan. 28, 2003) [68 FR 5982]; Release No. 33–8183, *Strengthening the Commission's Requirements Regarding Auditor Independence* (Jan. 28, 2003) [68 FR 6006]; and Release No. 33–8212, *Certification of Disclosure in Certain Exchange Act Reports* (Mar. 21, 2003) [68 FR 15600].

[23] *See* Section 3(a)(58) of the Exchange Act [15 U.S.C. 78c(a)(58)].

[24] 17 CFR 240.10A–3.

[25] *See* Release No. 34–48745, *NASD and NYSE Rulemaking: Relating to Corporate Governance* (Nov. 4, 2003); NYSE Listed Company Manual, Sections 303A.02 and 303A.07(a); and NASDAQ Listing Rules 5605(a)(2) and 5605(c)(2). For example, the NYSE requires audit committees to, among other things: (i) At least annually obtain a report from the independent auditor discussing certain quality control issues and relationships with its client, (ii) meet with management and the independent auditor, as applicable, to discuss the company's annual audited and quarterly unaudited financial statements, its press releases and public earnings guidance, and its risk assessment and management policies, (iii) meet separately, periodically, with management, the internal auditors, and the independent auditors, and (iv) review with the independent auditor any audit problems or difficulties and management's response. *See* NYSE Listed Company Manual, Section 303A.07.

[26] Item 407(d)(5)(ii) of Regulation S–K. Neither the NYSE nor NASDAQ use the term audit committee financial expert. However, both amended their listing standards to clarify that a member that satisfies the definition of an audit committee financial expert would also satisfy their respective listing standards that require at least one audit committee member with accounting or related financial management expertise. *See* Release No. 34–48745.

[27] *See* Release No. 34–47265, *Strengthening the Commission's Requirements Regarding Auditor Independence* (Jan. 28, 2003) [68 FR 6005]; 17 CFR 210.2–07.

[28] PCAOB standards also require certain auditor communications with audit committees, as discussed in Section IV.E of this Release.

[29] *See* Release No. 34–47265.

[30] *See* Release No. 33–8040, *Cautionary Advice Regarding Disclosure About Critical Accounting Policies* (Dec. 12, 2001) [66 FR 65013]. *See, also,* Release No. 33–8350, *Commission Guidance Regarding Management's Discussion and Analysis of Financial Condition and Results of Operations* (Dec. 19, 2003) [68 FR 75056].

management and auditor about critical accounting policies are appropriate.[31]

The way audit committees execute their oversight of auditors has evolved since the Sarbanes-Oxley Act. For instance, while the PCAOB does not have jurisdiction over audit committees, it collects information through its inspection program that could be useful for audit committees in overseeing their companies' auditors. Among other responsibilities, the PCAOB is required to inspect registered public accounting firms annually (for firms that regularly provide audit reports for more than 100 issuers) or triennially (for firms that regularly provide audit reports for 100 or fewer issuers).[32] Consistent with the limitations of the Sarbanes-Oxley Act, the PCAOB makes certain information available publicly, such as public portions of inspection reports, disciplinary sanctions, and information in annual and special reports filed by audit firms. In addition, in part in response to audit committee members' requests, the PCAOB provides information to help audit committees better understand the PCAOB inspection process, including questions they may wish to ask their audit firms to better understand and assess the firm's inspection results and evaluate audit quality.[33] The PCAOB also includes an executive summary for its general inspection reports and provides insights within Staff Audit Practice Alerts to further assist audit committee oversight of the auditor.[34]

III. Current Audit Committee Disclosure Requirements

A. Audit Committee Report and Other Disclosures About the Audit Committee

In 1999, following the recommendations from the Blue Ribbon Committee's report, the Commission adopted new rules to improve disclosure relating to the functioning, governance and independence of audit committees and to enhance the credibility of financial statements of public companies.[35] These reporting requirements for audit committees[36] predate the Sarbanes-Oxley Act and the SRO listing standards, which expanded the role of the audit committee in the financial reporting process.

Disclosure requirements for the audit committee report are contained in Item 407 of Regulation S–K. The disclosure is only required in the proxy or information statement relating to a registrant's annual meeting where directors are elected or chosen by written consents.[37] An audit committee is required to make certain statements related to its responsibilities for overseeing financial reporting, internal control, and the audit. These statements include that the audit committee has:

- Reviewed and discussed the audited financial statements with management;
- discussed with the independent auditor the matters required by AU sec. 380, *Communication with Audit Committees;*
- received the required written communications from the independent accountant concerning independence, as required by the rules of the PCAOB, and has discussed with the independent accountant his or her independence; and
- recommended to the board of directors that the audited financial statements be included in the company's annual report on Form 10–K (or other form of annual report) for the last fiscal year for filing with the Commission.[38]

The name of each member of the company's audit committee must appear below these required disclosures.

Item 407 also requires disclosure of whether the audit committee members are independent, the number of meetings held, and certain information about member attendance at these meetings, in addition to the following:

- Whether or not the audit committee has a charter; [39]
- The circumstances surrounding any appointment of a director to the audit committee who is not independent; [40]
- Whether there is a separately-designated standing audit committee or a committee performing similar functions, and the identity of each member of such committee; [41] and
- Whether or not the registrant has at least one audit committee financial expert serving on its audit committee.[42]

If the audit committee has a charter, the registrant should either disclose where security holders may access a current copy of the audit committee's charter or include a copy of the charter in an appendix to the registrant's proxy or information statement that is provided to security holders at least once every three fiscal years, or sooner if the charter has been materially amended since the beginning of the registrant's last fiscal year.[43]

B. Disclosure Requirements Regarding Preapproval of Services and Auditor Fees

The Sarbanes-Oxley Act also enhanced the ability of audit committees to promote auditor independence. Section 202 of the Sarbanes-Oxley Act added Section 10A(i) of the Exchange Act, which gave the audit committee responsibility to preapprove all audit and permissible non-audit services provided by the independent auditor.[44] In 2003, the Commission finalized its rules to implement Section 10A(i) of the Exchange Act.[45] Under the rules, the audit committee is required to preapprove all permissible non-audit services and all audit, review, or attest engagements required under the securities laws. Additionally, the issuer must provide disclosure of the audit committee's preapproval policies and procedures in proxy statements related to the election of directors or the ratification of the independent public accountant.[46]

Concurrently, the Commission adopted rules that changed both the types of fees paid to the independent auditor that must be described and the number of years for which the disclosures must be provided.[47] As a result, an issuer is required to disclose the fees paid to its independent auditor for each of the two most recent fiscal years, separated into the following four categories: (1) Audit Fees, (2) Audit-Related Fees, (3) Tax Fees, and (4) All Other Fees.[48] Additionally, registrants are required to describe the nature of the services provided that are categorized as Audit-Related Fees and All Other Fees. The registrant is also required to

[31] Release No. 33–8040.

[32] Section 104 of the Sarbanes-Oxley Act.

[33] *See http://pcaobus.org/Inspections/Documents/Inspection_Information_for_Audit_Committees.pdf.*

[34] *See, e.g. http://pcaobus.org/Inspections/Documents/Executive_Summary_02252013_Release_2013_001.pdf, http://pcaobus.org/Standards/QandA/10-24-2013_SAPA_11.pdf* at 36 and *http://pcaobus.org/Standards/QandA/9-9-14_SAPA_12.pdf* at page 33.

[35] *See, e.g.,* Release No. 34–42266 (stating that additional disclosures about a company's audit committee and its interaction with the company's auditors and management will promote investor confidence in the integrity of the financial reporting process).

[36] Audit committee reports are currently reported by issuers pursuant to the disclosure requirements of Regulation S–K and closed-end investment companies through the proxy statement requirements of Item 22(b)(16) of Schedule 14A.

[37] *See* Instruction 3 to Item 407(d) of Regulation S–K.

[38] *See* Item 407(d)(3) of Regulation S–K.

[39] *See* Item 407(d)(1) of Regulation S–K.

[40] *See* Item 407(d)(2) of Regulation S–K.

[41] *See* Item 407(d)(4) of Regulation S–K.

[42] *See* Item 407(d)(5) of Regulation S–K.

[43] *See* Item 407(d)(1) of Regulation S–K.

[44] Section 202 of the Sarbanes-Oxley Act; 15 U.S.C. 78j–1(i)(1)(A).

[45] *See* Release No. 34–47265.

[46] *See* Item 9(e)(5) of Schedule 14A [17 CFR 240.14a–101].

[47] *See* Release No. 34–47265.

[48] *See* Item 9(e) of Schedule 14A.

disclose the percentage of services in the Audit-Related Fees, Tax Fees, and All Other Fees captions that were approved by the audit committee pursuant to its preapproval policies and procedures.[49]

C. Disclosure Requirements Regarding Proposal To Ratify Selection of Independent Auditors

While the audit committees of listed issuers are required to appoint the issuer's auditors, many issuers solicit the approval or ratification of the independent auditors from shareholders.[50] If such a proposal is solicited, the issuer must provide the information required by Item 9 of Schedule 14A. Specifically, in addition to the fee information and preapproval policies noted above, shareholders of listed issuers must receive disclosure of the following:

- The name of the auditor selected or being recommended for the current year;
- the auditor for the most recently completed fiscal year, if different from the one subject to the ratification;
- whether a representative from the auditor's firm will be present at the meeting, will have the opportunity to make a statement, and be available to respond to questions; and
- information regarding dismissed or resigned auditors as required by Item 304(a) of Regulation S–K.[51]

The rules do not require issuers to provide information about the audit committee's process and reasons that lead to the selection of the independent auditor subject to the ratification solicitation.

IV. Reasons To Seek Comment on the Audit Committee Reporting Requirements

While current audit committee reporting requirements provide information about the role of the audit committee with respect to its oversight of the auditor, these disclosures do not describe how the audit committee executes its responsibilities. The ways in which an audit committee discharges its responsibilities can be influenced by its composition and the environment in which it operates. As discussed below, the fact that a significant number of audit committees voluntarily provide information beyond the disclosures required by our current rules raises a question of whether there may be market demand for such information.[52] Similarly, during a series of roundtables attended by audit committee members from various jurisdictions, participants stated that investors and other stakeholders have requested greater transparency about audit committee activities.[53] However, there appears to be limited research as to why some companies provide voluntary disclosure regarding audit committee activities and whether and how such additional information impacts investors' investment or voting decisions. For instance, variability in the nature and extent of current voluntary disclosures could, to some extent, be the result of tailoring the disclosures to a company's facts and circumstances.

Providing additional disclosure about the audit committee's oversight of the independent auditor could further inform investors about the oversight process and provide them with useful context for audit committee decisions. It may also enable investors to differentiate between companies based on the quality of audit committee oversight, and determine whether such differences in quality of oversight may contribute to differences in performance or quality of financial reporting among companies. Therefore, the Commission is seeking feedback to better understand whether additional audit committee reporting requirements related to oversight of the auditor would be useful to investors and if so, what information would be useful.[54]

A. Public Discussion of the Need for Updated Audit Committee Reporting

Investors, organizations representing audit committee members, and auditors are among those that have expressed the need for audit committees to evaluate their disclosures and consider whether improvements can be made to provide investors with relevant information that more transparently conveys the oversight responsibilities performed by the audit committee relative to an issuer's auditor. For example, a group of corporate governance and policy organizations has expressed the view that public company audit committee reporting can and should be strengthened.[55] At a meeting in June of 2013, several delegates from the Audit Committee Chair Advisory Council acknowledged that ''[f]rankly, we don't do a good job of communicating what we do. The public doesn't see all the work we do, quarter after quarter.'' [56]

Investors have also increased their focus on the activities and transparency of audit committees, including those activities related to enhancing audit quality through oversight of the independent auditor. Some investors have sought greater disclosure from audit committees of a number of public companies about matters such as the responsibility of the audit committee for the appointment, compensation, and oversight of the external auditor; audit firm tenure; audit firm fee determinations; and audit committee involvement in the selection of the audit engagement partner.[57] Institutional investor groups have called for additional audit committee disclosures as part of their published ''good corporate governance policies.'' [58]

---

[49] *Id.*

[50] *See* Ernst & Young, ''Audit Committee Reporting to Shareholders: Going Beyond the Minimum,'' (Feb. 2013), available at *http://www.ey.com/Publication/vwLUAssets/Audit_committee_reporting_to_shareholders%3A_going_beyond_the_minimum/%24FILE/Audit_committee_reporting_CF0039.pdf* (noting that more than 90 percent of Fortune 100 companies seek annual shareholder ratification of the auditor chosen by the audit committee); Ernst & Young, ''Let's Talk: Governance—Audit Committee Reporting to Shareholders 2014 Proxy Season Update,'' (Aug. 2014), available at *http://www.ey.com/Publication/vwLUAssets/ey-lets-talk-governance-august-2014/$FILE/ey-lets-talk-governance-august-2014.pdf.*

[51] Item 9 of Schedule 14A (referring to Item 304(a) of Regulation S–K [17 CFR 229.304(a)]).

[52] *See* CAQ and Audit Analytics, ''2014 Audit Committee Transparency Barometer,'' (Dec. 2, 2014), available at *http://www.thecaq.org/docs/reports-and-publications/2014-audit-committee-transparency-barometer.pdf?sfvrsn=2* (''Audit Committee Transparency Barometer''). In addition, a report based on a 2014 review of proxy disclosures of Fortune 100 companies noted an upward trend in voluntary disclosures by audit committees since 2012. *See also* Ernst & Young, ''Let's Talk: Governance—Audit Committee Reporting to Shareholders 2014 Proxy Season Update,'' (Aug. 2014).

[53] *See* Federation of European Accountants, the Institute of Chartered Accountants Australia and the CAQ, ''Global Observations on the Role of the Audit Committee,'' (May 13, 2013), available at *http://www.thecaq.org/docs/reports-and-publications/globalobservationsontheroleoftheauditcommittee.pdf?sfvrsn=2* (''Global Observations'').

[54] For example, an academic paper indicates that events that negatively impact the image of a company, such as a reporting failure, have a direct impact on turnover of audit committee members, while negative disclosures alone about audit committee members appear to have limited or mixed impact on member turnover. *See* Kachelmeier, S. *et al., Why Do Ineffective Audit Committee Members Experience Turnover*? (September 18, 2013), available at *http://ssrn.com/abstract=1920850.*

[55] *See* A Call to Action *supra* note 2.

[56] *Id.* at 7, (quoting National Association of Corporate Directors (''NACD'') Summary of Proceedings, Audit Committee Chair Advisory Council, at 6 (June 19, 2013), available at *http://www.nacdonline.org/Resources/Article.cfm?ItemNumber=7284*). The Audit Committee Chair Advisory Council is a group of audit committee chairs, shareholder representatives, regulators and other stakeholders that discuss ways to improve communications between corporations and stakeholders, improve audit committee practices, and give voice to audit committee members.

[57] *See* A Call to Action at 6 (describing investors' increasing interest and focus on the audit committee).

[58] *See, e.g.,* Council of Institutional Investors, Policies on Corporate Governance, Section 2.13 (updated Sept. 27, 2013), available at *http://www.cii.org/corp_gov_policies#BOD.*

Internationally, there appears to be interest in improving the communication coming from audit committees. For example, one of the themes that emerged at a 2013 summit hosted by the members of the Audit Committee Leadership Networks in North America and Europe was the recognition that ''[r]egulators, policy-makers, and many investors would benefit from a more robust understanding of what the public company audit committee does and how it oversees the external audit firm and performs its other responsibilities.'' [59]

Some audit committee members, however, see additional reporting as possibly contributing to a state of ''disclosure overload.'' [60] Some are also skeptical whether additional reporting would be helpful to ''stakeholders,'' ''in light of a lack of interest in audit committee reporting currently required.'' [61] Others have suggested the need for principles-based reporting to allow for flexibility and to avoid a ''one size fits all'' approach.[62] Given these varied views on the usefulness and relevance of audit committee disclosures, the Commission is seeking input on whether and how additional reporting may be useful to investors.

B. Divergence in Current Audit Committee Reporting Practice

Some issuers, including their audit committees, already provide disclosures that go beyond the required disclosures.[63] For example, a report by the CAQ and Audit Analytics reviewing the 2014 proxy disclosures of 1,500 Standard & Poor's (''S&P'') composite companies, including the S&P 500 (''S&P 500'') companies, the S&P MidCap 400 (''S&P MidCap'') companies, and the S&P SmallCap 600 (''S&P SmallCap'') companies noted the following:

- 83% of S&P 500, 69% of S&P MidCap, and 58% of S&P SmallCap companies discussed how non-audit services may impact auditor independence;
- 47% of S&P 500, 42% of S&P MidCap, and 50% of S&P SmallCap companies disclosed the length of time an auditor has been engaged;
- 13% of S&P 500, 10% of S&P MidCap, and 8% of S&P SmallCap companies discussed the audit committee's considerations of qualifications, geographic reach, and firm expertise when appointing the auditor;
- 8% of S&P 500, 7% of S&P MidCap, and 15% of S&P SmallCap companies discussed the criteria considered when evaluating the audit firm;
- 3% of S&P 500, 2% of S&P MidCap, and 1% of S&P SmallCap companies disclosed the significant areas addressed with the auditor;
- 13% of S&P 500 and 1% of both S&P MidCap and S&P SmallCap companies included an explicit statement that the audit committee is involved in the selection of the audit engagement partner; and
- 13% of S&P 500, 4% of S&P MidCap and 1% of S&P SmallCap companies discussed audit fees and their connection to audit quality.[64]

These additional disclosures are voluntary, not consistently provided and may vary among registrants, depending on company characteristics.[65] Some audit committees may disclose only what is specifically required, for a variety of reasons, for instance, to avoid legal exposure,[66] to avoid incremental associated efforts of the disclosure process, or because they do not believe such additional information would be useful to investors.

C. PCAOB Standard-Setting Projects

The PCAOB is engaged in standard-setting initiatives that could result in additional information being disclosed related to the auditor and its work. One project has been exploring a requirement that the auditor disclose, in the auditor's report, the name of the engagement partner as well as the names, locations, and extent of participation of other independent public accounting firms that took part in the audit and the locations and extent of participation of other persons not employed by the auditor that took part in the audit.[67]

Some investors have indicated that the engagement partner's track record compiled from the disclosure of the partner's name would be relevant in ''overseeing the audit committees and determining how to cast votes on more than two thousand proposals that are presented annually to shareholders on whether to ratify the board's choice of outside auditor.'' [68] Audit firms and other commenters questioned whether the auditor's report is the most appropriate place to provide this information, for example, due to potential liability concerns.[69] As a

---

[59] *See* A Call to Action at 7, (citing Tapestry Networks, ViewPoints, Issue 22, p.1 (May 2, 2013), available at *http://www.tapestrynetworks.com/initiatives/corporate-governance/global-audit-committee-leadership-networks/upload/Tapestry_EY_ACLS_Summit_View22-May13.pdf*).

[60] *See* Global Observations at 7; *See also* Center for Capital Markets Competitiveness, Corporate Disclosure Effectiveness: Ensuring a Balanced System that Informs and Protects Investors and Facilitates Capital Formation, (Jul. 28, 2014), available at *http://www.centerforcapitalmarkets.com/wp-content/uploads/2014/07/CCMC_Disclosure_Reform_Final_7-28-20141.pdf.*

[61] *Id.*

[62] *Id.*

[63] *See, e.g.,* A Call to Action at 7.

[64] *See* Audit Committee Transparency Barometer.

[65] According to the observations of an accounting firm, variability in reporting may also be the result of, among other things, differences in regulatory and listing requirements across jurisdictions and interest by investors and others for disclosures that go beyond the minimum. *See* Ernst & Young, ''Enhancing audit committee transparency: Themes in audit committee disclosures in Australia, Canada, Singapore, the UK and the US'' (Mar. 2015), available at *http://www.ey.com/Publication/vwLUAssets/EY-Enhanced-audit-committee-transparency-themes-in-audit-committee-disclosures/$FILE/EY-Enhanced-audit-committee-transparency-themes-in-audit-committee-disclosures.pdf.*

[66] *See* NACD Summary of Proceedings, Audit Committee Chair Advisory Council, (June 19, 2013).

[67] *See* PCAOB Release No. 2013–009, *Improving Transparency Through Disclosure of Engagement Partner and Certain Other Participants in Audits* (Dec. 4, 2013), available at *http://pcaobus.org/Rules/Rulemaking/Pages/Docket029.aspx.* Similar requirements exist in other jurisdictions, including but not limited to, the European Union, United Kingdom, Australia, Sweden, China, and Taiwan. Academic research has supported that, in at least these particular jurisdictions, information about individual audit partners, over and above information about the audit firm, is relevant to financial statement users for both public and private firms. *See* Carcello, J. and C. Li., *Cost and Benefits of Requiring an Engagement Partner Signature: Recent Experience in the United Kingdom,* 88 The Accounting Review, 1511 (2013); Aobdia, D. et al., *Capital Market Consequences of Individual Audit Partners, The Accounting Review*, (forthcoming) available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2321333* (discussing Taiwan's mandate regarding disclosure of individual audit partners); Knechel, R. et al., *Does the Identity of Engagement Partners Matter? An Analysis of Audit Partner Reporting Decisions,* Contemporary Accounting Research, (forthcoming) available at *https://www.caaa.ca/_files/file.php?fileid=filerSDAxJgThx&filename=file_Knechel__Vanstraelen__Zerni__Does_the_Identity_of_Engagement_Partners_Matter.pdf* (discussing Sweden's disclosure requirement); Gul, F.A. et al., *Do Individual Auditors Affect Audit Quality? Evidence From Archival Data,* 88 The Accounting Review, 1993 (2013) (discussing China's disclosure requirement); and The Association of Chartered Certified Accountants and Macquarie University, *The Drivers of Audit Quality: Views From Australian CFOs,* (2014), available at *http://www.accaglobal.com/content/dam/acca/global/PDF-technical/audit-publications/pol-tp-daq1(cfo)-drivers-audit-quality.pdf.*

[68] *See,* Reproposed Rule Comment Letter of the Council of Institutional Investors (Aug. 15, 2014), available at *http://pcaobus.org/Rules/Rulemaking/Pages/Docket029Comments.aspx.*

[69] Some commenters voiced the concern, for example, that the PCAOB's December 2013 reproposal on disclosure of the engagement partner and other participants in the audit may lead to the engagement partner and other participants (other independent public accounting firms and other persons not employed by the auditor) being deemed experts for purposes of liability under Section 11 of the Securities Act of 1933 (''Securities Act''). *See, e.g.,* Reproposed Rule Comment Letters of Deloitte & Touche LLP (Feb. 3, 2014), PricewaterhouseCoopers LLP (Feb 4, 2014), Ernst &

Continued

result, the PCAOB is seeking further comment on whether these concerns would be sufficiently addressed by providing the information in an alternative location, outside of the auditor's report and outside of the issuer's filing.[70]

Commenters on the PCAOB's proposal have also suggested that it may be more appropriate for any requirement for proposed disclosures to be considered by the Commission, rather than the PCAOB, because having these disclosures made by the issuer, in the audit committee report or proxy statement, appears aligned with the responsibilities outlined in Section 10A(m) of the Exchange Act.[71] Requiring any such disclosure by the audit committee would require Commission action because the PCAOB does not have authority over issuer disclosures.

Another PCAOB initiative could result in disclosure of additional information about the audit and the auditor, including the auditor's tenure, in the auditor's report.[72] Some commenters believe the disclosure of auditor tenure in the auditor's report would be useful because it could help investors evaluate the audit committee's oversight of the auditor (including its rationale for selecting or retaining the auditor) and develop a basis for shareholders to ratify the audit committee's selection of the auditor, when applicable.[73] Others raised concerns about the lack of evidence correlating auditor tenure and audit quality and whether the placement of this data in the auditor's report would imply that some correlation exists.[74] Some believe that issuer filings with the Commission would be a more appropriate location for this disclosure.[75]

D. Initiatives in Other Jurisdictions To Enhance Audit Committee Reporting

Other jurisdictions also have been exploring expanded reporting with respect to audit committees. For example, in 2012, the UK Financial Reporting Council adopted amendments to its Corporate Governance Code that require a separate section of the annual report that describes the work of the audit committee in discharging its responsibilities.[76] The report now includes, among other things, the significant issues considered in relation to the financial statements and how they were addressed; how the audit committee assessed the effectiveness of the audit process; the approach to appointing the auditor and how objectivity and independence are safeguarded relative to non-audit services; as well as information on the length of tenure of the current audit firm and when a tender was last conducted.

The International Auditing and Assurance Standards Board (the ''IAASB'') has also acknowledged the merits of enhanced disclosure around the activities of the audit committee. In connection with its efforts to develop a framework for audit quality, it has stated:

> While users are likely to conclude that the active involvement of a high-quality audit committee will have a positive impact on audit quality, there is considerable variability in the degree to which audit committees communicate to users the way they have fulfilled these responsibilities. There is potential for fuller disclosure of the activities of audit committees to benefit both actual audit quality and user perception of it. Consequently, some countries are actively exploring whether to include more information in annual reports about the activities of audit committees in relation to the external audit.[77]

An amendment to the Directive on Statutory Audits adopted by the European Union in April 2014 [78] included measures to strengthen the independence of statutory auditors, make the audit report more informative, and strengthen audit supervision. The Directive amendment reinforces the role of the audit committee by expanding its responsibilities in ensuring the quality of the audit being performed, giving it responsibility for the auditor appointment process, and enhancing the auditor's reporting requirements to the audit committee.[79] Specifically, the Directive requires that the audit committee explain to the issuer's board how the auditor contributed to the integrity of the financial statements and how the committee assessed threats to the auditor's independence and implemented appropriate safeguards, and also requires the audit committee obtain a detailed report from the auditor on the results of the audit.

Corporate governance practices, regulations, and enforcement vary across countries.[80] Therefore, the Commission is interested in understanding whether enhanced audit committee disclosures would result in benefits for U.S. investors.

E. References to PCAOB Auditing Standards

With the Commission's approval of PCAOB Auditing Standard No. 16, *Communications with Audit Committees* (''AS 16'') in 2012, changes

---

Young LLP (Feb 12, 2014), Society of Corporate Secretaries & Governance Professionals (Mar. 12, 2014), available at *http://pcaobus.org/Rules/Rulemaking/Pages/Docket029Comments.aspx.*

[70] PCAOB Release No. 2015–004, *Supplemental Request for Comment: Rules to Require Disclosure of Certain Audit Participants on a New PCAOB Form* (June 30, 2015), available at *http://pcaobus.org/Rules/Rulemaking/Pages/Docket029.aspx.*

[71] *See* Reproposed Rule Comment Letters of Dennis R. Beresford (Jan 6, 2014), Institute of Management Accountants (Jan 21, 2014), Charles Noski (Jan 13, 2014), James L. Fuehrmeyer, Jr. (Jan 22, 2014), Audit and Assurance Services Committee of the Illinois CPA Society (Feb 3, 2014), Professional Standards Committee of the Texas Society of Certified Public Accountants (Feb 3, 2014), CAQ (Feb 3, 2014), Auditing Standards and SEC Committees of the New York State Society of Certified Public Accountants (Feb 4, 2014), PricewaterhouseCoopers LLP (Feb 4, 2014), Ernst & Young LLP (Feb 12, 2014), Crowe Horwath (Feb 12, 2014), G. Lawrence Buhl, CPA (Mar 5, 2014), U.S. Chamber of Commerce, Center for Capital Market Competitiveness (Mar 10, 2014), KPMG LLP (Mar 13, 2014), Financial Management and Assurance, U.S. Government Accountability Office (Mar 17, 2014), Robert N. Waxman, CPA (Mar 17, 2014), and CohnReznik LLP (Mar 17, 2014), available at *http://pcaobus.org/Rules/Rulemaking/Pages/Docket029Comments.aspx.*

[72] *See* PCAOB Release No. 2013–005, *Proposed Auditing Standards on the Auditor's Report and the Auditor's Responsibilities Regarding Other Information and Related Amendments* (Aug. 13, 2013), available at *http://pcaobus.org/Rules/Rulemaking/Pages/Docket034.aspx.*

[73] *See, e.g.,* Proposed Rule Comment Letters of Counsel of Institutional Investors (Dec. 16, 2013), CFA Institute (Dec. 30, 2013), and Peter Clapman (Dec. 5, 2013), available at *http://pcaobus.org/Rules/Rulemaking/Pages/Docket034Comments.aspx.*

[74] *See, e.g.,* Proposed Rule Comment Letters of Deloitte and Touche, LLP (Dec. 11, 2013), NAREIT (Dec. 11, 2013), Tyson Foods, Inc. (Dec. 11, 2013), Nucor (Dec. 10, 2013), Williams (Dec. 4, 2013), Acuity Brands (Nov. 26, 2013), available at *http://pcaobus.org/Rules/Rulemaking/Pages/Docket034Comments.aspx.* Despite commenters' views, there is some academic evidence connecting auditor tenure and audit quality, which is discussed in Section VI.C.3.

[75] *See, e.g.,* Proposed Rule Comment Letters of National Association of Corporate Directors (Dec. 11, 2013) (suggesting that the Commission should consider inclusion of tenure information in proxy statements if there is sufficient investor interests), Federation of European Accountants (Dec. 11, 2013) (stating its belief that an auditor could disclose tenure if it is not already disclosed in management's report or annual financial statements), Institute of Management Accountants (Nov. 12, 2013) (objecting to inclusion in the auditor's report and noting that it may be a corporate governance matter included in the proxy statement), and BlackRock, Inc. (Oct. 30, 2013) (not objecting to the inclusion while noting that inclusion in an issuer filing may be preferable), available at *http://pcaobus.org/Rules/Rulemaking/Pages/Docket034Comments.aspx.*

[76] Section C.3.8 of the UK Corporate Governance Code, available at *https://www.frc.org.uk/Our-Work/Codes-Standards/Corporate-governance/UK-Corporate-Governance-Code.aspx.*

[77] IAASB, ''A Framework for Audit Quality,'' p. 48 (Jan. 15, 2013), available at *http://www.ifac.org/publications-resources/framework-audit-quality.*

[78] *See* Directive 2014/56/EU of the European Parliament and Council of April 16, 2014, available at *http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0056&from=EN.*

[79] *Id.*

[80] OECD, ''Corporate Governance Factbook,'' (Feb. 2014), available at *http://www.oecd.org/daf/ca/CorporateGovernanceFactbook.pdf.*

to the required audit committee communications by the auditor, among others, were incorporated within PCAOB auditing standards and superseded the prior communication requirements in AU sec. 380.[81] As a result, Item 407(d) of Regulation S–K is no longer current because it references AU sec. 380. In addition to this outdated reference, there are required communications in other PCAOB standards that are not reflected in current audit committee disclosure requirements.[82] Moreover, the existing audit committee report does not address the Commission's communication requirements in Rule 2–07 of Regulation S–X.

The change to the communication requirements within the auditing standards without a corresponding change in the audit committee reporting requirements has resulted in divergent practices. For example, some companies' audit committee reports refer to matters required to be communicated under AS 16; others refer to matters required to be communicated under all PCAOB standards. Still others continue to refer to communications under AU sec. 380, even though AU sec. 380 has been superseded. These differences in reporting may result in confusion among readers of the audit committee reports as to whether appropriate auditor and audit committee communications have occurred and therefore, suggest a need to consider updating the audit committee disclosure requirements.

V. Focus on Audit Committee Oversight of the Auditor

The Commission is interested in understanding whether changes should be made to required disclosures about audit committees regarding oversight of the audit and the auditor relationship. The Commission is also interested in understanding whether this additional information would help inform investment decisions and, where applicable, voting decisions regarding the ratification of auditors and the election of directors who are members of the audit committee.

Request for Comment

1. Do the current audit committee reporting requirements result in disclosures that provide investors with useful information? Why or why not? Are there changes to the current audit committee disclosure requirements that the Commission should consider that would better inform investors about the audit committee's oversight of the audit and the independent auditor?

2. Are there existing disclosure requirements in this area that should be revised, reconsidered or removed? If so, which ones? How and why should they be changed?

3. Would investors find additional or different audit committee reporting requirements useful given the committee's strengthened and expanded role in overseeing a company's independent auditor that resulted from the Sarbanes-Oxley Act? For example, to what extent is information regarding how the audit committee discharges its responsibilities useful to investors given the nature of the requirements and likely variability in performance? Also, are there particular audit committee responsibilities for which information would be likely more or less useful and why?

4. What, if any, are potential challenges that issuers or audit committees may face that the Commission should consider as it assesses potential changes to disclosures in this area?

5. Are there other areas where changes to the current audit committee disclosure requirements would be desirable? If so, what are they?

6. Should the audit committee provide disclosure of its work in other areas, for example, its oversight of the financial reporting process or the internal audit function? If so, what types of disclosures would be most useful and why?

VI. Potential Changes to Disclosures

The Commission is seeking comment on potential changes to required disclosures regarding an audit committee's role and responsibilities relative to the audit and the auditor, and other potential related changes. The Commission is seeking feedback on the disclosure requirements to determine the extent to which adding, removing, or modifying certain audit committee disclosures would enhance the usefulness of such disclosures for investors.

The purpose of the disclosures discussed below would be to address the audit committee's responsibilities with respect to the appointment, compensation, retention, and oversight of the work of the registered public accounting firm and better inform investors about how the audit committee executes those responsibilities. The Commission is seeking feedback on the content and scope of the audit committee disclosures, as well as commenters' views on which of these disclosures, if any, would be most useful in conveying how the audit committee executes its oversight of the auditor and whether such enhanced disclosures would be useful to investors' investment or voting decisions.

Such disclosures could provide information that frequently is either not readily available or inconsistently available today to investors. These disclosures could also minimize the ''expectations gap'' that some have expressed exists between investors and the audit committee regarding the role of the audit committee.[83] In a series of roundtables organized by the CAQ, the Federation of European Accountants, and the Institute of Chartered Accountants Australia in January and February of 2013, participants noted that stakeholders' expectations are not consistent with the audit committee's actual responsibilities and how they are discharged, which results in the current expectations gap.[84]

For purposes of this concept release, the Commission has categorized the specific audit committee disclosures about which the Commission is interested in receiving comment into three groups: the audit committee's oversight of the auditor, the audit committee's process for selecting the auditor, and the audit committee's consideration of the qualifications of the audit firm and certain members of the engagement team when selecting the audit firm. The Commission is also interested in receiving comments on where the audit committee disclosures should be located and whether there are specific concerns relating to smaller reporting companies [85] and emerging growth companies.[86] In Section VII of this release, the Commission also asks more general questions with respect to any potential new disclosures.

[81] *See* Release No. 34–68453, *Public Company Accounting Oversight Board; Order Granting Approval of Proposed Rules on Auditing Standard No. 16, Communications with Audit Committees, and Related and Transitional Amendments to PCAOB Standards* (Dec. 17, 2012) [77 FR 75689].

[82] Appendix B to AS 16 identifies other PCAOB rules and standards that require audit committee communications, such as communications related to an audit of internal control over financial reporting that is integrated with an audit of financial statements, related party transactions, fraud considerations, and illegal acts, among others.

[83] *See* Global Observations.

[84] *Id.*

[85] *See* Rule 12b–2 of the Exchange Act [17 CFR 240.12b–2].

[86] *See* Section 2(a)(19) of the Securities Act [15 U.S.C. 77b(a)(19)] and Section 3(a)(80) of the Exchange Act [15 U.S.C. 78c(a)(80)].

A. Audit Committee's Oversight of the Auditor

1. Additional Information Regarding the Communications Between the Audit Committee and the Auditor

As noted in Section III.A, the audit committee report today discloses whether certain communications have occurred. Potential additional disclosures about the communications might provide additional information about the actions the audit committee has taken during the most recently completed fiscal year to oversee the auditor and the audit. Also, as previously discussed, current requirements for the audit committee report contain an outdated reference to AU sec. 380, which was superseded by AS 16. In addition to correcting this reference, the Commission is considering whether to require additional qualitative disclosures about the nature and timing of the required communications between the audit committee and the auditor.

For instance, the PCAOB has required that the auditor communicate with the audit committee prior to the issuance of the auditor's report.[87] The disclosure rules could require the audit committee to discuss not just whether and when all of the required communications occurred, but also the audit committee's consideration of the matters discussed. Such communications and related disclosures could address, for instance, the nature of the audit committee's communications with the auditor related to items such as the auditor's overall audit strategy, timing, significant risks identified, nature and extent of specialized skill used in the audit, planned use of other independent public accounting firms or other persons, planned use of internal audit, basis for determining that the auditor can serve as principal auditor, and results of the audit, among others, and how the audit committee considered these items in its oversight of the independent auditor.

Request for Comment

7. Should the Commission consider modifying any of the existing audit committee disclosure requirements regarding communications with the auditor? If so, which disclosure requirements should the Commission consider modifying and what modifications should be made?

8. Should the Commission update the existing disclosure requirements to include all communications required by Commission rules and PCAOB standards rather than only those required by AS 16? Would expanding the requirements to encompass all required communications create difficulties for issuers or audit committees in complying with the disclosure requirements? Why or why not?

9. Should there be disclosure about the audit committee's consideration beyond a statement that they have received and discussed the matters communicated by the auditor as required by PCAOB Rule 3526, *Communication with Audit Committees Concerning Independence*? If so, what should be included in the disclosure?

10. Currently, audit committees are only required to disclose whether the required communications occurred. Are statements confirming that required communications have occurred helpful disclosure? Why or why not?

11. Should there be disclosures regarding the nature or substance of the required communications between the auditor and the audit committee? Are there other types of communications between the audit committee and the auditor about which the Commission should consider mandating disclosure?

12. Should such discussion be required to address all required communication topics or a subset of overarching topics related to how the auditor planned and performed the audit? For instance, should the audit committee disclose information regarding how the audit committee considered the nature of the required communications that were made under paragraphs 9 and 10 of AS 16 as it relates to significant risks identified, nature and extent of specialized skill used in the audit, planned use of the company's internal auditors, involvement by other independent public accounting firms or other persons, and the basis for determining that the auditor can serve as the principal auditor in its oversight of the independent auditor? Should the audit committee disclose how it dealt with disagreements between company management and the auditor? If so, what should be included in the disclosure? Are there other categories of the communications between auditors and the audit committee that should be considered for disclosure?

13. For audits involving multiple locations, should the audit committee report disclose information regarding how the audit committee considered, in its oversight of the auditor, the scope of the audit, locations visited by the auditor, and the relative amount of account balances related to such locations compared to the consolidated financial statements?

14. Communications between the auditor and the audit committee may not be limited to the items required by Commission rules and PCAOB standards. Should the audit committee report be required to disclose any information about the extent to which additional matters were discussed with the auditor? If so, what level of detail should be required?

15. Are there benefits, costs or unintended consequences that could result from requiring disclosure that goes beyond a statement that the required discussions have occurred? How would the disclosures be used by institutional and retail investors, investment advisers, and proxy advisory firms in making voting decisions and recommendations on matters such as director elections, executive compensation, or shareholder proposals, among others?

16. Would the potential disclosures referenced here be decision-useful to investors? If so, would it be sufficient for the disclosure to address the consideration given by the audit committee without necessarily disclosing the underlying substance? Would disclosing the substance of the communications between the audit committee and the auditor be useful to investors? Why or why not?

17. Could these potential disclosures chill communications between the audit committee and the auditor? If so, how? Could they reveal proprietary information about the issuer or the audit methodology? If so, how?

2. The Frequency With Which the Audit Committee Met With the Auditor

The audit committee and auditor can determine the timing, frequency and forum (*e.g.,* in-person or telephonically and extent of committee participation) for meetings, provided that required communications are made in accordance with PCAOB standards and Commission rules.[88] Also, there are listing requirements that the audit committee meet separately and periodically with management, the internal auditor, and the independent auditor.[89] Recognizing that the number of audit committee meetings is already required to be disclosed,[90] requiring additional disclosure about the specific meetings with the auditor may provide

[87] *See* paragraph 26 of AS 16.

[88] AS 16 and Rule 2–07 of Regulation S–X.

[89] *See* NYSE Listed Company Manual, Section 303A.07(E) and the Commentary to Section 303A.07(E).

[90] *See* Item 407(b)(3) of Regulation S–K.

additional insight into the audit committee's oversight of the auditor.

Request for Comment

18. Should there be additional disclosures required about the meetings the audit committee has had with the auditor? If so, what type of disclosures should be made and why? If not, why not?

19. Should the audit committee report disclose the frequency with which it met privately with the auditor? Would confirmation that private conversations occurred be useful disclosure even if there are no disclosures about the topics discussed? Should there be a requirement to disclose the topics discussed?

3. Review of and Discussion About the Auditor's Internal Quality Review and Most Recent PCAOB Inspection Report

Pursuant to certain listing requirements, the audit committee must obtain and review a report by the independent auditor describing the firm's internal quality-control procedures,[91] any material issues raised by the most recent internal quality-control review, or peer review, of the firm, or by any inquiry or investigation by governmental or professional authorities, within the preceding five years, with respect to one or more independent audits carried out by the firm.[92] Audit committees not subject to these listing standards may choose to request or discuss this information with their auditors, but they are not required to do so.

Information about the results of internal quality reviews, or a PCAOB inspection of a company's audit, as well as more general inspection results, can help an audit committee in carrying out its oversight role. Inspection reports can inform an audit committee about how its auditor performed in high-risk areas across audits. As the PCAOB has stated, ''[t]he [Sarbanes-Oxley] Act does not permit the [PCAOB] to make public, or otherwise to share with an audit committee, all of the information obtained by the PCAOB that could assist an audit committee in carrying out its role. . . . Beyond the public portion of an inspection report, voluntary disclosure by the inspected audit firm is an audit committee's only means of obtaining information concerning a PCAOB inspection.'' [93] The PCAOB also has provided sample questions an audit committee may wish to ask auditors. Specifically, the PCAOB stated:

> [W]ithout necessarily framing discussions in terms of an inspection or an inspection report, an audit committee might benefit from having an understanding with its audit firm through which the audit committee receives timely information (both during the conduct of the inspection and when the Board has issued a final inspection report) about—
>
> • whether anything has come to the firm's attention suggesting the possibility that an audit opinion on the company's financial statements is not sufficiently supported, or otherwise reflecting negatively on the firm's performance on the audit, and what if anything the firm has done or plans to do about it;
>
> • whether a question has been raised about the fairness of the financial statements or the adequacy of the disclosures;
>
> • whether a question has been raised about the auditor's independence relative to the company;
>
> • whether any of the matters described in the public portion of an inspection report on the firm, whether or not they involve the company's audit, involve issues and audit approaches similar to those that arise or could arise in the audit of the company's financial statements;
>
> • to the extent any such similarity exists, whether and how the firm has become comfortable that the same or similar deficiencies either did not occur in the audit of the company's financial statements or have been remedied; and how issues described by the Board in general reports summarizing inspection results across groups of firms relate to the firm's practices, and potentially the audit of the company's financial statements, and how the firm is addressing those issues.[94]

Disclosure could be required as to whether this type of discussion has occurred. There also could be disclosure required about the nature of any discussions held with the auditor about the results of the firm's internal quality review and most recent PCAOB inspection. These disclosures may provide transparency with respect to the extent of the audit committee's oversight of the auditor.

Request for Comment

20. Would disclosure about the audit committee's review and discussion of the audit firm's internal quality-control review and most recent PCAOB inspection report be useful to investors? If so, what types of disclosures should be made in this regard? Would disclosures about the nature and extent of such discussions be useful without disclosure of the specific review or inspection results? Should the disclosures include information about how the audit committee considered any deficiencies described in the PCAOB inspection report on the audit process? If not, why not?

21. Is there a risk that the confidentiality of the nonpublic PCAOB inspection results could be undermined (*e.g.,* if this information is sought and provided through the audit committee)? If so, what type of information could be presented that might be problematic?

22. Should we require disclosure about how the audit committee considered the results described in PCAOB inspection reports in its oversight of the auditor? Why or why not?

23. Are there particular issues or challenges in this area that should be considered? If so, please describe and provide data.

4. Whether and How the Audit Committee Assesses, Promotes and Reinforces the Auditor's Objectivity and Professional Skepticism

Through its interactions with the auditor, the audit committee may be in a position to assess, promote, and reinforce the auditor's objectivity and professional skepticism. Heightened oversight by the audit committee of the auditor's objectivity and professional skepticism should promote greater audit quality. The audit committee could disclose whether, and if so how, as part of its oversight of the auditor, it assesses, promotes, or reinforces the auditor's objectivity and professional skepticism. Additionally, the audit committee could disclose the results of its evaluation of the auditor's objectivity and professional skepticism.

Request for Comment

24. Would investors find disclosure about whether, and if so how, the audit committee assesses, promotes, and reinforces the auditor's objectivity and professional skepticism useful? Why or why not?

25. What specific types of disclosures could the audit committee make in this regard? For example, should the audit committee disclose whether, and if so how, it evaluated the auditor's objectivity and professional skepticism, as well as the results of such an evaluation? Commenters are encouraged to provide examples of such disclosures.

[91] Paragraphs .04–.07 of PCAOB QC Section 30, *Monitoring a CPA Firms Accounting and Auditing Practice,* discuss the requirements related to an audit firm's internal quality-control review.

[92] *See* NYSE Listed Company Manual, Section 303A.07(b)(iii)(A).

[93] *See* PCAOB Release No. 2012–003, *Information for Audit Committees about the PCAOB Inspection Process* (Aug. 1, 2012), available at *http://pcaobus.org/Inspections/Documents/Inspection_Information_for_Audit_Committees.pdf.*

[94] *Id.* at p. 10–11.

B. Audit Committee's Process for Appointing or Retaining the Auditor

For listed issuers, the audit committee is responsible for appointing the auditor and deciding whether to retain an auditor.[95] However, satisfying this requirement can involve a wide range of activities. In fulfilling this responsibility, the audit committee may conduct an assessment of the current auditor. It may also decide to seek requests for proposals from other auditors. Potential disclosures could provide information about the actions the audit committee took in reaching a decision about which auditor to select for the upcoming fiscal year's audit.

1. How the Audit Committee Assessed the Auditor, Including the Auditor's Independence, Objectivity and Audit Quality, and the Audit Committee's Rationale for Selecting or Retaining the Auditor

Disclosure about the process the audit committee undertook and the criteria used to assess the auditor and the audit committee's rationale for selecting or retaining the auditor could provide transparency into how the audit committee oversees the auditor and the rigor with which the audit committee exercises its responsibility to appoint a new, or retain an existing, auditor. In addition to the steps involved in the process to assess the auditor, disclosure also could be provided regarding the specific elements or criteria the audit committee considered during the process. Disclosures could, for example, include a description of the nature of the audit committee's involvement in evaluating and approving the auditor's compensation.

There are also numerous ongoing efforts to identify ways to assess audit quality (''audit quality indicators'') and these efforts may result in published metrics and criteria that could be used for providing insight into audit quality.[96] Audit committees may choose to use the output from these efforts to guide discussion with the auditor about audit quality. To the extent the audit committee uses such indicators or metrics in assessing the quality of the auditor and the audit, disclosure about the use and consideration of such metrics may provide useful information about the audit committee's process for assessing the auditor and determining whether to select or retain the auditor.

Request for Comment

26. What types of disclosures could be made regarding the process the audit committee undertook to evaluate the external audit and performance and qualifications of the auditor, including the rationale for selecting or retaining the auditor?

27. Should the disclosures include a description of the nature of the audit committee's involvement in approving the auditor's compensation, including how compensation is determined and evaluated? Should the disclosures include the criteria or elements the audit committee considered? Should the audit committee provide additional disclosure about the nature and extent of non-audit services and its evaluation on how such services relate to its assessment of independence and objectivity?

28. If audit quality indicators are used in the evaluation of the auditor, should there be disclosure about the indicators used, including the nature, timing, and extent of audit quality indicators considered by the audit committee? [97] If audit quality indicators are not used in the evaluation of the auditor, what, if any, disclosures regarding the assessment of audit quality should be provided?

2. If the Audit Committee Sought Requests for Proposal for the Independent Audit, the Process the Committee Undertook To Seek Such Proposals and the Factors They Considered in Selecting the Auditor

The audit committee may periodically seek requests for proposals for the independent audit. Disclosures about the process the audit committee undertook, including the number of auditors that were asked to propose, information on how those auditors were selected, and the information that the audit committee used in its decision, may provide information about the audit committee's process in selecting or retaining an auditor and about the quality and qualifications of the auditor selected. Additionally, academic research is mixed as to whether companies engage in ''opinion-shopping.'' [98] The Commission is interested in knowing whether relevant disclosures of the audit committee's process in selecting the auditor might be useful to investors.

Request for Comment

29. What types of disclosures could be made about requests for proposals for the audit, including the process undertaken and the factors considered in selecting the audit firm?

30. Should there be disclosure as to whether the audit committee sought proposals for the audit (including the reason the request for proposal was made), or whether the audit committee has a policy in this regard?

3. The Board of Directors' Policy, if any, for an Annual Shareholder Vote on the Selection of the Auditor, and the Audit Committee's Consideration of the Voting Results in its Evaluation and Selection of the Audit Firm

In those cases where a company voluntarily seeks ratification of its auditor, requiring additional disclosure may be useful to promote informed voting decisions. The Commission is interested in feedback on potential disclosure about the board of directors' policy, if any, for annual shareholder vote on the selection of the auditor, and the audit committee's consideration of the voting results in evaluating and selecting the audit firm, including situations where the audit firm fails to achieve majority support. Such disclosure could provide useful information to shareholders as to how and why the board is seeking ratification of the auditor, as well as the implication of the shareholder vote being solicited.

Request for Comment

31. Would additional disclosures in this area provide meaningful additional information with respect to the selection of the auditor? If so, what types of disclosures should the Commission require to be made in this regard? For example, in addition to disclosure of whether there is a policy about shareholder ratification, should there

[95] Even for non-listed issuers, the audit committee may have a role in the selection of the auditor. *See, e.g.,* paragraphs 4–7 of AS 16.

[96] Organizations such as the PCAOB, IAASB, and CAQ have discussed projects related to audit quality frameworks or indicators. The CAQ has published, ''The CAQ Approach to Audit Quality Indicators'' available at *http://www.thecaq.org/docs/reports-and-publications/caq-approach-to-audit-quality-indicators-april-2014.pdf?sfvrsn=2.*

[97] *See* PCAOB Release No. 2015–005, *Concept Release on Audit Quality Indicators* (June 30, 2015).

[98] *See* Lennox, C., *Do Companies Successfully Engage in Opinion-Shopping? Evidence from the UK,* 29 Journal of Accounting and Economics, 321 (2000); and Chan, H.K. et al., *A Political-Economic Analysis of Auditor Reporting and Auditor Switches,* 11 Review of Accounting Studies, 21 (2006), both of which provide evidence that opinion shopping may occur. In contrast, in the United States, a study of auditor changes from the four largest U.S. accounting firms to small, not mid-market, audit firms found market reactions that support the notion of auditor changes in the post-Sarbanes-Oxley Act and PCAOB inspection era as being driven by better services. These results refute a notion of opinion shopping or shopping for lower audit fees. These authors also note that academic research in the 1980s and 1990s indicated that opinion shopping is generally unsuccessful. Chang, H. et al., *Market Reaction to Auditor Switching from Big 4 to Third-Tier Small Accounting Firms,* 29 Auditing: A Journal of Practice and Theory, 85 (2010).

also be disclosure of the factors the board considered in establishing the policy?

32. If there are a significant number of votes against the ratification, and the board nevertheless proceeds with the auditor in question, should the audit committee report provide the reasons why the board determined to go forward with that auditor? If not in the audit committee report, where should this information be provided and when should it be provided?

33. If it is determined that additional disclosure is required in this area, should voting on ratifications of independent auditors continue to be considered a ''routine matter'' allowing for discretionary voting by brokers on such ratifications pursuant to NYSE Rule 452? [99]

C. Qualifications of the Audit Firm and Certain Members of the Engagement Team Selected By the Audit Committee

In the course of carrying out its responsibilities related to auditor oversight, an audit committee is likely to gain an understanding of the key participants in the audit, their experience, and their qualifications to perform a high-quality audit. The key participants in the audit can vary, but at a minimum include the engagement partner and engagement quality reviewer. Given this knowledge, the audit committee is in a position to evaluate the independence and qualifications of both the audit firm and key members of the engagement team, including the engagement partner, and determine whether to select or retain the auditor. Disclosures could convey the factors the audit committee considered most relevant in selecting or retaining the auditor and provide information about the auditor selected by the audit committee for the upcoming fiscal year's audit.

1. Disclosures of Certain Individuals on the Engagement Team

Disclosure could be provided with the name of the engagement partner, alone or with the name(s) of other key members of the audit engagement team (*e.g.,* the engagement quality reviewer), the length of time such individual(s) have served in that role and any relevant experience.[100] Regarding experience, information could be provided about the number of prior audit engagements performed and whether they were in the same industry. To the extent it is known that the individual(s) disclosed will be changing for the upcoming year's audit, that information could also be disclosed.

Request for Comment

34. Would disclosure of the name of the engagement partner be useful to investors? Would disclosure of any additional members of the engagement team be useful and, if so, which? (For example, should the names of all partners who are required to rotate under SEC independence rules be disclosed? Why or why not?) Should there be other disclosures about the engagement team or others involved in the audit? If so, what additional information should be disclosed? Are there any costs to such disclosure?

35. Are there incremental benefits to disclosing the name (such as increased accountability)? Is disclosure of the name helpful in promoting audit quality? Are current risks of potential legal liability, regulatory sanction and significant reputational costs strong enough incentives to develop a team that is capable of executing the audit in accordance with professional standards? Why or why not? In addition to disclosure of the name, there could be disclosure regarding other qualifications, such as the length of time the individual has served in that role, professional licenses, or his or her experience. What, if any, additional information should be disclosed? Why?

36. Is the audit committee the appropriate party to provide such disclosure? If not, what other party or parties should provide the disclosure and why?

37. Would such disclosure be more appropriately disclosed in the auditor's report? Why or why not? Would it be better disclosed in a separate filing with the PCAOB? Why or why not? If the disclosure is provided in a separate filing with the PCAOB, what information should the disclosure include?

38. If the name of the engagement partner is available elsewhere (*e.g.,* included in the auditor's report or a supplemental filing with the PCAOB), would investors benefit from having it also reported as part of the audit committee's disclosures? Why or why not? Also, if the name of the engagement partner is available elsewhere, should the audit committee's report refer to where the disclosure is otherwise located?

39. If the name of the engagement partner is reported in the audit committee report, would investors benefit from this information also being available in one location for all audits?

40. If disclosures are required and it is known that the person(s) disclosed will change for the next audit, should there be disclosure of this fact including who will, or is expected to, take on the role for the next audit? Why or why not?

41. If there is a change in the engagement partner during the year, should this be disclosed sooner than in the next annual update? If other named individuals change during the year, should this be disclosed as well?

42. Are there any liability implications (*e.g.,* for engagement partners, audit committee members, the company or other participants) with respect to disclosure of participants in the audit? If so, what are these implications? Do the implications change based on where or how the disclosure is made?

2. Audit Committee Input in Selecting the Engagement Partner

The audit committee may provide input into an audit firm's assignment of the individual who will serve as the engagement partner for the upcoming audit. Disclosures about the involvement of the audit committee in this selection, and any input the audit committee had in the decision, may provide transparency and insight into the exercise of the audit committee's responsibilities in overseeing the auditor.

Request for Comment

43. Should the audit committee be required to disclose what it considered in providing input to the firm's assignment of the engagement partner? If so, what information should such disclosures contain?

44. Should the disclosures be limited to whether the audit committee participated in the selection of the engagement partner, or should there be more detail regarding the audit committee's input?

3. The Number of Years the Auditor Has Audited the Company

The number of years the auditor, or its predecessor(s) in the case of merged audit firms, has audited the company may be a relevant consideration to the audit committee's determination of

[99] NYSE General Rules, Operation of Member Organizations, Rule 452 available at *http://nyserules.nyse.com/nysetools/PlatformViewer.asp?SelectedNode=chp_1_2&manual=/nyse/rules/nyse-rules/*.

[100] Both the PCAOB and the IAASB have been pursuing projects that would require naming the engagement partner in the audit report. *See* PCAOB Release No. 2013–009; PCAOB Release No. 2015–004; and the IAASB final rule *International Standard on Auditing (ISA) 700 (Revised), Forming an Opinion and Reporting on Financial Statements),* including paragraph 45 of ISA 700, available at *http://www.ifac.org/publications-resources/international-standard-auditing-isa-700-revised-forming-opinion-and-reporting.*

whether or not to engage or retain the auditor. The role of auditor tenure in audit quality has attracted significant attention over the past few years.[101] Most academic research indicates that engagements with short-term tenure are relatively riskier or that audit quality is improved when auditors have time to gain expertise in the company under audit and in the related industry.[102] However, some academic research suggests that both short and long tenure can have detrimental effects on audit quality.[103] Audit committees may view auditor tenure as a positive or negative influence on audit quality, depending on the length of such tenure. In light of the public interest in the subject of auditor tenure, disclosure of this data could provide insight into the audit committee's overall decision to engage or retain the auditor.

Request for Comment

45. Should the audit committee's report include information about the length of the audit relationship? What types of disclosures could the audit committee make in this regard? Should it be just the years of auditor tenure?

46. Should there also be disclosure as to whether and, if so, how auditor tenure was considered by the audit committee in retaining the auditor? Should there be disclosure of how tenure was considered in evaluating the auditor's independence and objectivity? Why or why not?

47. Would disclosure of auditor tenure be more appropriately disclosed in the auditor's report? Why or why not? Would it be better disclosed somewhere else (such as in a form filed with the PCAOB)? Why or why not?

4. Other Firms Involved in the Audit

In many audits, especially audits of companies with multiple locations and international operations, the firm signing the auditor's report involves other affiliated accounting firms, non-affiliated accounting firms, and other third-party participants, such as tax advisors or actuaries, in the conduct of a portion of the audit work. The auditor is required to communicate to the audit committee the names, locations, and planned responsibilities of other independent public accounting firms or other persons, who are not employed by the auditor, that perform audit procedures in the current period audit. Specifically, paragraph 10 of AS 16 requires:

As part of communicating the overall audit strategy, the auditor should communicate the following matters to the audit committee, if applicable:

- The nature and extent of specialized skill or knowledge needed to perform the planned audit procedures or evaluate the audit results related to significant risks;
- the extent to which the auditor plans to use the work of the company's internal auditors in an audit of financial statements;
- the extent to which the auditor plans to use the work of internal auditors, company personnel (in addition to internal auditors), and third parties working under the direction of management or the audit committee when performing an audit of internal control over financial reporting;
- the names, locations, and planned responsibilities of other independent public accounting firms or other persons, who are not employed by the auditor, that perform audit procedures in the current period audit; and

Note: The term ''other independent public accounting firms'' in the context of this communication includes firms that perform audit procedures in the current period audit regardless of whether they otherwise have any relationship with the auditor.

- the basis for the auditor's determination that the auditor can serve as principal auditor, if significant parts of the audit are to be performed by other auditors.[104]

After receiving the above information from the auditor, the audit committee may choose to meet with and discuss with the auditor, the other firms, or other persons who will be performing work on the audit. The audit committee is not required to disclose these communications with the auditor to investors.

Request for Comment

48. Should the Commission require any additional disclosures in this regard? For example, should the names of the other independent public accounting firms and other persons involved in the audit be disclosed? Should the extent of involvement by these other participants be disclosed? Why or why not?

49. Should the names of other participants be included in the required disclosure instead of in the auditor's report? Should the names be disclosed elsewhere? If so, why? Would investors benefit from having all of the information located in the audit committee report?

D. Location of Audit Committee Disclosures in Commission Filings

As noted in Section III, current audit committee disclosures can appear in different places. None of the disclosures are specifically listed in the registration statement forms used for public offerings. As such, audit committee disclosures are not generally included in the prospectus delivered to investors for initial public offerings. Some of the audit committee disclosures are required in an issuer's annual report on Form 10–K filed with the Commission.[105] These disclosures would be considered part of the prospectus when the registration statements incorporate an issuer's annual report by reference.[106]

The audit committee report[107] and the disclosure of the function and number of meetings held by the audit committee[108] is not generally considered part of the prospectus in a registered offering, since it is not required by the Securities Act registration forms or the annual report on Form 10–K.[109] As the audit committee disclosures may inform investors' investment decisions, the Commission solicits feedback regarding the placement of current and potential additional audit committee disclosures, including the audit committee report.

[101] *See, e.g.,* PCAOB Release No. 2011–006, *Concept Release on Auditor Independence and Audit Firm Rotation* (Aug. 16, 2011), available at *http://pcaobus.org/Rules/Rulemaking/Pages/Docket037.aspx;* and PCAOB Release No. 2013–005, *Proposed Auditing Standards on the Auditor's Report and the Auditor's Responsibilities Regarding Other Information and Related Amendments* (Aug. 13, 2013), available at *http://pcaobus.org/Rules/Rulemaking/Pages/Docket034.aspx.*

[102] *See* Myers, J. et al., *Exploring the Term of the Auditor-Client Relationship and the Quality of Earnings: A Case for Mandatory Auditor Rotation?* 78 The Accounting Review, 779 (2003); and Carcello, J. and Nagy, A., *Audit Firm Tenure and Fraudulent Financial Reporting,* 23 Auditing: A Journal of Practice and Theory, 55 (2004).

[103] *See, e.g.,* Davis, L. et al., *Auditor Tenure and the Ability to Meet or Beat Earnings Forecasts,* 26 Contemporary Accounting Research, 517 (2009).

[104] AS 16.

[105] Item 10 of Form 10–K references the disclosure requirements in Items 407(d)(4) and (5) of Regulation S–K. A similar requirement is also included in Item 7(b) of Schedule 14A.

[106] In practice, many registrants provide the Items 407(d)(4) and (5) disclosures in their definitive proxy statements in reliance on General Instruction G(3) of Form 10–K. Once the definitive proxy statements are filed, the information is incorporated by reference into their Form 10–K, which is then incorporated by reference into any currently effective Form S–3 or other registration statement subsequently filed, as applicable.

[107] Item 407(d)(3) of Regulation S–K.

[108] Item 407(b)(3) of Regulation S–K.

[109] Pursuant to Instruction 1 to Item 407(d) of Regulation S–K, the information required by Items 407(d)(1), (2), and (3) is not deemed to be soliciting material or filed with the Commission, except to the extent that a registrant specifically requests such information be treated as soliciting material or is incorporated by reference into a Securities Act registration statement.

Request for Comment

50. Would investors benefit from the audit committee disclosures being presented in one location? If so, where should the disclosures appear and how would investors benefit? If not, why is the existing location of the various audit committee disclosures appropriate?

51. Should all or any of the audit committee disclosures, including the audit committee report, be included in registration statements filed pursuant to the Securities Act? If not, why not? If so, why and should the disclosure requirements be included within Securities Act registration statement forms or as a Form 10–K disclosure requirement that may then be incorporated by reference into Securities Act registration statements?

52. With respect to the additional disclosures discussed in this release, where should they be made? If required, should they be in the audit committee report, a separate section of the proxy statement, the annual report, on the company's Web site, or elsewhere? Please provide an explanation as to why the disclosure should be made in a suggested location. If required, should the disclosure be furnished but not filed? Why or why not?

E. Smaller Reporting Companies and Emerging Growth Companies

Item 407(g) of Regulation S–K provides the only audit committee disclosure accommodation within Item 407 that is specific to smaller reporting companies.[110] The Jumpstart Our Business Start-Ups Act (the ''JOBS Act'') [111] did not change the audit committee disclosure requirements for emerging growth companies. As such, the Commission is soliciting feedback regarding the application of the current and potential audit committee disclosure requirements to smaller reporting companies and emerging growth companies.

Request for Comment

53. Should current audit committee disclosure requirements be changed for smaller reporting companies or emerging growth companies? If so, which requirements and why? Would investors in smaller reporting companies or emerging growth companies find this information any more or less useful than similar disclosure requirements for other issuers? If so, how, and why?

54. With respect to the additional disclosures discussed in this release, should any disclosure requirements, if adopted, apply to smaller reporting companies or emerging growth companies? If so, which requirements and why? If not, why not? Would different disclosure requirements impact the issuers (*e.g.,* secondary market liquidity)?

VII. Additional Request for Comment Regarding Audit Committee Disclosures

In addition to seeking public comment on the foregoing topics for disclosure, the Commission seeks public comment in response to the following questions about the disclosures as a whole. If views of these questions would differ based on what type of disclosure is being considered, please differentiate and explain why.

Request for Comment

55. Should additional disclosures, such as those presented in Section VI, be required, or should they be voluntary as they are today? Should the Commission consider requiring specific disclosures, or requiring certain categories of disclosures? If so, which categories?

56. Are there specific issuer, industry, audit committee member, or auditor characteristics that should be considered in establishing new disclosure requirements? Are there particular disclosures that should always be required and, if so, which? Are there particular disclosures that should only be required if certain conditions or characteristics are present and, if so, which disclosures and under what circumstances? Are there particular disclosures for which specificity in the requirement is important and, if so, for which disclosures and elements of disclosures should the requirements be specific?

57. Would the disclosures prompt the audit committee to change how it oversees the auditor? If so, how?

58. Would such disclosures provide insight into the nature, timing, and extent of the audit committee's oversight of the auditor?

59. Would the disclosures promote audit quality? If so, how?

60. Would the disclosures discussed herein result in boilerplate information? If so, how could the requirements be crafted to avoid boilerplate disclosure?

61. Would any of the additional disclosures discussed in this concept release result in disclosure that is not useful to investors? Why or why not?

62. Would additional information need to be disclosed in order to place any or all of the disclosures discussed above in the appropriate context? If so, what additional disclosures might be needed, and should they be required or discretionary?

63. If the Commission were to proceed with requiring some or all of the disclosures proposed above, should the disclosures be made by all issuers? For example, should the disclosures be required only for those subject to the proxy rules? Should they be required for foreign private issuers? [112] Why or why not? Should there be accommodations made for certain types of companies or certain circumstances? If so, what should they be?

64. If the Commission proceeds with requiring some or all of the disclosures proposed above, should there be a requirement to update these disclosures for changes between proxy or information statements? If so, what should trigger amended disclosures? Should any such updates be made quarterly or more frequently?

65. If the Commission proceeds with requiring some or all of the disclosures discussed above, should the disclosures be required to be provided in an interactive data format? If so, what elements of disclosure should be provided in that manner and in what format should the information be provided?

66. The audit committee disclosure requirements may reference other documents, such as an audit committee charter. Should such documents be provided along with the required disclosures? If not, should information be provided to help locate the information referenced? Why or why not? Should information be hyperlinked? If so, are there any unintended consequences or implementation challenges that may result from information being presented in this manner?

67. If the Commission proceeds with requiring some or all of the disclosures proposed above, under existing reporting deadlines, would there be sufficient time to prepare these disclosures? Would there be difficulties in making these disclosures?

68. Would the additional disclosures discussed above help minimize information asymmetries that may exist between management and investors? If so, how? What other benefits may accrue from providing this information?

69. Expanded disclosures may have direct and indirect economic impacts on market participants. What direct and indirect economic impacts would these disclosures have on market participants? Are there any unintended

[110] 17 CFR 229.407(g).

[111] Public Law 112–106, 126 Stat. 306 (2012).

[112] Foreign private issuers are not subject to the proxy rules. *See* Rule 3a12–3(b) of the Exchange Act [17 CFR 240.3a12–3(b)].

consequences that could result from such disclosures with respect to audit firms, individual audit partners, audit committee members, audit committees, issuers, investors, or others? For instance, could potential changes chill or overly formalize audit committee communications with auditors? Are there specific liability implications with respect to additional disclosure made by the audit committee? If so, please describe.

70. Would other categories of disclosures about the audit committee's role relative to the auditor be useful? If so, what other categories?

71. How should the Commission address potential changes in the auditor's report with respect to audit committee oversight of the auditor?

72. If audit committees are required to provide disclosure that relates to information provided by the auditor (and it is not currently required to be communicated by the auditor under existing PCAOB auditing standards), would changes to PCAOB auditing standards be necessary to ensure that additional information beyond existing required communications is provided to the audit committee?

73. Are there improvements that the Commission should consider to the reporting on the audit committee's oversight of the accounting and financial reporting process or internal audits? For instance, should the audit committee disclose how it interacts with the company's management?

74. Should the Commission consider the potential for changes that would affect the role and responsibilities of the audit committee, such as those related to qualifications of members of the audit committee or areas for which audit committees should (or should not) be responsible? Should the audit committee disclose its role, if any, in risk governance? Should the audit committee report on other areas of oversight? For example, audit committees may be charged with overseeing treatment of complaints, cyber risks, information technology risks, or other areas. Would this disclosure distract from the report's focus on oversight of the audit function? In this regard, we note that commentators have recently indicated concern that audit committees are becoming the catch all of board committees by overseeing anything related to risk.[113]

In addition to the areas for comment identified above, we are interested in any other issues that commenters may wish to address and the benefits and costs relating to investors, issuers and other market participants of revising disclosure rules pertaining to the audit committee and the audit committee report included in Commission filings. Please be as specific as possible in your discussion and analysis of any additional issues. Where possible, please provide empirical data or observations to support or illustrate your comments.

By the Commission.

Dated: July 1, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–16639 Filed 7–7–15; 8:45 am]

BILLING CODE 8011–01–P

[113] Michael Rapoport & Joann S. Lublin, *Meet the Corporate Board's ''Kitchen Junk Drawer,'' Wall St. J.* (Feb. 3, 2015).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 342

[Docket No. RM15–20–000]

Five-Year Review of the Oil Pipeline Index

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of inquiry.

SUMMARY: The Federal Energy Regulatory Commission (Commission) invites comments on its proposed five-year review of the index level used to determine annual changes to oil pipeline rate ceilings. The Commission proposes an index level between the Producer Price Index for Finished Goods (PPI–FG)+2.0 percent and PPI–FG+2.4 percent for the five-year period commencing July 1, 2016. The Commission invites interested persons to submit comments regarding this proposal and any alternative methodologies for calculating the index level.

DATES: Initial Comments are due August 24, 2015, and Reply Comments are due September 21, 2015.

ADDRESSES: You may submit comments, identified by docket number by any of the following methods:

• *Agency Web site: http://www.ferc.gov.* Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. All supporting workpapers must be submitted with formulas and in a spreadsheet format acceptable under the Commission's eFiling rules.

• *Mail/Hand Delivery:* Commenters unable to file comments electronically must mail or hand deliver an original to: Federal Energy Regulatory Commission, Office of the Secretary, 888 First Street NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT:

Monil Patel (Technical Information); Office of Energy Market Regulation; Federal Energy Regulatory Commission; 888 First Street NE.; Washington, DC 20426; (202) 502–8296; Andrew Knudsen (Legal Information); Office of the General Counsel; Federal Energy Regulatory Commission; 888 First Street NE.; Washington, DC 20426; (202) 502–6527.

SUPPLEMENTARY INFORMATION:

1. The Commission annually applies an index to existing oil pipeline transportation rate ceilings to establish new rate ceiling levels. The Commission reexamines this index every five years.[1] In this notice of inquiry (NOI), the Commission invites comments on its proposal to use an index level between the Producer Price Index for Finished Goods [2] (PPI–FG)+2.0 percent and PPI–FG+2.4 percent for the next five years beginning July 1, 2016.[3] This proposal is based upon the Kahn Methodology established in Order No. 561 and applied in subsequent five-year review proceedings.[4] The Commission proposes a range because not all pipelines have filed Form No. 6 data for 2014. The Commission will select a final index level at the conclusion of this proceeding. Commenters are invited to submit comments on, and justify alternatives to, the proposed index level. In addition to inviting comments, the Commission plans to hold a conference on July 30, 2015, to discuss the issues raised by this notice. A subsequent notice will provide

[1] The five-year review process was established in Order No. 561. *See Revisions to Oil Pipeline Regulations Pursuant to the Energy Policy Act,* Order No. 561, FERC Stats. & Regs. ¶ 30,985 (1993), *order on reh'g,* Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 (1994), *aff'd, Assoc. of Oil Pipelines* v. *FERC,* 83 F.3d 1424 (D.C. Cir. 1996).

[2] The PPI–FG represents the Producer Price Index for Finished Goods. The PPI–FG is determined and issued by the Bureau of Labor Statistics, U.S. Department of Labor.

[3] As provided by 18 CFR 342.3(d)(2) (2014), ''The index will be calculated by dividing the PPI–FG for the calendar year immediately preceding the index year by the previous calendar year's PPI–FG.'' Multiplying the rate ceiling on June 30 of the index year by the resulting number gives the rate ceiling for the year beginning the next day, July 1.

[4] *Five-Year Review of Oil Pipeline Index,* 133 FERC ¶ 61,228, at PP 5–9, 60–63 (2010), *order on reh'g,* 135 FERC ¶ 61,172 (2011). *See also Five-Year Review of Oil Pipeline Index,* 102 FERC ¶ 61,195 (2003), *aff'd, Flying J Inc., et al.,* v. *FERC,* 363 F.3d 495 (D.C. Cir. 2004); *Five-Year Review of Oil Pipeline Index,* 114 FERC ¶ 61,293 (2006).

additional details regarding the conference.

I. Background

2. In Order No. 561, the Commission established an indexing methodology that allows oil pipelines to change rates based upon an annual index as opposed to making cost-of-service filings.[5] In Order No. 561, the Commission committed to review the index level every five years to ensure that the index level chosen by the Commission adequately reflects changes to industry costs.[6]

3. In Order No. 561 and each successive index review, the Commission calculated the index level based upon a methodology developed by Dr. Alfred E. Kahn.[7] The Kahn Methodology measures changes in operating costs and capital costs on a per barrel-mile basis using FERC Form No. 6 (Form No. 6) data from the prior five-year period (for example, between 2009 and 2014 in this proceeding).[8] The Kahn Methodology uses net carrier property per barrel-mile as a proxy for capital cost data. The Kahn Methodology assigns a weight to the Form No. 6 operating expenses relative to the net carrier property using an ''operating ratio.'' [9] The weighted operating expense and the weighted net carrier property are then added together to establish the cumulative cost change for each pipeline.[10]

4. Once these cumulative cost changes have been calculated for each pipeline with sufficient Form No. 6 data, the Kahn Methodology culls a data set consisting of pipelines with cumulative per-barrel-mile cost changes in the middle 50 percent of all pipelines. This trimming removes statistical outliers or spurious data points that could bias the sample in either direction. For the middle 50 percent data set, the Kahn Methodology considers three different measures of central tendency. One measure is the median of each data set. Another measure, the weighted mean, calculates an average barrel-mile cost change in which each pipeline's cost change is weighted by its barrel-miles. A third measure, the un-weighted average, calculates the simple average of the percentage cost change per barrel-mile for each pipeline. A composite is calculated by taking the simple average of the median, the weighted mean, and the un-weighted mean. This composite is compared to the value of the PPI–FG index data over the same period. The index level is then set at PPI–FG plus (or minus) this differential.

II. Commission Proposal

5. The Commission proposes to use an index level between PPI–FG+2.0 percent and PPI–FG+2.4 percent as the index level for the five-year period commencing July 1, 2016. This proposal is based upon the Kahn Methodology as applied to Form No. 6 data from the 2009 through 2014 period. The Commission's calculations are included in Attachment A to this order.

III. Conference and Comment Procedures

6. The Commission invites interested persons to submit comments regarding this proposal and any alternative methodologies for calculating the index level for the five-year period commencing July 1, 2016.

7. Initial Comments are due August 24, 2015 and Reply Comments are due September 21, 2015. Comments must refer to Docket No. RM15–20–000, and must include the name of the commenter, and if applicable, the organization represented and their address. On July 30, 2015, the Commission plans to hold a conference to discuss the issues raised by this notice. A subsequent notice will provide additional details regarding the conference.

8. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov.* The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. All supporting workpapers must be submitted with formulas and in a spreadsheet format acceptable under the Commission's eFiling rules. Commenters filing electronically do not need to make a paper filing.

9. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

10. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters are not required to serve copies of their comments on other commenters.

IV. Document Availability

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

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

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

By direction of the Commission.

Dated: June 30, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–16628 Filed 7–7–15; 8:45 am]

BILLING CODE 6717–01–P

[5] Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,947.

[6] *Id.*

[7] The Commission's use of the Kahn Methodology has been affirmed by the United States Court of Appeals for the District of Columbia Circuit. *Assoc. of Oil Pipelines* v. *FERC,* 83 F.3d 1424 (D.C. Cir. 1996) and *Flying J Inc., et al.,* v. *FERC,* 363 F.3d 495 (D.C. Cir. 2004).

[8] Specifically, this data is drawn from the Form No. 6: Carrier Property, page 110; Accrued Depreciation, page 111; Operating Revenues and Operating Expenses, page 114; Crude and Products Barrel-Miles, page 600. To the extent this information is incomplete, alternate data reported in the Form No. 6 has been substituted.

[9] The ''operating ratio'' = ((Operating Expense at Year 1/Operating Revenue at Year 1) + (Operating Expense at Year 5/Operating Revenue at Year 5))/2. If the operating ratio is greater than one, then it is assigned the value of 1 in the Kahn Methodology calculations.

[10] Cumulative Cost Change = (1-operating ratio) * net plant + operating ratio * operating expenses.

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AO44

Schedule for Rating Disabilities—The Endocrine System

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to revise the portion of the VA Schedule for Rating Disabilities (Rating Schedule) that addresses the endocrine system. The intended effects of these changes are to update medical terminology, add medical conditions not currently in the Rating Schedule, revise the criteria to reflect medical advances since the last revision in 1996, and clarify the criteria.

DATES: Comments must be received by VA on or before September 8, 2015.

ADDRESSES: Written comments may be submitted through *www.Regulations.gov;* by mail or hand-delivery to the Director, Regulations Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to ''RIN 2900–AO44–Schedule for Rating Disabilities—The Endocrine System.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.Regulations.gov*

FOR FURTHER INFORMATION CONTACT: Nick Olmos-Lau, M.D., FAAN, Medical Officer, Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, (211C) 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–9700. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: As part of the ongoing revision of the VA Schedule for Rating Disabilities (''Rating Schedule''), VA is proposing changes to 38 CFR 4.119, Schedule of ratings-endocrine system. This section was last updated in 1996. The endocrine system is made up of multiple hormone-producing glands. Hormones are chemical messengers that control the function of many body processes. While the actual dysfunction occurs at the site of the gland, the signs and symptoms manifest in the body systems on which the specific hormones act. For diagnosis and acute management of endocrine diseases, medical professionals focus on addressing the problem within the endocrine system. However, the residual effects of an endocrine disease may manifest within multiple body systems. Therefore, in general, VA proposes specific criteria for the initial rating of endocrine diseases within § 4.119 to account for the unique functional impairments associated with attempts to bring the condition under control. Once the condition is effectively managed or has reached maximal medical outcome, VA proposes to evaluate for the residual effects of disease within the appropriate (adversely impacted) body system. For rating clarity, the most commonly impacted systems would be referenced within the specific diagnostic code (DC). By the revisions discussed herein, VA aims to update medical terminology, add medical conditions not currently in the Rating Schedule, revise the criteria to reflect medical advances, and clarify the criteria.

In preparing this proposed revision, VA conducted a mini-summit in Washington, DC, on December 2, 2009. VA also researched current medical information and consulted with Veterans Health Administration (VHA) subject matter experts.

DC 7900: Hyperthyroidism, Including, But Not Limited to, Graves' Disease

VA proposes to update the title of DC 7900. Currently, this DC is titled ''Hyperthyroidism.'' The most common cause of hyperthyroidism is Graves' disease, an autoimmune disease that affects multiple organ systems, including the eyes and skin. ''Hyperthyroidism (overactive thyroid),'' Mayo Clinic, *http://www.mayoclinic.com/health/hyperthyroidism/DS00344/DSECTION*=causes. Given the prevalence of hyperthyroidism due to Graves' Disease, VA proposes to explicitly recognize Graves' disease under this DC by changing the title of DC 7900 from ''Hyperthyroidism'' to ''Hyperthyroidism, including, but not limited to, Graves' disease.'' This is not a substantive change, but simply an effort to increase rating efficiency. To account for less common causes of hyperthyroidism not addressed by other DCs, VA does not propose to limit this DC so that it is only applicable to Graves' disease.

Hyperthyroidism refers to the excess synthesis or secretion of thyroid hormone. Regardless of the specific cause, the symptoms directly caused by excess thyroid hormone are the same. Therefore, VA proposes to evaluate the disability associated with excess thyroid hormone using a single set of rating criteria that reflects an earlier diagnosis and current treatment options. Medical advances have facilitated earlier diagnosis and treatment of hyperthyroidism. Treatment is directed at symptom relief and includes antithyroid medications, radioactive iodine therapy, and thyroidectomy (surgical removal of the thyroid gland). Earlier treatment has decreased the duration and severity of both acute and chronic symptoms of hyperthyroidism, as well as its disabling residual effects. Therefore, the existing evaluations of 100 and 60 percent for this condition are no longer appropriate and VA proposes to no longer assign them.

In the majority of cases, by the time patients present with the symptoms currently reflected in the criteria for a 30 percent evaluation (tachycardia, tremor, and increased blood pressure or pulse pressure), treatment is initiated. With treatment, these symptoms generally resolve completely within three to six months. Therefore, VA proposes to evaluate hyperthyroidism at 30 percent for six months after initial diagnosis. Because symptoms generally resolve completely while the 30 percent evaluation is applicable, VA also proposes to no longer assign a 10 percent evaluation. To account for symptoms that do not resolve completely within six months, VA proposes adding a directive instructing VA personnel to ''rate residuals of disease or complications of medical treatment . . . within the appropriate body system.''

Since cardiovascular abnormalities are common in hyperthyroidism, and some persist despite treatment with antithyroid medications, VA proposes an alternative to the current approach which rates certain cardiovascular manifestations within DC 7900 but refers VA personnel to DC 7008 (hyperthyroid heart disease) if heart disease is the predominant disability (see current Note (1)). Hyperthyroidism is associated with a variety of cardiovascular problems including tachycardia, systolic hypertension, cardiac arrhythmias particularly atrial fibrillation, supraventricular tachycardia, congestive heart failure or angina among others. See Faizel Osman et al., ''Cardiovascular manifestations of hyperthyroidism before and after antithyroid therapy,'' 49 (1) J. Am. College of Cardiology, 71–81 (2007). In order to address more specifically cardiovascular issues related to hyperthyroidism, VA proposes to modify the existing Note (1) to state that if cardiovascular or cardiac problems related to hyperthyroidism are present separately evaluate under DC 7008.

In order to clarify a potentially confusing element in DC 7008 that directs hyperthyroid heart disease to be part of the overall evaluation of hyperthyroidism under DC 7900, VA

proposes to amend DC 7008 by directing that hyperthyroid heart disease be rated under the appropriate cardiovascular diagnostic code, depending on particular findings.

Currently, DC 7008 states that only when atrial fibrillation is present hyperthyroidism may be evaluated either under DC 7900 or under 7010 (supraventricular arrhythmia), whichever results in a higher evaluation. As described above, the potential cardiovascular conditions related to hyperthyroidism are numerous and complex, and the current approach limits the alternatives and precludes optimal assessment in instances other than for atrial fibrillation.

Currently, Note (2) of DC 7900 states: ''If ophthalmopathy is the sole finding, evaluate as field vision, impairment of (DC 6080); diplopia (DC 6090); or impairment of central visual acuity (DC 6061–6079).'' In the case of Graves' disease, which is evaluated under proposed DC 7900, eye abnormalities can occur independently and in the absence of hyperthyroidism. As such, it is not appropriate to limit evaluation of such manifestations under either DC 7900 or an appropriate DC within the eye body system. VA therefore proposes to revise current Note (2) to read: Separately evaluate eye involvement occurring as a manifestation of Graves' Disease as diplopia (DC 6090); impairment of central visual acuity (DCs 6061–6066); or under the most appropriate DCs in § 4.79.

DC 7901: Thyroid Enlargement, Toxic

VA proposes to update the title of DC 7901 from ''Thyroid gland, toxic adenoma of'' to ''Thyroid enlargement, toxic.'' When discussing thyroid enlargement, ''toxic'' is the term used by the medical community to indicate overactive thyroid function, also known as hyperthyroidism. Currently, the rating criteria accompanying this DC are identical to that accompanying current DC 7900. Therefore, rather than repeating the criteria for hyperthyroidism, VA proposes Note (1) to direct raters to evaluate toxic thyroid enlargement under proposed DC 7900 (hyperthyroidism, including, but not limited to, Graves' disease).

An enlarged thyroid may cause a visible swelling at the base of the neck or thyroidectomy may result in disfigurement. To account for such disfigurement, VA proposes Note (2) directing VA personnel: If disfigurement of the neck is present due to thyroid disease or enlargement, separately evaluate under DC 7800 (burn scar(s) of the head, face, or neck; scar(s) of the head, face, or neck due to other causes; or other disfigurement of the head, face, or neck).

DC 7902: Thyroid Enlargement, nontoxic

VA proposes to change the current title of DC 7902, ''Thyroid gland, nontoxic adenoma of,'' to ''Thyroid enlargement, nontoxic.'' In the context of thyroid function, ''nontoxic'' means that thyroid function is normal.

Because thyroid function is normal, the disabling effects of nontoxic thyroid enlargement are a result of disfigurement or pressure on adjacent organs. A person with this condition may experience one or both of these effects. However, under the current criteria an evaluation may only be assigned for the more disabling effect. Therefore, to better reflect the full impact of the condition, VA proposes to amend the existing criteria to account for both effects occurring simultaneously.

When the enlarged thyroid gland compresses adjacent organs, it may produce symptoms due to pressure on anterior neck structures, including the trachea (wheezing, cough), the esophagus (dysphagia), and the recurrent laryngeal nerve (hoarseness). The severity of disabilities related to pressure on adjacent organs is best evaluated under the DC(s) within the appropriate body system. Therefore, VA proposes to edit the current note under DC 7902, which would be proposed Note (1), to clarify VA's intention to evaluate the symptoms due to pressure on adjacent organs under the appropriate diagnostic code within the appropriate body system and to delete the current phrase ''if doing so would result in a higher evaluation than using this [DC].'' Currently, DC 7902 provides a 20 percent evaluation when there is disfigurement of the head or neck and a 0 percent evaluation when there is no such disfigurement. Disfigurement due to an enlarged thyroid gland is not defined in the existing criteria and, therefore, is subject to individual interpretation. Objective criteria for evaluating disfigurement of the neck already exist under DC 7800 (burn scar(s) of the head, face, or neck; scar(s) of the head, face, or neck due to other causes; or other disfigurement of the head, face, or neck). Because this set of criteria covers all types of disfigurement of the neck and provides a wider range of disability compensation, VA proposes deletion of the current criteria and addition of proposed Note (2) stating that disfigurement of the neck related to nontoxic thyroid enlargement should be evaluated under DC 7800.

The proposed notes read as follows: ''Note (1): Evaluate symptoms due to pressure on adjacent organs (such as the trachea, larynx, or esophagus) under the appropriate diagnostic code(s) within the appropriate body system.'' ''Note (2): If disfigurement of the neck is present due to thyroid disease or enlargement, separately evaluate under DC 7800 (burn scar(s) of the head, face, or neck; scar(s) of the head, face, or neck due to other causes; or other disfigurement of the head, face, or neck).''

DC 7903: Hypothyroidism

Hypothyroidism is currently evaluated at levels of 100, 60, 30, and 10 percent. Severe hypothyroidism is characterized by myxedema (coma or crisis), a life-threatening form of hypothyroidism found predominantly in undiagnosed or undertreated individuals that requires inpatient hospitalization for stabilization. Medical advances in the diagnosis and treatment of hypothyroidism have decreased the incidence of myxedema to the point that myxedema coma occurs in only 0.1 percent of all cases of hypothyroidism. Erik D Schraga, MD, ''Hypothyroidism and Myxedema Coma in Emergency Medicine,'' Medscape Reference (Mar. 29, 2012), *http://emedicine.medscape.com/article/768053-overview.* Symptoms of myxedema are currently evaluated at 100 and 60 percent. However, given the severity of the condition, a 60 percent evaluation is insufficient. Therefore, VA proposes a 100 percent evaluation for all instances of hypothyroidism with myxedema. VA proposes to add a note to provide: ''This evaluation shall continue for six months beyond the date that an examining physician has determined crisis stabilization. Thereafter, the residual effects of hypothyroidism shall be rated under the appropriate diagnostic code(s) within the appropriate body system(s) (*e.g.,* eye, digestive, and mental disorders).''

Medical management of hypothyroidism, in the absence of myxedema, results in improvement of laboratory values within a few weeks. However, alleviation of other clinical symptoms may take up to six months to resolve. See Bijay Vaidya, ''Management of Hypthyroidism,'' BMJ 337:a801 (2008). Therefore, VA proposes to evaluate hypothyroidism in the absence of myxedema at 30 percent for six months after initial diagnosis and would explain this in a note that would also provide that, thereafter, the residual effects of hypothyroidism shall be rated under the most appropriate diagnostic code(s) within the appropriate body

system(s) (*e.g.,* eye, digestive, and mental disorders).

VA also proposes to add a note to provide that eye involvement associated with hypothyroidism would also be evaluated under § 4.79. Specifically, the proposed note reads: ''If eye involvement, such as exophthalmos, corneal ulcer, blurred vision, or diplopia, is also present due to thyroid disease, also separately evaluate under appropriate diagnostic code(s) in § 4.79, Schedule of Ratings—Eye (such as diplopia (DC 6090) or impairment of central visual acuity (DCs 6061–6066)).''

DC 7904: Hyperparathyroidism

Hyperparathyroidism, DC 7904, is currently evaluated at levels of 100, 60, and 10 percent. Due to increased routine laboratory testing, hyperparathyroidism is usually diagnosed before patients develop severe disease and often before any signs or symptoms, such as kidney stones, gastrointestinal problems or weakness, are present. John I. Lew, ''Surgical Management of Primary Hyperparathyroidism: State of the Art,'' 89 Surgical Clinics of N. Am. 1205–25 (2009); ''Hyperparathyroidism,'' Mayo Clinic, *http://www.mayoclinic.com/health/hyperparathyroidism/DS00396.* Therefore, the existing criteria for evaluations at the 100 and 60 percent rating are no longer appropriate, and VA proposes revision of all the criteria consistent with medical advances.

Individuals diagnosed with hyperparathyroidism, but without symptoms (asymptomatic), require annual monitoring of their serum calcium levels and creatinine clearance (renal function). Bone density monitoring is also required every one to two years. These tests help medical professionals monitor the progression of the disease and to determine when surgery is necessary. Therefore, VA proposes to evaluate asymptomatic hyperparathyroidism at 0 percent.

Individuals with mild hyperparathyroidism may develop symptoms of hypercalcemia before surgery is determined to be necessary. Even after surgery, mild symptoms may persist. Therefore, VA proposes a 10 percent evaluation for the presence of symptoms, such as fatigue, anorexia, nausea, or constipation, despite surgery or in subjects deemed not to be candidates for surgery who require continuous medications for control.

Potential complications of hyperparathyroidism include gastric ulcers, kidney stones, decrease kidney function, and decreased bone mass associated with fragility fractures. Early intervention through laboratory monitoring generally prevents these complications. An increase in serum calcium, decreases in creatinine clearance, and decreases in bone density are used as laboratory indicators for the worsening of disease and evaluation for surgical intervention. Therefore, VA proposes a 60 percent evaluation for hypercalcemia indicated by at least one of the following: Total Ca greater than 12mg/dL (3–3.5 mmol/L), Ionized Ca greater than 5.6 mg/dL (2–2.5 mmol/L), creatinine clearance less than 60 mL/min, bone mineral density T-score less than 2.5 (SD below mean) at any site or previous fragility fracture). Because these findings indicate that surgical or pharmacologic intervention is warranted and such intervention usually resolves symptoms, VA proposes that the 60 percent evaluation shall continue until such intervention occurs. If surgery is not indicated, the 60 percent evaluation would continue for 6 months after pharmacological treatment begins. After six months, rating would be based on residuals under the appropriate diagnostic code(s) within the appropriate body system based on examination.

Parathyroidectomy is the treatment of choice for symptomatic hyperparathyroidism. Therefore, VA proposes a 100 percent evaluation for six months after surgical intervention for hyperparathyroidism and thereafter, an evaluation based on the residuals of hyperparathyroidism or medical treatment under the appropriate diagnostic code(s) within the appropriate body system.

VA proposes to amend the current note under DC 7904 by numbering the note as proposed Note (4) and clarifying that the residuals of hyperparathyroidism are to be rated under the appropriate DC. The current note reads: ''Following surgery or treatment, evaluate as digestive, skeletal, renal, or cardiovascular residuals or as endocrine dysfunction.'' The proposed Note (4) reads: ''Following surgery or other treatment, evaluate chronic residuals, such as nephrolithiasis (kidney stones), decreased renal function, fractures, vision problems, and cardiovascular complications, under the appropriate diagnostic codes.''

DC 7905: Hypoparathyroidism

Parathyroid hormone controls the balance of calcium in the body. When there is not enough of this hormone, the condition is known as hypoparathyroidism. The predominant symptoms of hypoparathyroidism is neuromuscular irritability, including, but not limited to, paresthesias (tingling and numbness involving fingertips, toes, or perioral area), hyperirritability, fatigue, anxiety, mood swings and/or personality disturbances, seizures, hoarseness (due to laryngospasm), wheezing and dyspnea (due to bronchospasm), muscle cramps, and electrolyte imbalances (hypomagnesemia, hypokalemia, and alkalosis).

Currently, evaluations are assigned based on some of these symptoms. However, because many of the symptoms of parathyroid hormone deficiency are caused by an imbalance of calcium in the body (decreased extracellular ionized calcium levels and hypocalcemia), when hypoparathyroidism is treated with calcium and vitamin D supplementation, the symptoms are generally eliminated. Paul Fitzgerald, ''Chapter 26. Endocrine Disorders'' (2014), *http://accessmedicine.mhmedical.com/content.aspx?bookid=330&Sectionid=44291028.* Therefore, VA proposes new evaluation criteria that account for this treatment. Specifically, VA proposes a 100 percent evaluation for three months after initial diagnosis and, thereafter, to rate residual effects, such as nephrolithiasis (kidney stones), cataracts, decreased renal function, and congestive heart failure under the appropriate DCs.

New DC 7906: Thyroiditis

VA proposes to add a new DC for thyroiditis, which is inflammation of the thyroid gland. The condition most often results from an autoimmune disease (known as Hashimoto's thyroiditis), where the immune system attacks the thyroid gland.

However, regardless of the specific cause, thyroiditis may manifest as hyperthyroidism, hypothyroidism, or with no change in thyroid function. Because hyperthyroidism and hypothyroidism would be addressed in the Rating Schedule as proposed DCs 7900 and 7903, respectively, VA proposes a note to clarify that these manifestations be rated under those DCs.

While thyroiditis may also be present in a person with normal thyroid function, because thyroiditis increases the likelihood of developing hyperthyroidism or hypothyroidism, the thyroid function of these individuals must be monitored. This factor is not currently accounted for in the Rating Schedule. Therefore, for these individuals, VA proposes that a 0 percent evaluation for asymptomatic thyroiditis be associated with this DC.

DC 7907: Cushing's Syndrome

Cushing's syndrome is the result of prolonged elevation in the amount of glucocorticoid in the body. The severity of the signs and symptoms is determined by the duration and level of glucocorticoid exposure.

Currently, evaluations for Cushing's syndrome are assigned based in part on enlargement of the adrenal gland (which produces these hormones) and the pituitary gland (which produces hormones that trigger the adrenal gland). However, glandular enlargement is not indicative of disease severity. Exogenous glucocorticoid exposure (the intake of glucocorticoids), the most common cause of Cushing's syndrome, does not involve enlargement of the pituitary or adrenal glands. Therefore, VA proposes to delete the requirement for the presence of enlargement of the pituitary or adrenal gland as one of the criteria required for 100 and 60 percent evaluations.

The muscle weakness associated with Cushing's syndrome is a result of proximal muscle wasting and weakness caused by excess glucocorticoid hormones. This muscle wasting results in the inability to rise from a squatting position without assistance, and, in more severe cases, the inability to climb stairs or get up from a deep chair. Lynnette K. Nieman, MD, ''Epidemiology and clinical manifestations of Cushing's syndrome'' UpToDate (Oct. 22, 2013), *http://www.uptodate.com/contents/epidemiology-and-clinical-manifestations-of-cushings-syndrome.* To clarify the criteria for 100 and 60 percent evaluations, VA proposes to replace ''loss of muscle strength'' with the more specific criteria of ''proximal upper and lower extremity muscle wasting that results in inability to rise from squatting position, climb stairs, rise from a deep chair without assistance, or raise arms.'' VA also proposes to remove ''weakness'' from the list of criteria for a 100 percent evaluation because it is already captured with language replacing ''loss of muscle strength.'' With these proposed modifications, a 100 percent evaluation would be assigned for Cushing's syndrome if there is ''active, progressive disease, including areas of osteoporosis, hypertension, and proximal upper and lower extremity muscle wasting that results in inability to rise from a squatting position, climb stairs, rise from a deep chair without assistance, or raise arms.'' Similarly, VA proposes a 60 percent evaluation for Cushing's syndrome if there is ''[p]roximal upper or lower extremity muscle wasting that results in inability to rise from a squatting position, climb stairs, rise from a deep chair without assistance, or raise arms.'' VA proposes no change to the current 30 percent evaluation criteria.

The treatment for Cushing's syndrome is determined by the glucocorticoid source. Endogenous hypercortisolism (overproduction of glucocorticoid hormones by the adrenal gland) is treated by surgical removal of the adrenal gland, medical adrenalectomy, surgical resection of a pituitary tumor, or radiation therapy of the pituitary gland. Exogenous hypercortisolism is treated via gradual reduction of the outside source, such as corticosteroid medications. Because early medical intervention has decreased the complications associated with Cushing's syndrome, VA proposes evaluations for Cushing's syndrome at the 100, 60, or 30 percent level for six months after initial diagnosis. Because treatment may not completely eliminated complications or may itself be associated with complications, after six months, VA proposes to rate residuals such as adrenal insufficiency, cardiovascular, psychiatric, skin, or skeletal complications under the appropriate diagnostic code(s) within the appropriate body system. Therefore, VA proposes to amend the note following DC 7907 to reflect the above proposed changes.

DC 7908: Acromegaly

Acromegaly, DC 7908, is a condition in which the pituitary gland produces excess growth hormone, usually due to a benign tumor. The excessive amount of hormone results in enlargement of various body tissues, including bone. Acromegaly is currently evaluated at levels of 100, 60, and 30 percent. VA proposes no changes in the evaluation criteria for the 100 and 60 percent levels. The current 30 percent evaluation criteria for acromegaly require that there be enlargement of acral parts or overgrowth of long bones, and an enlarged sella turcica (the depression at the base of the skull where the pituitary gland is located). VA proposes to remove ''enlarged sella turcica'' as one of the required criteria. Although acromegaly is generally due to a pituitary tumor (which commonly results in enlargement of the sella turcica), it occasionally arises from causes that do not produce an enlarged sella turcica. Further, enlargement of the sella turcica is not an indicator of the severity of the condition. Therefore, it is not appropriate to retain ''enlarged sella turcica'' as a required criterion, and VA proposes to remove it.

DC 7909: Diabetes Insipidus

Inadequate secretion of or a resistance to antidiuretic hormone (ADH) is the cause of diabetes insipidus (DI). ADH limits the amount of water that the kidneys allow to leave the body. A lack of or resistance to ADH causes excessive excretion of free water. This disease is characterized by polyuria (frequent urination), polydipsia (excessive thirst), and nocturia (frequent night time urination). Without treatment, dehydration and bladder enlargement commonly result. If treated, diabetes insipidus does not cause severe problems or a reduction in life expectancy. See Goldman's Cecil Medicine Chapter 232 (24th ed. 2011). The prognosis for this disease is excellent, because it is frequently transient and there are excellent medications with different means of administration to treat the condition on a chronic basis if this condition becomes permanent. Most individuals, even in emergency situations, can replace urine loss with increased fluid intake. Therefore, the reliance in the current criteria on the need for parenteral (IV) hydration is no longer appropriate, and VA proposes deletion of the current criteria.

In its place, in order to allow the condition to become stabilized and to determine if the condition is transient or becoming permanent, VA proposes a 30 percent evaluation for three months after the initial diagnosis. Once the condition is stabilized, the need for long term medication can be assessed. Many patients are able to control their condition with oral or trans-nasal medication, while others require parenteral treatment (when oral or trans-nasal medications are either not tolerable or effective). Therefore, VA proposes a reevaluation of diabetes insipidus after the three month period. If DI has subsided, VA would rate any residuals under the appropriate diagnostic code(s) within the appropriate body system. For those DI cases with persistent polyuria or requiring continuous hormonal therapy, VA proposes a 10 percent rating.

DC 7911: Addison's Disease (Adrenocortical Insufficiency)

The medical community has shifted from the term ''adrenal cortical hypofunction'' to the term ''adrenocortical insufficiency.'' Therefore, for clarity and consistency with current medical terminology, VA proposes to retitle this DC ''Addison's disease (adrenocortical insufficiency).'' VA does not propose changes to the

rating criteria and notes associated with this DC.

DC 7912: Polyglandular Syndrome (Multiple Endocrine Neoplasia, Autoimmune Polyglandular Syndrome)

''Pluriglandular syndrome'' refers, not to a single condition, but to a group of conditions that impact multiple glands in the body. Therefore, a person is likely to be given a more specific diagnosis, rather than one with this general term. Therefore, VA proposes to include the most common forms of the condition in the title of the DC. Also, over time, the medical community has shifted from the term ''pluriglandular'' to ''polyglandular'' when referring to this condition. Therefore, to better reflect the terminology currently associated with the condition, VA proposes to update the title of DC 7912 to ''Polyglandular syndrome (multiple endocrine neoplasia, autoimmune polyglandular syndrome).'' The current guidance for evaluation is to evaluate according to major manifestations. VA proposes to revise the guidance to include some of the common manifestations of the syndrome. The proposed guidance reads: ''Evaluate according to major manifestations to include, but not limited to, Type I diabetes mellitus, hyperthyroidism, hypothyroidism, hypoparathyroidism, or Addison's disease.''

DC 7913: Diabetes Mellitus

Diabetes mellitus is a complex condition that impacts individuals in a variety of ways. At this time, VA proposes only one clarifying amendment to this DC. VA proposes to clarify that the rating criteria for a 20, 40, or 60 percent rating require ''one or more daily injection'' of insulin. This clarifying amendment is not a substantive change but rather a clarification of VA's interpretation of this DC that an injection of insulin is required to achieve a 20, 40, 60, or 100 percent rating. To ensure that the full range of relevant factors is adequately addressed, VA is not proposing to amend the remaining rating criteria pertaining to this DC at this time. Rather, VA intends to establish a work group to specifically address this condition. Upon consideration of the work group's findings, VA will determine whether amendments to the remaining existing criteria are necessary and such amendments, if any, will be addressed in a future proposal.

DC 7914: Neoplasm, Malignant, Any Specified Part of the Endocrine System

VA proposes no changes at this time.

DC 7915: Neoplasm, Benign, Any Specified Part of the Endocrine System

VA proposes to retain the existing direction to rate this condition based on residuals of endocrine dysfunction, but separate the rating direction from the title of DC 7915.

DC 7916: Hyperpituitarism (Prolactin Secreting Pituitary Dysfunction)

The existing note regarding the evaluation of this condition also applies to DCs 7917 and 7918 and is given after DC 7918. Therefore, it can be overlooked with regard to the other DCs. Therefore, VA proposes to include the same note regarding the evaluation of each condition directly under each DC and to amend the current note to reflect the proposed change. The conditions would all continue to be evaluated as malignant or benign neoplasm, as appropriate, so no substantive change is being made.

DC 7917: Hyperaldosteronism (Benign or Malignant)

See discussion of DC 7916.

DC 7918: Pheochromocytoma (Benign or Malignant)

See discussion of DC 7916.

DC 7919: C-cell Hyperplasia of the Thyroid

Currently, this condition is rated in the same way as a malignant neoplasm. However, this does not adequately address all potential manifestations of this condition. Therefore, VA proposes to replace the existing note with one that provides as follows: ''If antineoplastic therapy is required, evaluate as a malignant neoplasm under DC 7914. If a prophylactic thyroidectomy is performed (based upon genetic testing) and antineoplastic therapy is not required, evaluate as hypothyroidism under DC 7903.'' These changes are in keeping with current medical information about C-cell hyperplasia.

Technical Amendments

VA also proposes several technical amendments. We would add a citation reference to 38 U.S.C. 1155 at the end of § 4.119, and we would update Appendix A, B, and C of part 4 to reflect the above noted proposed amendments.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This proposed rule would directly affect only individuals and would not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action'' requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined to be a significant regulatory action under Executive Order 12866 because it is likely to result in a rule that may raise novel policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. VA's impact

analysis can be found as a supporting document at *http://www.regulations.gov*, usually within 48 hours after the rulemaking document is published. Additionally, a copy of this rulemaking and its impact analysis are available on VA's Web site at *http://www.va.gov/orpm/*, by following the link for ''VA Regulations Published From FY 2004 Through Fiscal Year to Date.''

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.104, Pension for Non-Service-Connected Disability for Veterans, and 64.109, Veterans Compensation for Service-Connected Disability.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Nabors, II, Chief of Staff, approved this document on June 30, 2015, for publication.

List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

Dated: July 1, 2015.

William F. Russo,

Acting Director, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.

For the reasons set out in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 4 as set forth below:

PART 4—SCHEDULE FOR RATING DISABILITIES

Subpart B—Disability Ratings

■ 1. The authority citation for part 4 continues to read as follows:

Authority: 38 U.S.C. 1155, unless otherwise noted.

■ 2. Amend § 4.104 by revising the entry for 7008 to read as follows:

§ 4.104 Schedule of ratings—cardiovascular system.

DISEASES OF THE HEART

	Rating
* * * * *	
7008 Hyperthyroid heart disease.	
Rate under the appropriate cardiovascular diagnostic code, depending on particular findings.	
* * * * *	

■ 3. Section 4.119 is revised to read as follows:

The Endocrine System

§ 4.119 Schedule of ratings—endocrine system.

	Rating
7900 Hyperthyroidism, including, but not limited to, Graves' disease:	
For six months after initial diagnosis	30
Thereafter, rate residuals of disease or complications of medical treatment within the appropriate diagnostic code(s) within the appropriate body system.	
Note (1): If hyperthyroid cardiovascular or cardiac disease is present, separately evaluate under DC 7008 (hyperthyroid heart disease).	
Note (2): Separately evaluate eye involvement occurring as a manifestation of Graves' Disease as diplopia (DC 6090); impairment of central visual acuity (DCs 6061–6066); or under the most appropriate DCs in § 4.79.	
7901 Thyroid enlargement, toxic.	
Note (1): Evaluate symptoms of hyperthyroidism under DC 7900, hyperthyroidism, including, but not limited to, Graves' disease.	
Note (2): If disfigurement of the neck is present due to thyroid disease or enlargement, separately evaluate under DC 7800 (burn scar(s) of the head, face, or neck; scar(s) of the head, face, or neck due to other causes; or other disfigurement of the head, face, or neck).	
7902 Thyroid enlargement, nontoxic:	
Note (1): Evaluate symptoms due to pressure on adjacent organs (such as the trachea, larynx, or esophagus) under the appropriate diagnostic code(s) within the appropriate body system.	
Note (2): If disfigurement of the neck is present due to thyroid disease or enlargement, separately evaluate under DC 7800 (burn scar(s) of the head, face, or neck; scar(s) of the head, face, or neck due to other causes; or other disfigurement of the head, face, or neck).	
7903 Hypothyroidism:	
Hypothyroidism manifesting as myxedema (cold intolerance, muscular weakness, cardiovascular involvement (including, but not limited to hypotension, bradycardia, and pericardial effusion), and mental disturbance (including, but not limited to dementia, slowing of thought and depression))	100
Note (1): This evaluation shall continue for six months beyond the date that an examining physician has determined crisis stabilization. Thereafter, the residual effects of hypothyroidism shall be rated under the appropriate diagnostic code(s) within the appropriate body system(s) (*e.g.*, eye, digestive, and mental disorders).	
Hypothyroidism without myxedema	30
Note (2): This evaluation shall continue for six months after the initial diagnosis. Thereafter, rate residuals of disease or medical treatment under the most appropriate diagnostic code(s)under the appropriate body system (*e.g.*, eye, digestive, mental disorders).	
Note (3): If eye involvement, such as exophthalmos, corneal ulcer, blurred vision, or diplopia, is also present due to thyroid disease, also separately evaluate under the appropriate diagnostic code(s) in § 4.79, Schedule of Ratings—Eye (such as diplopia (DC 6090) or impairment of central visual acuity (DCs 6061–6066)).	

	Rating
7904 Hyperparathyroidism	
For six months from date of discharge following surgery	100
Note (1): After six months, rate on residuals under the appropriate diagnostic code(s) within the appropriate body system(s) based on a VA examination.	
Hypercalcemia (indicated by at least one of the following: Total Ca greater than 12mg/dL (3–3.5 mmol/L), Ionized Ca greater than 5.6 mg/dL (2–2.5 mmol/L), creatinine clearance less than 60 mL/min, bone mineral density T-score less than 2.5 SD (below mean) at any site or previous fragility fracture)	60
Note (2): Where surgical intervention is indicated, this evaluation shall continue until the day of surgery, at which time the provisions pertaining to a 100 percent evaluation shall apply.	
Note (3): Where surgical intervention is not indicated, this evaluation shall continue for six months after pharmacologic treatment begins. After six months, rate on residuals under the appropriate diagnostic code(s) within the appropriate body system(s) based on a VA examination.	
Symptoms such as fatigue, anorexia, nausea, or constipation that occur despite surgery; or in individuals who are not candidates for surgery but require continuous medication for control	10
Asymptomatic	0
Note (4): Following surgery or other treatment, evaluate chronic residuals, such as nephrolithiasis (kidney stones), decreased renal function, fractures, vision problems, and cardiovascular complications, under the appropriate diagnostic codes.	
7905 Hypoparathyroidism:	
For three months after initial diagnosis	100
Thereafter, evaluate chronic residuals, such as nephrolithiasis (kidney stones), cataracts, decreased renal function, and congestive heart failure under the appropriate diagnostic codes.	
7906 Thyroiditis	
With normal thyroid function (euthyroid)	0
Note: Manifesting as hyperthyroidism, evaluate as hyperthyroidism, including, but not limited to, Graves' disease (DC 7900); manifesting as hypothyroidism, evaluate as hypothyroidism (DC 7903).	
7907 Cushing's syndrome:	
As active, progressive disease, including areas of osteoporosis, hypertension, and proximal upper and lower extremity muscle wasting that results in inability to rise from squatting position, climb stairs, rise from a deep chair without assistance, or raise arms	100
Proximal upper or lower extremity muscle wasting that results in inability to rise from squatting position, climb stairs, rise from a deep chair without assistance, or raise arms	60
With striae, obesity, moon face, glucose intolerance, and vascular fragility	30
Note: The evaluations specifically indicated under this diagnostic code shall continue for six months following initial diagnosis. After six months, rate on residuals under the appropriate diagnostic code(s) within the appropriate body system(s).	
7908 Acromegaly:	
Evidence of increased intracranial pressure (such as visual field defect), arthropathy, glucose intolerance, and either hypertension or cardiomegaly	100
Arthropathy, glucose intolerance, and hypertension	60
Enlargement of acral parts or overgrowth of long bones	30
7909 Diabetes insipidus:	
For three months after initial diagnosis	30
Note: Thereafter, if Diabetes insipidus has subsided, rate residuals under the appropriate diagnostic code(s) within the appropriate body system.	
With persistent polyuria or requiring continuous hormonal therapy	10
7911 Addison's disease (adrenalcortical insufficiency):	
Four or more crises during the past year	60
Three crises during the past year, or; five or more episodes during the past year	40
One or two crises during the past year, or; two to four episodes during the past year, or; weakness and fatigability, or; corticosteroid therapy required for control	20
Note (1): An Addisonian "crisis" consists of the rapid onset of peripheral vascular collapse (with acute hypotension and shock), with findings that may include: anorexia; nausea; vomiting; dehydration; profound weakness; pain in abdomen, legs, and back; fever; apathy, and depressed mentation with possible progression to coma, renal shutdown, and death.	
Note (2): An Addisonian "episode," for VA purposes, is a less acute and less severe event than an Addisonian crisis and may consist of anorexia, nausea, vomiting, diarrhea, dehydration, weakness, malaise, orthostatic hypotension, or hypoglycemia, but no peripheral vascular collapse.	
Note (3): Tuberculous Addison's disease will be evaluated as active or inactive tuberculosis. If inactive, these evaluations are not to be combined with the graduated ratings of 50 percent or 30 percent for non-pulmonary tuberculosis specified under § 4.88b. Assign the higher rating.	
7912 Polyglandular syndrome (multiple endocrine neoplasia, autoimmune polyglandular syndrome):	
Evaluate according to major manifestations to include, but not limited to, Type I diabetes mellitus, hyperthyroidism, hypothyroidism, hypoparathyroidism, or Addison's disease.	
7913 Diabetes mellitus	
Requiring more than one daily injection of insulin, restricted diet, and regulation of activities (avoidance of strenuous occupational and recreational activities) with episodes of ketoacidosis or hypoglycemic reactions requiring at least three hospitalizations per year or weekly visits to a diabetic care provider, plus either progressive loss of weight and strength or complications that would be compensable if separately evaluated	100
Requiring one or more daily injection of insulin, restricted diet, and regulation of activities with episodes of ketoacidosis or hypoglycemic reactions requiring one or two hospitalizations per year or twice a month visits to a diabetic care provider, plus complications that would not be compensable if separately evaluated	60
Requiring one or more daily injection of insulin, restricted diet, and regulation of activities	40
Requiring one or more daily injection of insulin and restricted diet, or; oral hypoglycemic agent and restricted diet	20
Manageable by restricted diet only	10

	Rating
Note (1): Evaluate compensable complications of diabetes separately unless they are part of the criteria used to support a 100 percent evaluation. Noncompensable complications are considered part of the diabetic process under DC 7913. Note (2): When diabetes mellitus has been conclusively diagnosed, do not request a glucose tolerance test solely for rating purposes.	
7914 Neoplasm, malignant, any specified part of the endocrine system	100
Note: A rating of 100 percent shall continue beyond the cessation of any surgical, X-ray, antineoplastic chemotherapy or other therapeutic procedure. Six months after discontinuance of such treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter. If there has been no local recurrence or metastasis, rate on residuals.	
7915 Neoplasm, benign, any specified part of the endocrine system:	
Rate as residuals of endocrine dysfunction.	
7916 Hyperpituitarism (prolactin secreting pituitary dysfunction):	
Note: Evaluate as malignant or benign neoplasm, as appropriate.	
7917 Hyperaldosteronism (benign or malignant):	
Note: Evaluate as malignant or benign neoplasm, as appropriate.	
7918 Pheochromocytoma (benign or malignant):	
Note: Evaluate as malignant or benign neoplasm as appropriate.	
7919 C-cell hyperplasia of the thyroid:	
If antineoplastic therapy is required, evaluate as a malignant neoplasm under DC 7914. If a prophylactic thyroidectomy is performed (based upon genetic testing) and antineoplastic therapy is not required, evaluate as hypothyroidism under DC 7903.	

(Authority: 38 U.S.C. 1155)

■ 3. Amend appendix A to part 4 by revising the entries for Secs. §§ 4.104 and 4.119 to read as follows:

Appendix A to Part 4—Table of Amendments and Effective Dates Since 1946

Sec.	Diagnostic code No.	
*	*	* * * * * * *
4.104	7000	Evaluation July 6, 1950; evaluation September 22, 1978; evaluation January 12, 1998.
*	*	* * * * * * *
	7008	Evaluation January 12, 1998; evaluation [*effective date of final rule*].
*	*	* * * * * * *
4.119	7900	Criterion August 13, 1981; evaluation June 9, 1996; title [*effective date of final rule*]; evaluation [*effective date of final rule*]; criterion [*effective date of final rule*]; note *[effective date of final rule*].
	7901	Criterion August 13, 1981; evaluation June 9, 1996; title [*effective date of final rule*]; evaluation [*effective date of final rule*]; criterion [*effective date of final rule*].
	7902	Evaluation August 13, 1981; criterion June 9, 1996; title [*effective date of final rule*]; evaluation [*effective date of final rule*]; criterion [*effective date of final rule*]; note [*effective date of final rule*].
	7903	Criterion August 13, 1981; evaluation June 9, 1996; evaluation [*effective date of final rule*]; criterion [*effective date of final rule*]; note [*effective date of final rule*].
	7904	Criterion August 13, 1981; evaluation June 9, 1996; evaluation [*effective date of final rule*]; criterion [*effective date of final rule];* note *[effective date of final rule*].
	7905	Evaluation; August 13, 1981; evaluation June 9, 1996; evaluation [*effective date of final rule*]; criterion [*effective date of final rule*]; note [*effective date of final rule*]. Added [*effective date of final rule*].
	7906	Evaluation; August 13, 1981; evaluation June 9, 1996; criterion [*effective date of final rule*]; note [*effective date of final rule*].
	7907	Criterion August 13, 1981; criterion June 9, 1996; criterion [*effective date of final rule*].
	7908	Evaluation August 13, 1981; criterion June 9, 1996; evaluation June 9, 1996; criterion [*effective date of final rule];* note *[effective date of final rule*].
	7909	Removed June 9, 1996.
	7910	Evaluation March 11, 1969; evaluation August 13, 1981; criterion June 9, 1996; title [*effective date of final rule*].
	7911	Title [*effective date of final rule*].
	7912	Criterion September 9, 1975; criterion August 13, 1981; criterion June 6, 1996; evaluation June 9, 1996; criterion [*effective date of final rule*].
	7913	Criterion March 10, 1976; criterion August 13, 1981; criterion June 9, 1996.
	7914	Criterion June 9, 1996.
	7915	Added June 9, 1996.
	7916	Added June 9, 1996.
	7917	Added June 9, 1996.
	7918	Added June 9, 1996; evaluation June 9, 1996; criterion [*effective date of final rule*].
	7919	* * *
*	*	* * * * * * *

■ 4. Amend Appendix B to Part 4 by revising the entries for diagnostic codes 7900, 7901, 7902, 7911, and adding diagnostic code 7906 to read as follows:

Appendix B to Part 4—Numerical Index of Disabilities

Diagnostic code No.						
*	*	*	*	*	*	*
THE ENDOCRINE SYSTEM						
7900	Hyperthyroidism, including, but not limited to, Graves' disease.					
7901	Thyroid enlargement, toxic.					
7902	Thyroid enlargement, nontoxic.					
*	*	*	*	*	*	*
7906	Thyroiditis.					
*	*	*	*	*	*	*
7911	Addison's disease (adrenocortical insufficiency).					
7912	Polyglandular syndrome (multiple endocrine neoplasia, autoimmune polyglandular syndrome).					
*	*	*	*	*	*	*

■ 4. Amend appendix C by:
■ a. Adding entries for Graves' disease. Polyglandular syndrome and Thyroiditis in alphabetical order; and
■ b. Revising the disability entry for Thyroid gland. The additions and revision read as follows:

Appendix C to Part 4—Alphabetical Index of Disabilities

	Diagnostic code No.
* * * * *	
Graves' disease	7900
* * * * *	
Polyglandular syndrome	7912
* * * * *	
Thyroid gland	
Nontoxic thyroid enlargement	7902
Toxic thyroid enlargement	7901
Thyroiditis	7906
* * * * *	

[FR Doc. 2015–16666 Filed 7–7–15; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0164; FRL–9927–77–Region 9]

Revisions to the California State Implementation Plan, Feather River Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Feather River Air Quality Management District (FRAQMD) portion of the California State Implementation Plan (SIP). Included in this approval are the following three SIP demonstrations from FRAQMD: 2006 Reasonably Available Control Technology (RACT) Analysis for State Implementation Plan (SIP), November 2006; Reasonably Available Control Technology State Implementation Plan Revision Negative Declaration for Control Techniques Guidelines Issued 2006–2008, June 1, 2009; and Reasonably Available Control Technology Analysis and Negative Declarations, July 3, 2014. The first two demonstrations address the 1997 8-hour National Ambient Air Quality Standards (NAAQS) for ozone, and the third demonstration addresses the 2008 8-hour NAAQS for ozone. The submitted SIPs also contain negative declarations for volatile organic compound (VOC) source categories for the years 2006, 2009 and 2014. We are proposing to approve the submitted SIP revisions under the Clean Air Act as amended in 1990 (CAA or the Act). We are also proposing to approve a local rule that regulates gasoline dispending facilities.

DATES: Any comments on this proposal must arrive by August 7, 2015.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2015–0164, by one of the following methods:

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

2. *Email: steckel.andrew@epa.gov.*

3. *Mail or deliver:* Andrew Steckel (Air–4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *www.regulations.gov* or email. *www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps), and some may not be publicly available in either location

(*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: James Shears, EPA Region IX, (213) 244–1810, *shears.james@epa.gov*.

SUPPLEMENTARY INFORMATION: This proposal addresses revisions to the FRAQMD portion of the California SIP. In the rules and regulations section of the **Federal Register**, we are approving the three RACT SIP revisions in a direct final action without prior proposal because we believe these SIP revisions are not controversial. This proposal also addresses the following local rule: FRAQMD Rule 3.8, Gasoline Dispensing Facilities. In the Rules and Regulations section of this **Federal Register**, we are approving this local rule in a direct final action without prior proposal because we believe this SIP revision is not controversial. Please note that if we receive adverse comment on a specific provision of these SIP revisions or the rule, we will publish a timely withdrawal of the direct final rule and address the comments in a subsequent action. If that provision may be severed from the remainder of the SIP revisions or the rule, we may adopt as final those provisions of the SIP revisions or the rule that are not the subject of an adverse comment.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: April 30, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2015–16629 Filed 7–7–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Part 1201

[Docket No. EP 720]

Accounting and Reporting of Business Combinations, Security Investments, Comprehensive Income, Derivative Instruments, and Hedging Activities

AGENCY: Surface Transportation Board, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Surface Transportation Board proposes to revise its regulations to update the accounting and reporting requirements under its Uniform System of Accounts (USOA) for Class I Railroads to be more consistent with current generally accepted accounting principles (GAAP) and revise the schedules and instructions for the Annual Report for Class I Railroads (R–1 or Form R–1) to better meet regulatory requirements and industry needs. The intent of the proposed revisions is to promote sound and uniform accounting and financial reporting for the types of transactions and events described herein.

DATES: Comments on this proposed rulemaking are due on or before August 7, 2015; reply comments are due by September 8, 2015.

ADDRESSES: Any filings submitted in this proceeding must be submitted either via the Board's e-filing format or in the traditional paper format. Any person using e-filing should attach a document and otherwise comply with the instructions found at the E-FILING link on the Board's Web site at *www.stb.dot.gov.* Any person submitting a filing in the traditional paper format should send an original and 10 copies and also an electronic version to: Surface Transportation Board, Attn: Docket No. EP 720, 395 E Street SW., Washington, DC 20423–0001.

FOR FURTHER INFORMATION CONTACT: Pedro Ramirez at (202) 245–0333. Assistance for the hearing impaired is available through the Federal Information Relay Services (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Introduction

In this notice of proposed rulemaking (NPR), the Surface Transportation Board (Board) proposes to amend its USOA and Form R–1.[1] The Board proposes to add new general instructions and accounts to recognize changes in the fair value of certain security investments, items of other comprehensive income, derivative instruments, and hedging activities. Additionally, the Board proposes to revise the USOA to reflect current accounting practices for business combinations by removing existing instructions for the pooling-of-interest method of accounting. The Board also seeks to revise Form R–1 to include the new accounts and the new reporting schedule proposed by this rulemaking.

The Board also solicits comments on the proposed elimination of certain schedules currently contained in Form R–1 that are not used for any regulatory or other purposes by the Board. As there may be other governmental agencies or interested parties that rely on the information in some of these schedules, we are requesting comments concerning their elimination.

The purpose of the proposed revisions is to provide sound and uniform accounting and financial reporting for certain types of transactions and events. The Board believes that such requirements are needed because these types of transactions and events are neither specifically nor correctly addressed in the existing USOA. The new instructions, accounts, and reporting schedule would result in improved, consistent, and complete accounting and reporting.

Background

A. General

The Interstate Commerce Act, as amended by the ICC Termination Act of 1995 (ICCTA), Public Law 104–88, 109 Stat. 803, authorizes the Board, in 49 U.S.C. 11142, to prescribe a uniform accounting system for rail carriers subject to our jurisdiction and, in 49 U.S.C. 11161, to maintain cost accounting rules for rail carriers. Sections 11142 and 11161 both require the Board to conform its accounting rules to GAAP ''[t]o the maximum extent practicable.''

In keeping with this requirement, we propose updates to the USOA to provide for: (1) Fair value presentation of certain security investments, derivative instruments and hedging activities; (2) presentation of comprehensive income and components of other comprehensive income; and (3) accounting for business combinations. The proposed revisions are based on the generally accepted accounting principles promulgated by the FASB in the following Accounting Standards Codifications (ASC): ASC 320 Investments—Debt and Equity Securities; ASC 220 Comprehensive Income; ASC 815 Derivatives and Hedging; and ASC 805 Business Combinations.[1]

[1] The Board has broad economic regulatory oversight of railroads, addressing such matters as rates, service, construction, acquisition and abandonment of rail lines, carrier mergers, and interchange of traffic among carriers (49 U.S.C. 10101–11908). The Board monitors the financial condition of railroads as part of its oversight of the rail industry. The Board prescribes a uniform accounting system for railroads to use for regulatory purposes. 49 U.S.C. 11141–43, 11161–64; 49 CFR parts 1200 and 1201. In addition, the Board requires Class I railroads to submit quarterly and annual reports containing financial and operating statistics, including employment and traffic data (49 U.S.C. 11145; 49 CFR parts 1241 through 1246 and 1248).

[1] These accounting pronouncements are available at *https://asc.fasb.org.*

The Board considers the requirements in ASC 320, 220, 815, and 805 to be an improvement in financial accounting and reporting practices. The Board also considers it important that its accounting requirements are consistent with the industry's general purpose financial reporting requirements. Therefore, the Board proposes to implement the principles and concepts set forth in ASC 320, 220, 815, and 805 for railroad accounting and reporting purposes effective upon issuance of a final rule in this proceeding. The Board believes that the proposed accounting and reporting changes would provide consistent accounting and reporting of changes in the fair value of security investments, derivative instruments, and hedging activities. The proposed changes would also minimize the accounting and reporting burden on railroads under the Board's jurisdiction, assist the Board in its overall monitoring effort, and improve transparency.

To provide context for the Board's proposed changes, the key aspects of the relevant FASB pronouncements are discussed in sections B through E of this Background.

B. Investments in Debt and Equity Securities (ASC 320)

ASC 320 establishes standards of financial accounting and reporting for investments in equity securities that have readily determinable fair values and for all investments in debt securities. Fair value of an equity security is readily determinable if sales prices and bid-and-asked quotations are currently available on a securities exchange registered with the U.S. Securities and Exchange Commission, or publicly reported in the over-the-counter market.

ASC 320 requires entities to classify all debt securities and selected equity securities into one of three categories: (1) Trading securities; (2) available-for-sale securities; or (3) held-to-maturity securities. Classification of the securities is based primarily on management's intent for holding a particular investment.

Trading securities. Trading securities are debt and equity securities that are bought and held principally for the purpose of selling them in the near term, usually less than one year. These securities are held for short periods of time with the objective of generating profits from short-term differences in price.

Available-for-sale securities. Available-for-sale securities are investments in debt and equity securities that have readily determinable fair values not classified as trading securities or held-to-maturity securities.

Held-to-maturity securities. Held-to-maturity securities are debt securities that the entity has the positive intent and ability to hold to maturity. For debt securities held to maturity, amortized cost is a more relevant measure than fair value because that cost will be realized, absent default. Therefore, changes in the fair value of securities held to maturity are not recognized during the period the entity holds the security investment. ASC 320 states that a debt security that is available to be sold in response to changes in market interest rates, changes in the security's prepayment risk, the enterprise's need for liquidity, changes in foreign exchange risks, or other similar factors should not be included in the held-to-maturity category because the possibility of a sale indicates that the enterprise does not have a positive intent and ability to hold the security to maturity. However, under certain circumstances, a company may change its intent concerning securities originally classified as held-to-maturity, resulting in the securities' sale or reclassification without calling into question the company's intent to hold other securities to maturity.

C. Comprehensive Income (ASC 220)

The purpose of comprehensive income is to measure all changes in an entity's equity that result from recognized transactions and other economic events of a period other than those transactions resulting from investment by owners and distributions to owners. When paired with disclosure notes and other information in the financial statements, the reporting of comprehensive income is intended to help investors, creditors, and others assess an entity's activities and future cash flows.

Under GAAP, comprehensive income is comprised of traditional net income and all components of other comprehensive income. ''Other comprehensive income'' includes revenues, expenses, gains and losses that are included in comprehensive income but not in net income. This includes foreign currency translation adjustments, unrealized holding gains and losses on available-for-sale securities, changes in pension or other post-retirement benefits, and changes in the fair value of derivative financial instruments classified as cash-flow hedges.

GAAP requires financial statements to present comprehensive income in two parts: (1) Net income and its components (such as income from continuing operations, discontinued operations, and extraordinary items); and (2) Other Comprehensive Income and its components.

Reclassifications of items from accumulated Other Comprehensive Income to net income must be measured and presented by income statement line item in both the statement where net income is presented and the statement where Other Comprehensive Income is presented. This accounting standard applies only to entities with items of Other Comprehensive Income. Entities without Other Comprehensive Income items are exempt from providing a statement of comprehensive income and instead should report only net income in the statement displaying the results of operations.

D. Derivatives and Hedging (ASC 815)

A derivative instrument is a security whose price is dependent upon or derived from one or more underlying assets. Derivative instruments represent rights or obligations that meet the definition of an asset or liability and should be reported in financial statements. For accounting purposes, a derivative instrument is a financial instrument or other contract that has all of the following characteristics:

1. The instrument has one or more underlyings. An underlying is a specified interest rate, security price, commodity price, foreign exchange rate, index of prices or rates, or other variable. An underlying may be a price or rate of an asset or liability but is not the asset or liability itself.

2. The instrument must have one or more notional amounts or payment provisions. A notional amount represents a quantity such as a number of currency units, shares, bushels, pounds, or other units specified in a derivative instrument. Those terms determine the amount of a contract's settlement or settlements, and, in some cases, determine whether or not a settlement is required.

3. The instrument requires either no initial net investment or an initial net investment that is smaller than would be required for other types of contracts that would be expected to have a similar response to changes in market factors.

4. The instrument requires or permits net settlement, and can readily be settled net by a means outside the contract, or provides for delivery of an asset that puts the recipient in a position not substantially different from net settlement.

Certain types of contracts are exempted from the requirements of ASC 815 to avoid burdening certain industries and markets. For example, normal purchases and normal sales

contracts that provide for the purchase or sale of goods that will be delivered in quantities expected to be used or sold by the reporting entity over a reasonable period of time and in the normal course of business are not considered derivative instruments. This exception is commonly referred to as the normal purchases and normal sales scope exception. The exception would include typical purchases and sales of inventory items, certain insurance contracts, and employee compensation agreements. Derivative instruments that do not qualify for the normal purchases and normal sales scope exception or other exceptions provided for under the statement are reflected in the financial statements. Consequently, most futures, forwards, swaps, and option contracts meet the definition of a derivative instrument and changes in their fair value would be reflected in the financial statements.

Accounting for a Derivative Instrument. Accounting for changes in the fair value of a derivative instrument depends upon its intended use and designation. Essentially, for certain derivative instruments not designated as hedging instruments, gain or loss is recognized as earnings in the period of change. The change in the value of the derivative instrument is reflected on the balance sheet as an asset or liability with a corresponding amount recognized in earnings. This accounting effectively provides users of the financial statements with information concerning the value of the derivative instrument as if it had been settled in the market place.

Hedge Accounting. A hedge is an instrument's position intended to offset potential losses or gains that may be incurred by a companion investment. Entities hedge to manage risk to prices or interest rates (among other things). Provided certain criteria are met, a derivative may be specifically designated as a fair-value or cash-flow hedge. Under the rules for hedge accounting, the changes in the fair value of the derivative instrument are measured at fair value with adjustments made to the carrying amount of the items being hedged (as in a fair-value hedge) or to Other Comprehensive Income (as in a cash-flow hedge) to the extent the hedge is effective.

1. *Fair-Value Hedge.* In a fair-value hedge, a derivative instrument is designated as a hedge against exposure to changes in the fair value of a recognized asset, liability, or a firm commitment.[2] The change in value of the derivative instrument is recognized in earnings in the period of the change together with the offsetting gain or loss on the hedged item attributable to the risk. To the extent that a hedge is perfectly effective, it will produce the same offsetting amounts in earnings so that net income is not impacted by the hedge. However, amounts would be reflected in earnings to the extent that the hedge is not effective in offsetting the change in value of the item being hedged. Additionally, fair-value accounting results in an adjustment of the carrying amount of the hedged asset or liability. In the case of a fair-value hedge of a firm commitment, a new asset or liability is created. As a result of the hedge relationship, the new asset or liability ultimately becomes part of the carrying amount of the item being hedged.

2. *Cash-Flow Hedge.* A cash-flow hedge uses a derivative instrument to protect against the risk caused by variable prices or costs, which may cause future cash flows to be uncertain. This type of instrument protects against an anticipated or forecasted transaction that probably will occur in the future but the amount of which has not been fixed.

In a cash-flow hedge, the effective portion of the derivative instrument's gain or loss is initially reported as a component of Other Comprehensive Income (outside net income). The ineffective portion of the gain or loss is reported in earnings immediately. Amounts in accumulated Other Comprehensive Income are reclassified into earnings in the same period during which the hedged forecasted item affects earnings.

Documentation of Hedge Relationship. Entities must keep extensive documentation of the hedge relationship. An entity that elects to apply the special hedge accounting principles is required to document, at the inception of the hedge, the risk management objective and strategy for undertaking the hedge, including the hedge instrument, the related transaction, the nature of the risk being hedged, and how effectiveness will be determined.

A company's documentation of its overall risk management philosophy is essential in addressing the role that derivative instruments and hedging activities play in achieving the company's risk management objectives. Concurrent designation and documentation of a hedge is critical because an entity could retroactively identify a transaction as a hedge or change a method of measuring effectiveness to achieve a desired outcome. At the inception of the hedge, formal documentation is required that identifies the hedging instrument, and specifically the hedged item or transaction, along with the nature of the risk being hedged. Entities are required to formally document how effectiveness will be assessed at the adoption of the hedge and on an ongoing basis.

E. Business Combinations (ASC 805)

A business combination is a transaction or other event in which one or more businesses obtain control of another business. It also includes transactions involving mergers of equals and certain acquisitions by a not-for-profit entity. ASC 805—Business Combinations requires that a business combination be accounted for by applying the acquisition method.

The acquisition method requires the acquiring entity to recognize and measure, as of the acquisition date, the identifiable assets acquired, liabilities assumed, and any noncontrolling interest in the acquired entity. The acquiring entity must also recognize and measure goodwill (the excess of purchase price over net assets, related to the acquisition) or a gain resulting from a bargain purchase.

Discussion

A. *General.* The Board's existing USOA does not specifically address the proper accounting and reporting for changes in the fair value of certain security investments, derivative instruments, and hedging activities. Additionally, the existing USOA does not contain specific accounts to record amounts related to items of Other Comprehensive Income or provide a format to display comprehensive income in the Form R–1. The USOA's accounting for business combinations must also be revised to reflect the acquisition accounting method, as required in ASC 805.

Without specific instructions and accounts for recording and reporting certain transactions and events, inconsistent and incomplete accounting would result. For example, if the effects of certain derivative instruments and hedging activities are not properly reported to the Board in the Form R–1, it would be difficult for the Board and others to determine the impact of derivatives on regulated carriers' financial statements and Results of

[2] A firm commitment is an agreement with an unrelated party, binding on both parties, that is usually legally enforceable and that specifies all significant terms and includes a disincentive for nonperformance.

Operations Statements.[3] The addition of new accounts and related general instructions is intended to improve the visibility, completeness, and consistency of accounting and reporting of changes in the fair value of certain investment securities, items of Other Comprehensive Income, derivatives instruments, and hedging activities.

Also, the addition of the proposed new accounts and related reporting requirements to the Form R–1 would reduce regulatory uncertainty as to the proper accounting and reporting for these items and minimize regulatory burden by reducing the potential differences in the manner in which these amounts are reported to shareholders and to the Board. Finally, the reporting of derivative instruments and hedging activities by regulated carriers would assist the Board in its overall monitoring effort as well as its ability to assess railroad industry growth and financial stability. Further, such reporting would assist the Board in identifying industry changes that may affect national transportation policy.

B. *Proposed Accounting for Trading and Available-for-Sale Type Securities.* Under the Board's USOA, all types of securities are recorded at cost, and subsequent changes in the fair value of security investments are not recognized in the financial statements.

The Board is of the view that fair-value measurement of trading and available-for-sale type securities presents relevant and useful information to existing and potential investors, creditors, regulators, and others in making credit and other decisions. Fair-value measurements would also provide useful information to the Board concerning the status of certain amounts set aside to fund future obligations.

Therefore, the Board proposes to add language to its investment account requirements for rail carriers to permit the recognition of changes in the fair value of trading and available-for-sale types of securities due to unrealized holding gains and losses. The security investment asset accounts for railroads are: Account 702, Temporary Cash Investments; Account 721, Investments and Advances: Affiliated Companies; Account 722, Other Investments and Advances; Account 715, Sinking Funds; Account 716, Capital Funds; and Account 717, Other Funds.

C. *Proposed Accounting for Other Comprehensive Income.* The existing USOA does not contain specific accounts to record amounts related to items of Other Comprehensive Income or provide a format to display comprehensive income in the Form R–1. Therefore, entities currently record items of Other Comprehensive Income in Account 606. However, as part of the proposed rule, the USOA would be revised to provide accounting for such items. Thus, the use of Account 606 in the USOA to record items of Other Comprehensive Income would no longer be appropriate. Instead, these items would be accounted for elsewhere in the USOA.

A new equity account (Account 799, Accumulated Other Comprehensive Income) is also proposed to include the accumulated balance for items of Other Comprehensive Income. The account would require that railroads maintain supporting records for each category of Other Comprehensive Income and report such information in their Form R–1. Detailed records would be maintained so that the current period activity, year-to-date activity, and reclassification adjustments related to items of Other Comprehensive Income could be readily identified. Maintaining detailed records for items included in accumulated Other Comprehensive Income is necessary to ensure that a railroad can readily identify amounts when an item is included in net income in subsequent periods.

As proposed, a new equity sub-account entitled Account 799.1, Other Comprehensive Income, would be established to include amounts for items of Other Comprehensive Income for the reporting year. The purpose of this account is to record the activity for items of Other Comprehensive Income during a fiscal year. At year end, the amounts recorded in sub-account 799.1 would be transferred to the new equity Account 799. Consequently, Account 799.1, as proposed, would always have a zero beginning and year-end balance. Therefore, the Board proposes not to include this account as part of the balance sheet schedules.

To increase the prominence of items that are recorded in Other Comprehensive Income and also to improve comparability and transparency in financial statements, the Board has developed a two-statement approach. This two-statement approach includes Schedule 210, Results of Operations, and Schedule 210A, Consolidated Statement of Other Comprehensive Income. Schedule 210 would show the components of net income and total net income. Schedule 210A, which would immediately follow Schedule 210, would reflect the components of Other Comprehensive Income, a total for Other Comprehensive Income, and a total for Comprehensive Income. Schedule 210A would begin with net income.

The proposed instructions for the Other Comprehensive Income accounts for all railroads would require that supporting records be maintained by each category of Other Comprehensive Income. This level of detail would be required to ensure that the railroad is able to identify the amounts associated with an item when it is entered into the determination of net income, and the railroad effectively moves the recognition of the item from Other Comprehensive Income to net income.

Finally, items recognized in Other Comprehensive Income that are later recognized in net income require a reclassification adjustment in order to avoid double counting an item in both net income and Other Comprehensive Income. The proposed instructions for Accounts 799 and 799.1 would require the railroad to make reclassification adjustments directly to these accounts, as appropriate. This proposed accounting treatment for reclassification adjustments would minimize the need for creating a new account to capture amounts solely related to reclassification adjustments. Items reclassified from Other Comprehensive Income to net income would no longer be presented in footnotes to the financial statements. Further, the adjustments must be shown on the face of the financial statements where the components of net income and Other Comprehensive Income are presented; corresponding adjustments must appear in both net income and Other Comprehensive Income.

D. *Proposed Accounting for Derivatives and Hedging Activities.* The Board proposes to revise the USOA to provide accounting for derivative instruments and hedging activities. The Board's existing USOA does not contain specific accounts to record changes in the fair value of derivative instruments used in hedging and non-hedging activities. The addition of new accounts and instructions would provide improved visibility and completeness of accounting and reporting of derivative instruments and hedging activities.

Proposed General Instructions for Fair-Value and Cash-Flow Hedges. The Board proposes to add a new general instruction that would require railroads to record changes in the fair value of the derivative instrument (the effective portion of the gain or loss) designated as a cash-flow hedge to Other

[3] Results of Operations Statements, also referred to as a Profit and Loss Statement, Statement of Operations, or Statement of Income, appear in the Form R–1 and reflect the profitability (*i.e.* revenues, expenses, gains, and losses) of a company during the year specified in the heading of the R–1 annual report. The statements do not show cash receipts or cash disbursements.

Comprehensive Income. The ineffective portion of the cash-flow hedge would be charged to the same income or expense account that would have been used if the hedged item had been disposed of, or otherwise settled.

The proposed instructions would also require railroads to record changes in the fair value of a derivative instrument designated as a fair-value hedge in this account with a concurrent charge to a sub account of the asset or liability that carries the item being hedged. The ineffective portion of the fair-value hedge would be charged to the same income or expense account that would have been used if the hedged item had been disposed of, or otherwise settled.

Proposed Accounting for Derivative Assets and Liabilities. The Board proposes to establish new asset and liability accounts that would include amounts related to the changes in the fair value of derivative instruments not designated as cash-flow or fair-value hedges. The proposed accounts are Account 713.5, Derivative Instrument Assets and Account 763.5, Derivative Instrument Liabilities. Railroads would charge Account 551, Miscellaneous Income Charges, with the corresponding amount of the change in the fair value of the derivative instruments.

Proposed Accounting for Fair-Value and Cash-Flow Hedges. As proposed, railroads would be required to establish a new asset and liability account that would include amounts related to the changes in the fair value of derivative instruments designated as a cash-flow or fair-value hedge. The new asset account is Account 713.6, Derivative Instrument Assets-Hedges and the new liability account would be Account 763.6, Derivative Instrument Liabilities—Hedges.

E. *Proposed Changes to and Elimination of Certain Schedules to the Form R–1.* The proposed accounting changes, if adopted, would require changes to existing Schedule 200, Comparative Statement of Financial Position, and Schedule 210, Results of Operations.[4] The Board also would add a new Schedule 210A, entitled ''Consolidated Statement of Comprehensive Income,'' with instructions on the proper footnote disclosures for the Form R–1 in order to provide consistent accounting and reporting of items of Other Comprehensive Income. This proposed schedule is modeled after an income-statement approach which provides the most transparency for the components of Other Comprehensive Income and is more consistent with the overall framework of the FASB Concepts Statement. The proposed income-statement format would also avoid duplication of data already reported on other schedules. This new schedule would show the components of Other Comprehensive Income and would require the following to be contained in a footnote to the schedule:

(1) Reporting of categories of Other Comprehensive Income on a net-of-tax basis, where appropriate, along with the reporting of related tax effects allocated to each component;

(2) Reporting of accumulated Other Comprehensive Income balances at year end by category;

(3) Reporting of fair-value hedge balances at year end by category.

The Board concludes that the proposed reporting requirements would not be a significant reporting burden to the railroad industry since the information is already being captured by the railroads' accounting systems for internal and external reporting.

F. *Proposed Accounting for Business Combinations.* FASB established ASC 805 Business Combinations requiring the acquisition method of accounting for all business combinations. This methodology is now standard practice in the accounting industry, and the Board agrees that the acquisition method better reflects the investment made in an acquired entity and has affirmed the use of this treatment in *Western Coal Traffic League—Petition for Declaratory Order,* FD 35506, slip op at 6–17 (STB served July 25, 2013). We propose to update the USOA to reflect this accounting treatment. We also seek comment on the application of Instruction 2–15, paragraph (d) with respect to the utilization of the pooling of interest method for transactions involving the acquisition and merger of property of subsidiaries in Instructions for Property Accounts.

G. *Elimination of Certain Schedules in Annual Report Form R–1.* The Board and its predecessor, the ICC, have collected financial and accounting data from regulated railroads since the 1880's. Information from the carriers' annual reports is used in the Board's oversight and regulatory missions. Reduction of unnecessary reporting requirements has been a long-standing goal of the Board and ICC. In a policy statement issued in 1979, the ICC specified that only information needed to carry out its functions should be collected.[5] Since then, reporting requirements have been eliminated for non-Class I carriers and the dollar threshold for inclusion as a Class I carrier has been raised to $250 million, indexed for inflation. Thus, significant reductions in the financial and accounting reporting burden for railroads have already been accomplished.

However, we have examined the current Form R–1 filed by the Class I railroads and have determined that 15 of the 47 schedules are no longer used by the STB to perform our regulatory and oversight functions. Therefore, we are proposing to eliminate these 15 schedules from the Form R–1, as listed below:

230 Capital Stock
339 Accrued Liability—Leased Property
340 Depreciation Base and Rates—Improvements to Road and Equipment Leased from Others
350 Depreciation Base and Rates—Road and Equipment Leased to Others
351 Accumulated Depreciation—Road and Equipment Leased to Others
416 Supporting Schedule—Road
418 Supporting Schedule—Capital Leases
460 Items in Selected Income and Retained Earnings Accounts for the Year
702 Miles of Road at Close of Year—By States and Territories (Single Track)
721 Ties Laid in Replacement
722 Ties Laid in Additional Tracks and in New Lines and Extensions
723 Rails Laid in Replacement
724 Rails Laid in Additional Tracks and in New Lines and Extensions
725 Weight of Rail
726 Summary of Track Replacements

Periodic Review

To ensure that the Board's accounting and reporting requirements reflect, to the extent practicable, current GAAP principles, the Board will conduct a periodic review of its accounting standards not less than every five years. This periodic review will be initiated through the rulemaking process, thereby affording interested parties an opportunity for notice and comment.

Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3549, and Office of Management and Budget (OMB) regulations at 5 CFR 1320.8(d)(3), the Board seeks comments regarding: (1) Whether the revisions to the collection of information proposed here are necessary for the proper performance of the functions of the Board, including whether the collection

[4] The proposed revised schedules appear in Appendix A.

[5] *See Policy Statement on Fin. & Statistical Reporting,* 44 FR 27537 (1979).

has practical utility; (2) the accuracy of the Board's burden assessment; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burdens of the collections of information on the respondents, including the use of automated collection techniques or other forms of information technology, when appropriate. Additional information related to these questions can be found in Appendix B below. The proposed information-collection revisions described in this decision are being submitted to OMB for review as required under the PRA, 5 U.S.C. 3507(d) and OMB regulations at 5 CFR 1320.11. Comments received by the Board regarding the information collection will also be forwarded to OMB for its review when the final rule is published.

Regulatory Flexibility Act Statement

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, generally requires a description and analysis of new rules that would have a significant economic impact on a substantial number of small entities. In drafting a rule, an agency is required to: (1) Assess the effect that its regulation will have on small entities; (2) analyze effective alternatives that may minimize a regulation's impact; and (3) make the analysis available for public comment. Sections 601–604. In its notice of proposed rulemaking, the agency must either include an initial regulatory flexibility analysis, section 603(a), or certify that the proposed rule would not have a ''significant impact on a substantial number of small entities,'' section 605(b).

Because the goal of the RFA is to reduce the cost to small entities of complying with federal regulations, the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates those entities. In other words, the impact must be a direct impact on small entities ''whose conduct is circumscribed or mandated'' by the proposed rule. *White Eagle Coop. Ass'n* v. *Conner,* 553 F.3d 467, 478, 480 (7th Cir. 2009).

This proposal will not have a significant economic impact upon a substantial number of small entities within the meaning of the RFA. The proposed rule would affect only entities that are required to file Form R–1 reports; these reports are only required to be submitted by Class I carriers. 49 CFR 1241.1. Class I carriers are large railroads; accordingly, there will be no impact on small railroads (small entities).

Authority. 49 U.S.C. 11142 and 11164.

List of Subjects in 49 CFR Part 1201

Railroads, Uniform System of Accounts.

Decided: June 18, 2015.

By the Board, Acting Chairman Miller and Vice Chairman Begeman.

Brendetta S. Jones,

Clearance Clerk.

For the reasons set forth in the preamble, the Surface Transportation Board proposes to amend part 1201 of title 49, chapter X, of the Code of Federal Regulations as follows:

PART 1201—RAILROAD COMPANIES

■ 1. The authority citation for part 1201 continues to read as follows:

Authority: 49 U.S.C. 11142 and 11164.

Subpart A—Uniform System of Accounts

■ 2. Amend Regulations Prescribed by revising paragraph (ii), item 16(c), to read as follows:

List of Instructions and Accounts

REGULATIONS PRESCRIBED

* * * * *

(ii) * * *

16. * * *

(c) *Cost,* as applied to a marketable equity security, refers to the original cost as adjusted for unrealized holding gains and losses.

* * * * *

3. Amend General Instructions by adding Instructions 1–19 and 1–20 to read as follows:

GENERAL INSTRUCTIONS

* * * * *

1–19 *Accounting for Other Comprehensive Income.* (a) Railroads will record items of Other Comprehensive Income in account 799.1, *Other comprehensive income.* Amounts included in this account will be maintained by each category of Other Comprehensive Income. Examples of categories of Other Comprehensive Income include foreign currency items, minimum pension liability adjustments, unrealized gains and losses on available-for-sale type securities and cash-flow hedge amounts.

(b) Supporting records will be maintained for account 799 so that the company can readily identify the cumulative amount of Other Comprehensive Income for each item included in this account.

(c) When an item of Other Comprehensive Income enters into the determination of earnings in the current or subsequent periods, a reclassification adjustment will be recorded in accounts 799 to avoid double counting of when an item included in net income was also included in Other Comprehensive Income in the same or prior period.

1–20 *Accounting for derivative instruments and hedging activities.* (a) A carrier will recognize derivative instruments as either assets or liabilities in the financial statements and measure those instruments at fair value. A derivative instrument is a financial instrument or other contract with all three of the following characteristics:

(1) The derivative instrument has one or more underlyings and a notional amount or payment provision. Those terms determine the amount of the settlement or settlements, and, in some cases, whether or not a settlement is required.

(2) The derivative instrument requires no initial net investment or an initial net investment that is smaller than would be required for other types of contracts that would be expected to have similar responses to changes in market factors.

(3) The derivative instrument's terms require or permit net settlement; the derivative instrument can readily be settled net by a means outside the contract; or the derivative instrument's terms provide for delivery of an asset that puts the recipient in a position not substantially different from net settlement.

(b) The accounting for the changes in the fair value of derivative instruments depends upon their intended use and designation. Changes in the fair value of derivative instruments not designated as fair value or cash flow hedges will be recorded in account 713.5, *Derivative instrument assets,* or account 763.5, *Derivative instrument liabilities,* as appropriate, with the gains or losses charged to earnings in account 551, *Miscellaneous income charges.*

(c) A derivative instrument may be specifically designated as a fair-value or cash-flow hedge. A hedge may be used to manage risk to price, interest rates, or foreign currency transactions. An entity will maintain documentation of the hedge relationship at the inception of the hedge that details the risk management objective and strategy for undertaking the hedge, the nature of the risk being hedged, and how hedge effectiveness will be determined.

(d) If the carrier designates the derivative instrument as a fair-value hedge against exposure to changes in the fair value of a recognized asset, liability, or a firm commitment, it will record the change in fair value of the derivative instrument designated as a

fair-value hedge to account 713.6, *Derivative instruments assets—hedges,* or account 763.6, *Derivative instrument liabilities—hedges,* as appropriate, with a corresponding adjustment to the sub-account of the item being hedged. The ineffective portion of the hedge transaction will be reflected in the same income or expense account that would have been used if the hedged item had been disposed of or settled. In the case of a fair-value hedge of a firm commitment, a new asset or liability is created. As a result of the hedge relationship, the new asset or liability will become part of the carrying amount of the item being hedged.

(e) If the carrier designates the derivative instrument as a cash-flow hedge against exposure to variable cash flows of a probable forecasted transaction it will record changes in the fair value of the derivative instrument in account 713.6, *Derivative instrument assets—hedges,* or account 763.6, *Derivative instrument liabilities—hedges,* as appropriate, with a corresponding amount in account 799.1, *Other comprehensive income,* for the effective portion of the hedge. The ineffective portion of the hedge transaction will be reflected in the same income or expense account that would have been used if the hedged item had been disposed of or settled. Amounts recorded in Other Comprehensive Income will be reclassified into earnings in the same period or periods that the hedged forecasted item affects earnings.

■ 4. Amend Instructions For Property Accounts by:

■ a. Revising paragraph (a) in Instruction 2–15;

■ b. Removing paragraph (b) in Instruction 2–15;

■ c. Redesignating paragraph (c) as paragraph (b) in Instruction 2–15;

■ d. Revising the newly designated paragraph (b) in Instruction 2–15; and

■ e. Redesignating paragraph (d) as paragraph (c) in Instruction 2–15.

The revisions read as follows:

INSTRUCTIONS FOR PROPERTY ACCOUNTS

* * * * *

2–15 * * * (a) When a railway or portion thereof constituting an operating unit or system is acquired in a business combination, that business combination shall be recorded in the accounts in the manner stated hereunder.

(b) Purchase:

(1) The amount includible in account 731, Road and equipment property, shall be the cost at the date of acquisition to the purchaser of the transportation property acquired. The cost assigned the property, as well as other assets acquired, shall be the amount of the cost consideration given. Where property and other assets are acquired for other than cash, including liabilities assumed and shares of stock issued, cost shall be determined by either the fair value of the consideration given or the fair value of the assets acquired, whichever is more clearly evident. In addition to any liabilities assumed, provision shall be made for such estimated liabilities as may be necessary.

(2) When the costs of individual units or classes of transportation property are not specified in the agreement, the cost assigned such property shall be apportioned among the appropriate primary accounts using the percentage relationship between the fair values for each class of property acquired and the total of such values.

* * * * *

■ 5. Amend Instructions For Income And Balance Sheet Accounts by revising Instruction 5–2, paragraph (a), items (2), (3), and (4) to read as follows:

INSTRUCTIONS FOR INCOME AND BALANCE SHEET ACCOUNTS

* * * * *

5–2 * * *

(a) * * *

(2) Account 702, *Temporary cash investments,* account 721, *Investments and advances; affiliated companies,* and account 722, *Other investments and advances,* shall be maintained in such a manner as to reflect the marketable equity portion (see definition 26) and other securities or investments.

(3) For the purpose of determining net ledger value, the marketable equity securities in account 702 shall be considered the current portfolio and the marketable equity securities in accounts 721 and 722 (combined) shall be considered the noncurrent portfolio.

(4) Carriers will categorize their security investments as held-to-maturity, trading, or available-for-sale. Unrealized holding gains and losses on trading type investment securities will be recorded in account 551, *Miscellaneous income charges.* Unrealized holding gains and losses on available-for-sale type investment securities will be recorded in account 799.1, *Other comprehensive income.*

* * * * *

■ 6. Amend Income Accounts—Ordinary Items by adding a sentence at the end of the list of inclusions for account 551 ''Miscellaneous income charges,'' paragraph (a) to read as follows:

INCOME ACCOUNTS

Ordinary Items

* * * * *

551 Miscellaneous income charges.

(a) * * *

Unrealized holding gains and losses on trading type investment securities.

* * * * *

■ 7. Amend General Balance Sheet Accounts Explanations—Assets, Current Assets by:

■ a. Adding a sentence to the end of the first paragraph in account 702 ''Temporary cash investment'';

■ b. Adding accounts 713.5 ''Derivative instrument assets'' and 713.6 ''Derivative instrument assets–hedges.''

The additions read as follows:

GENERAL BALANCE SHEET ACCOUNTS EXPLANATIONS

Assets

Current Assets

* * * * *

702 Temporary cash investments.

* * * This account shall also include unrealized holding gains and losses on trading and available-for-sale types of security investments.

* * * * *

713.5 Derivative instrument assets.

This account shall include the amounts paid for derivative instruments, and the change in the fair value of all derivative instrument assets not designated as cash-flow or fair-value hedges. Account 551, *Miscellaneous income charges,* will be charged with the corresponding amount of the change in the fair value of the derivative instrument.

713.6 Derivative instrument assets–hedges.

(a) This account shall include the amounts paid for derivative instruments, and the change in the fair value of derivative instrument assets designated by the utility as cash-flow or fair-value hedges.

(b) When a carrier designates a derivative instrument asset as a cash-flow hedge, it will record the change in the fair value of the derivative instrument in this account with a concurrent charge to account 799.1, *Other comprehensive income,* with the effective portion of the derivative's gain or loss. The ineffective portion of the cash-flow hedge will be charged to the same income or expense account that would have been used if the hedged item had been disposed of or otherwise settled.

(c) When a carrier designates a derivative instrument as a fair-value hedge, it will record the change in the fair value of the derivative instrument in this account with a concurrent charge to a sub-account of the asset or liability that carries the item being hedged. The ineffective portion of the fair-value hedge will be charged to the same income or expense account that would have been used if the hedged item had been disposed of or otherwise settled.

* * * * *

■ 8. Amend General Balance Sheet Accounts Explanations—Assets, Special Funds by:

■ a. In account 715 ''Sinking funds,'' adding two sentences to the end of paragraph (b);

■ b. In account 716 ''Capital funds,'' adding a sentence to the end of paragraph (a); and

■ c. In account 717 ''Other funds,'' adding Note E.

The additions read as follows:

GENERAL BALANCE SHEET ACCOUNTS EXPLANATIONS

Assets

Special Funds

715 Sinking funds.

* * * * *

(b) * * * This account shall also include unrealized holding gains and losses on trading and available-for-sale types of security investments. The cash value of life insurance policies on the lives of employees and officers to the extent that the carrier is the beneficiary of such policies shall also be included in this account.

* * * * *

716 Capital funds.

(a) * * * This account shall also include unrealized holding gains and losses on trading and available-for-sale types of security investments.

* * * * *

717 Other funds.

* * * * *

NOTE E: This account shall also include unrealized holding gains and losses on trading and available-for-sale types of security investments.

■ 9. Amend General Balance Sheet Accounts Explanations—Assets, Investments by:

■ a. In account 722 ''Other investments and advances,'' adding two sentences to the end of paragraph (a); and

■ b. Removing account 724 ''Allowance for net unrealized loss on noncurrent marketable equity securities—Cr.''

The addition reads as follows:

GENERAL BALANCE SHEET ACCOUNTS EXPLANATIONS

Assets

Investments

* * * * *

722 Other investments and advances.

(a) * * * This account shall also include unrealized holding gains and losses on trading and available-for-sale types of security investments. Include also the offsetting entry to the recording of amortization of discount or premium on interest bearing investments.

* * * * *

■ 10. Amend General Balance Sheet Accounts Explanations—Liabilities and Shareholders' Equity, Current Liabilities by adding accounts 763.5 ''Derivative instrument liabilities'' and 763.6 ''Derivative instrument liabilities–hedges'',to read as follows:

GENERAL BALANCE SHEET ACCOUNTS EXPLANATIONS

Liabilities and Shareholders' Equity

Current Liabilities

* * * * *

763.5 Derivative instrument liabilities.

This account shall include the change in the fair value of all derivative instrument liabilities not designated as cash-flow or fair-value hedges. Account 551, *Miscellaneous income charges,* will be charged with the corresponding amount of the change in the fair value of the derivative instrument.

763.6 Derivative instrument liabilities–hedges.

(a) This account shall include the change in the fair value of derivative instrument liabilities designated by the carrier as cash-flow or fair-value hedges.

(b) A carrier will record the change in the fair value of a derivative instrument liability related to a cash-flow hedge in this account, with a concurrent charge to account 799.1, *Other comprehensive income,* with the effective portion of the derivative instrument's gain or loss. The ineffective portion of the cash-flow hedge will be charged to the same income or expense account that would have been used if the hedged item had been disposed of or otherwise settled.

(c) A carrier will record the change in the fair value of a derivative instrument liability related to a fair-value hedge in this account, with a concurrent charge to a sub-account of the asset or liability that carries the item being hedged. The ineffective portion of the fair-value hedge will be charged to the same income or expense account that would have been used if the hedged item had been disposed of or otherwise settled.

* * * * *

■ 11. Amend General Balance Sheet Accounts Explanations—Liabilities and Shareholders' Equity, Shareholders' Equity by:

■ a. Removing account 798.1 ''Net unrealized loss on noncurrent marketable securities''; and

■ b. Adding account 799 ''Accumulated Other Comprehensive Income.''

The addition reads as follows:

GENERAL BALANCE SHEET ACCOUNTS EXPLANATIONS

Liabilities and Shareholders' Equity

Shareholders' Equity

* * * * *

799 Accumulated Other Comprehensive Income.

(a) This account shall include revenues, expenses, gains, and losses that are properly includable in Other Comprehensive Income during the period. Examples of items of Other Comprehensive Income include foreign currency items, minimum pension liability adjustments, unrealized gains and losses on certain investments in debt and equity securities, and cash-flow hedges. Records supporting the entries to this account shall be maintained so that the carrier can furnish the amount of Other Comprehensive Income for each item included in this account.

(b) This account shall also be debited or credited, as appropriate, with amounts of accumulated Other Comprehensive Income that have been included in the determination of net income during the period and in accumulated Other Comprehensive Income in prior periods. Separate records for each category of items will be maintained to identify the amount of the reclassification adjustments from accumulated Other Comprehensive Income to earnings made during the period.

■ 12. Revise the Form of General Balance Sheet Statement, Assets to read as follows:

Form of General Balance Sheet Statement

The classified form of general balance sheet statement is designed to show the financial condition of the accounting company at any specified date.

ASSETS

Current assets:
701. Cash.
702. Temporary cash investments.
703. Special deposits.
704. Loans and notes receivable.
705. Accounts receivable; Interline and other balances.
706. Accounts receivable; Customers.
707. Accounts receivable; Other.
708. Interest and dividends receivable.
708.5. Receivables from affiliated companies.
709. Accrued accounts receivable.
709.5. Allowance for uncollectible accounts.
Net receivables.
710. Working funds.
711. Prepayments.
712. Material and supplies.
713. Other current assets.
713.5 Derivative instrument assets
713.6 Derivative instrument assets—hedges
714. Deferred income tax debits.
Total current assets.
Special funds:
715. Sinking funds.
716. Capital funds.
717. Other funds.
Total special funds.
Investments:
721. Investments and advances; affiliated companies.
Undistributed earnings from certain investments in account 751.
721.5. Adjustments; investments and advances—affiliated companies.
Net—investments and advances—affiliated companies.
722. Other investments and advances.
723. Adjustments; Other investments and advances.
Net—other investments and advances.
Total investments.
Tangible property:
731. Road and equipment property.
735. Accumulated depreciation; Road and equipment property.
736. Accumulated amortization; Road and equipment property—Defense projects.

Net road and equipment property.
732. Improvements on leased property.
733. Accumulated depreciation; Improvements on leased property.
734. Accumulated amortization; Improvements on leased property—Defense projects.
Net improvements on leased property.
Total carrier property.
737. Property used in other than carrier operations.
738. Accumulated depreciation; Property used in other than carrier operations.
Net—property used in other than carrier operations.
Total tangible property.
Intangible property:
739. Organization expenses.
Other assets and deferred debits:
741. Other assets.
743. Other deferred debits.
744. Accumulated deferred income tax debits.
Total other assets and deferred debits.
Total assets.

LIABILITIES AND SHAREHOLDERS' EQUITY

Current liabilities:
751. Loans and notes payable.

ASSETS—Continued

752. Accounts payable; Interline and other balances.
753. Audited accounts and wages payable.
754. Accounts payable; Other.
755. Interest payable.
756. Dividends payable.
757. Payables to affiliated companies.
759. Accrued accounts payable.
760. Federal income taxes accrued.
761. State and other income taxes accrued.
761.5. Other taxes accrued.
762. Deferred income tax credits.
763. Other current liabilities.
763.5 Derivative instrument liabilities
763.6 Derivative instrument liabilities-hedges
764. Equipment obligations and other long-term debt due within one year.
Total current liabilities.
Long-term debt due after one year: [1]
765. Funded debt unmatured.
766. Equipment obligations.
766.5. Capitalized lease obligations.
767. Receivers' and trustees' securities.
768. Debt in default.
769. Accounts payable; Affiliated companies.
770.1 Unamortized debt discount.
770.2 Unamortized premium on debt.
Total long-term debt due after one year.
Other long-term liabilities:
771. Accrued liability; Pension and welfare.
772. Accrued liability; Leased property.
774. Accrued liability; Casualty and other claims.
775. Other accrued liabilities.
781. Interest in default.
782. Other liabilities.
Total other long-term liabilities.
Deferred credits:
783. Deferred revenues—transfers from government authorities.
784. Other deferred credits.
786. Accumulated deferred income tax credits.
Total deferred credits.
Shareholders' equity:
Capital stock:
791. Capital stock.
792. Liability for conversion of capital stock.
793. Discount on capital stock.
Total capital stock.
Additional capital:
794. Premiums and assessments on capital stock.
795. Other capital.
Total additional capital.
Retained earnings:
797. Retained earnings; Appropriated.
798. Retained earnings; Unappropriated.
Total retained earnings.
798.5 Treasury stock.
799. Accumulated Other Comprehensive Income
Total shareholders' equity.
Total liabilities and shareholders' equity.

[1]To be divided as to ''Total issued'' and ''Held by or for company.''

■ 13. Amend Conversion Tables by revising General Balance Sheet Accounts conversion table to read as follows:

CONVERSION TABLES

* * * * *

GENERAL BALANCE SHEET ACCOUNTS CONVERSION TABLE

System of accounts eff. prior to Month XX, 2015		System of accounts eff. Month, XX, 2015	
Account title	No.	No.	Account title
Cash	701	701	Cash.
Temporary cash investments	702	702	Temporary cash investments.
Special deposits	703	703	Special deposits.
Loans and notes receivable	704	704	Loans and notes receivable.
		708.5	Receivables from affiliated companies.
		709.5	Allowance for uncollectible accounts.
Traffic, car service and other balances—dr	705	705	Accounts receivable; interline and other balances.
		709.5	Allowances for uncollectible accounts.
		752	Accounts payable; interline and other balances.
Net balance receivable from agents and conductors	706	706	Accounts receivable; customers.
Miscellaneous accounts receivable	707	707	Accounts receivable; other.
		708.5	Receivables from affiliated companies.
		709.5	Allowance for uncollectible accounts.
Interest and dividends receivable	708	708	Interest and dividends receivable.
		708.5	Receivables from affiliated companies.
		709.5	Allowance for uncollectible accounts.
Accrued accounts receivable	709	709	Accrued accounts receivable.
Working fund advances	710	710	Working funds.
Prepayments	711	711	Prepayments.
Material and supplies	712	712	Material and supplies.
Other current assets	713	713	Other current assets.
		713.5	Derivative instrument assets
		713.6	Derivative instrument assets—hedges
Deferred income tax charges	714	714	Deferred income tax debits.
Sinking funds	715	715	Sinking funds.
Capital and other reserve funds	716	716	Capital funds.
Insurance and other funds	717	717	Other funds.
Investment in affiliated companies	721	721	Investments and advances; affiliated companies.
Other investments	722	722	Other investments and advances.
Reserve for adjustment of investment in securities—cr	723	721.5	Adjustments; investments and advances—affiliated companies.
		723	Adjustments; other investments and advances.
Road and equipment property	731	731	Road and equipment property.
Organization expenses	71	739	Organization expenses.
Improvements on leased property	732	732	Improvements on leased property.
Accrued depreciation; improvements on leased property.	733	733	Accumulated depreciation; improvements on leased property.
Accrued depreciation; road and equipment	735	735	Accumulated depreciation; road and equipment property.
Amortization of defense projects; road and equipment	736	736	Accumulated amortization; road and equipment property—defense projects.
		734	Accumulated amortization; improvements on leased property—defense projects.
Miscellaneous physical property	737	737	Property used in other than carrier operations.
Accrued depreciation; miscellaneous physical property.	738	738	Accumulated depreciation; property used in other than carrier operations.
Other assets	741	741	Other assets.
Unamortized discount on long-term debt	770.1	770.1	Unamortized debt discount.
Other deferred charges	743	743	Other deferred debits.
Accumulated deferred income tax charges	744	744	Accumulated deferred income tax debits.
Liabilities			
Loans and notes payable	751	751	Loans and notes payable.
		757	Payables to affiliated companies.
Traffic, car service and other balances—cr	752	752	Accounts payable; interline and other balances.
		705	Accounts receivable; interline and other balances.
		709.5	Allowance for uncollectible accounts.
Audited accounts and wages payable	753	753	Audited accounts and wages payable.
Miscellaneous accounts payable	754	754	Accounts payable; other.
		757	Payables to affiliated companies.
Interest matured unpaid	755	755	Interest payable.
		757	Payables to affiliated companies.
Dividends matured unpaid	756	756	Dividends payable.
		757	Payables to affiliated companies.
Unmatured interest accrued	757	755	Interest payable.
		757	Payables to affiliated companies.
Unmatured dividends declared	758	756	Dividends payable.
		757	Payables to affiliated companies.
Accrued accounts payable	759	759	Accrued accounts payable.

GENERAL BALANCE SHEET ACCOUNTS CONVERSION TABLE—Continued

System of accounts eff. prior to Month XX, 2015		System of accounts eff. Month, XX, 2015	
Account title	No.	No.	Account title
Federal income taxes accrued	760	760	Federal income taxes accrued.
Other taxes accrued	761	711	Prepayments.
		761	State and other income taxes accrued.
		761.5	Other taxes accrued.
Deferred income tax credits	762	762	Deferred income tax credits.
Other current liabilities	763	763	Other current liabilities.
		763.5	Derivative instrument liabilities
		763.6	Derivative instrument liabilities—hedges
Equipment obligations and other debt due within one year.	764	764	Equipment obligations and other long-term debt due within 1 year.
Funded debt unmatured	765	765	Funded debt unmatured.
Equipment obligations	766	766	Equipment obligations.
Capitalized lease obligations	766.5	766.5	Capitalized lease obligations.
Receivers' and trustees' securities	767	767	Receivers' and trustees' securities.
Debt in default	768	768	Debt in default.
Amounts payable to affiliated companies	769	769	Accounts payable; affiliated companies.
Pension and welfare reserves	771	771	Accrued liability; pension and welfare.
Casualty and other reserves	774	774	Accrued liability; casualty and other claims.
		775	Other accrued liabilities.
Interest in default	781	781	Interest in default.
Other liabilities	782	782	Other liabilities.
Deferred revenues—transfers from government authorities.	783	783	Deferred revenues—transfers from government authorities
Unamortized premium on long-term debt	790.2	770.2	Unamortized premium on debt.
Other deferred credits	784	784	Other deferred credits.
Accrued liability; leased property	785	772	Accrued liability; leased property.
Accumulated deferred income tax credits	786	786	Accumulated deferred income tax credits.
Shareholders' Equity			
Capital stock issued	791	791	Capital stock.
Stock liability for conversion	792	792	Liability for conversion of capital stock.
Discount on capital stock	793	793	Discount on capital stock.
Premiums and assessment on capital stock	794	794	Premiums and assessments on capital stock.
Paid-in surplus	795	795	Other capital.
Other capital surplus	796	795	Do.
Retained income; appropriated	797	797	Retained earnings; appropriated.
Retained income; unappropriated	798	798	Retained earnings; unappropriated.
Treasury stock	798.5	798.5	Treasury stock.
		799	Accumulated Other Comprehensive Income.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix A

BILLING CODE 4915–01–P

Road Initials:			Year:			5
200. COMPARATIVE STATEMENT OF FINANCIAL POSITION – ASSETS (Dollars in Thousands)						
Line No.	Cross Check	Account	Title (a)	Balance at close of year (b)	Balance at beginning of year (c)	Line No.
			Current Assets			
1		701	Cash			1
2		702	Temporary cash investments			2
3		703	Special deposits			3
			Accounts receivable			
4		704	- Loan and notes			4
5		705	- Interline and other balances			5
6		706	- Customers			6
7		707	- Other			7
8		709, 708	- Accrued accounts receivables			8
9		708.5	- Receivables from affiliated companies			9
10		709.5	- Less: Allowance for uncollectible accounts			10
11		710, 711, 714	Working funds prepayments deferred income tax debits			11
12		712	Materials and supplies			12
13		713, 713.5, 713.6	Other current assets			13
14			TOTAL CURRENT ASSETS			14
			Other Assets			
15		715, 716, 717	Special funds			15
16		721, 721.5	Investments and advances affiliated companies (Schs. 310 and 310A)			16
17		722, 723	Other investments and advances			17
18		737, 738	Property used in other than carrier operation (Less depreciation) $			18
19		739, 741	Other assets			19
20		743	Other deferred debits			20
21		744	Accumulated deferred income tax debits			21
22			TOTAL OTHER ASSETS			22
			Road and Equipment			
23		731, 732	Road (Sch. 330) L-30 Col h & b			23
24		731, 732	Equipment (Sch 330) L-39 Col h & b			24
25		731, 732	Unallocated items			25
26		733, 735	Accumulated depreciation and amortization (Schs. 335, 342)			26
27			Net Road and Equipment			27
28	*		Total Assets			28
NOTES AND REMARKS						
Railroad Annual Report R-1						

6			Road Initials:		Year:	
200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - LIABILITIES AND SHAREHOLDERS' EQUITY (Dollars in Thousands)						
Line No.	Cross Check	Account	Title (a)	Balance at close of year (b)	Balance at beginning of year (c)	Line No.
			Current Liabilities			
30		751	Loans and notes payable			30
31		752	Accounts payable: interline and other balances			31
32		753	Audited accounts and wages			32
33		754	Other accounts payable			33
34		755, 756	Interest and dividends payable			34
35		757	Payables to affiliated companies			35

36		759	Accrued accounts payable			36
37		760, 761, 761.5 762	Taxes accrued			37
38		763, 763.5, 763.6	Other current liabilities			38
39		764	Equipment obligations and other long-term debt due within one year			39
40			TOTAL CURRENT LIABILITIES			40
			Non-Current Liabilities			
41		765, 767	Funded debt unmatured			41
42		766	Equipment obligations			42
43		766.5	Capitalized lease obligations			43
44		768	Debt in default			44
45		769	Accounts payable: affiliated companies			45
46		770.1, 770.2	Unamortized debt premium			46
47		781	Interest in default			47
48		783	Deferred revenues - transfers from govt. authorities			48
49		786	Accumulated deferred income tax credits			49
50		771, 772, 774, 775, 782, 784	Other long-term liabilities and deferred credits			50
51			TOTAL NON-CURRENT LIABILITIES			51
			Shareholders' Equity			
52		791, 792	Total capital stock			52
53			Common stock			53
54			Preferred stock			54
55			Discount on capital stock			55
56		794, 795	Additional capital			56
			Retained earnings:			
57		797	Appropriated			57
58		798	Unappropriated			58
59		798.5	Less treasury stock			59
60		799	Accumulated Other Comprehensive Income or (loss)			60
61			Total stockholders equity			61
62			Non-controlling interest			62
63			Total equity (Lines 61 + 62)			63
64			Total Liabilities & Shareholders' Equity			64

NOTES AND REMARKS

Road Initials: Year: 7

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES
(Dollars in Thousands)

The notes listed below are provided to disclose supplementary information on matters which have an important effect on the financial condition of the carrier. The carrier shall give the particulars called for herein and where there is nothing to report, insert the word "none"; and in addition thereto shall enter in separate notes with suitable particulars other matters involving material amounts of the character commonly disclosed in financial statements under generally accepted accounting principles, except as shown in other schedules. This includes statements explaining (1) service interruption insurance policies and indicating the amount of indemnity to which respondent will be entitled for work stoppage losses and the maximum amount of additional premium respondent may be obligated to pay in the event such losses are sustained by other railroads; (2) particulars concerning obligations for stock purchase options granted to officers and employees; and (3) what entries have been made for net income or retained income restricted under provisions of mortgages and other arrangements.

1. Amount (estimated, if necessary) of net income or retained income which has to be provided for capital expenditures, and for sinking funds, pursuant to provisions of reorganization plans, mortgages, deeds of trust, or other contracts. _____ $_____

2. Estimated amount of future earnings which can be realized before paying Federal income taxes because of unused and available net operating loss carryover on January 1 of the year following that for which the report is made. _____ $_____

3. (a) Explain the procedure in accounting for pension funds and recording in the accounts the current and past service pension costs, indicating whether or not consistent with the prior year. _____

_____

_____

(b) State amount, if any, representing the excess of the actuarially computed value of vested benefits over the total of the pension fund. _____ $_____

(c) Is any part of the pension plan funded? Specify. Yes _____ No _____

If funding is by insurance, give name of insuring company _____

If funding is by trust agreement, list trustee(s) _____

Date of trust agreement or latest amendment _____

If respondent is affiliated in any way with the trustee(s), explain affiliation. _____

_____

(d) List affiliated companies which are included in the pension plan funding agreement and describe basis for allocating charges under the agreement.

_____

(e) Is any part of the pension plan fund invested in stock or other securities of the respondent or its affiliates? Specify Yes ___ No ___

If yes, give number of the shares for each class of stock or other security. _____

_____

Are voting rights attached to any securities held by the pension plan? Specify Yes ___ No ___ If yes, who determines how stock is voted?

_____

4. State whether a segregated political fund has been established as provided by the Federal Election Campaign Act of 1971 (18 U.S.C. 610).

Yes ___ No ___

5. (a) The amount of employer's contribution to employee stock ownership plans for the current year was $_____

(b) The amount of investment tax credit used to reduce current income tax expense resulting from contributions to qualified employee stock ownership plans for the current year was $_____

6. In reference to Docket 37465, specify the total amount of business entertainment expenditures charged to the non-operating expense account. $_____

Continued on following page

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES – Continued

7. Give particulars with respect to contingent assets and liabilities at the close of the year, in accordance with instruction 5-6 in the Uniform System of Accounts for Railroad Companies, that are not reflected in the amounts of the respondent.

Disclose the nature and amount of contingency that is material.

Examples of contingent liabilities are items which may become obligations as a result of pending or threatened litigation, assessments or possible assessments of additional taxes, and agreements or obligations to repurchase securities or property. Additional pages may be added if more space is needed. (Explain and/or reference to the following pages.)

(a) Changes in valuation accounts.

8. Marketable equity securities.

		Cost	Market	Dr. (Cr.) to Income	Dr. (Cr.) to Stockholder's Equity
(Current Yr.)	Current Portfolio				N/A
as of / /	Noncurrent Portfolio			N/A	
(Previous Yr.)	Current Portfolio			N/A	N/A
as of / /	Noncurrent Portfolio			N/A	N/A

At / / , gross unrealized gains and losses pertaining to marketable equity securities were as follows:

	Gains	Losses
Current		
Noncurrent		

A net unrealized gain (loss) of $_____ on the sale of marketable securities was included in net income for _____ (year)

The cost of securities was based on the _____ (method) cost of all the shares of each security held at time of sale.

Significant net realized and net unrealized gains and losses arising after date of the financial statements but prior to the filing, applicable to marketable equity securities owned at balance sheet date shall be disclosed below:

NOTE: / / (date) Balance sheet date of reported year unless specified as previous year.

Railroad
Annual Report R-1

Road Initials: Year: 9

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

Railroad Annual
Report R-1

10	Road Initials:	Year:

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

Road Initials: Year: 11

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

12	Road Initials:	Year:

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

Road Initials:	Year:	13

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

Railroad Annual
Report R-1

14	Road Initials:	Year:

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

Railroad Annual Report R-1

Road Initials: Year: 15

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

Railroad Annual Report R-1

16 Road Initials: Year:

210. RESULTS OF OPERATIONS
(Dollars in Thousands)

1. Disclose requested information for respondent pertaining to results of operations for the year.

2. Report total operating expenses from Sched. 410. Any differences between this schedule and Sched. 410 must be explained on page 1.

3. List dividends from investments accounted for under the cost method on line 19, and list dividends accounted for under the equity method on line 25.

4. All contra entries should be shown in parenthesis.

Cross-Checks	
Schedule 210 Line 15, col b	= Schedule 210 Line 65, col b
Lines 47,48,49 col b	= Line 66, col b
Line 50, col b	= Line 67, col b
	Schedule 410
Line 14, col b	= Line 620, col h
Line 14, col d	= Line 620, col f
Line 14, col e	= Line 620, col g

Line No.	Cross Check	Item (a)	Amount for current year (b)	Amount for preceding year (c)	Freight-related revenue & Expense (d)	Passenger-related revenue & expenses (e)	Line No.
		ORDINARY ITEMS OPERATING INCOME Railway Operating Income					
1		(101) Freight					1
2		(102) Passenger					2
3		(103) Passenger-related					3
4		(104) Switching					4
5		(105) Water transfers					5
6		(106) Demurrage					6
7		(110) Incidental					7
8		(121) Joint facility - credit					8
9		(122) Joint facility - debit					9
10		(501) Railway operating revenues (Exclusive of transfers from government authorities-lines 1-9)					10
11		(502) Railway operating revenues - transfers from government authorities					11
12		(503) Railway operating revenues - amortization of deferred transfers from government authorities					12
13		TOTAL RAILWAY OPERATING REVENUES (lines 10-12)					13
14	*	(531) Railway operating expenses					14
15	*	Net revenue from railway operations					15
		OTHER INCOME					
16		(506) Revenue from property used in other than carrier operations					16
17		(510) Miscellaneous rent income					17
18		(512) Separately operated properties - profit					18
19		(513) Dividend income (cost method)					19
20		(514) Interest income					20
21		(516) Income from sinking and other funds					21
22		(517) Release of premiums on funded debt					22
23		(518) Reimbursements received under contracts and agreements					23
24		(519) Miscellaneous income					24
25		Income from affiliated companies: 519 a. Dividends (equity method)					25
26		b. Equity in undistributed earnings (losses)					26
27		TOTAL OTHER INCOME (lines 16-26)					27
28		TOTAL INCOME (lines 15, 27)					28
		MISCELLANEOUS DEDUCTIONS FROM INCOME					
29		(534) Expenses of property used in other than carrier operations					29
30		(544) Miscellaneous taxes					30
31		(545) Separately operated properties-Loss					31
32		(549) Maintenance of investment organization					32
33		(550) Income transferred under contracts and agreements					33
34		(551) Miscellaneous income charges					34
35		(553) Uncollectible accounts					35
36		TOTAL MISCELLANEOUS DEDUCTIONS					36
37		Income available for fixed charges					37

Road Initials: Year: 17

210. RESULTS OF OPERATIONS – Continued
(Dollars in Thousands)

Line No.	Cross Check	Item (a)	Amount for current year (b)	Amount for preceding year (c)	Line No.
		FIXED CHARGES			
38		(546) Interest on funded debt: (a) Fixed interest not in default			38
39		(b) Interest in default			39
40		(547) Interest on unfunded debt			40
41		(548) Amortization of discount on funded debt			41
42		TOTAL FIXED CHARGES (lines 38 through 41)			42
43		Income after fixed charges (line 37 minus line 42)			43
		OTHER DEDUCTIONS			
44		(546) Interest on funded debt: (c) Contingent interest			44
		UNUSUAL OR INFREQUENT ITEMS			
45		(555) Unusual or infrequent items (debit) credit			45
46		Income (Loss) from continuing operations (before inc. taxes)			46
		PROVISIONS FOR INCOME TAXES			
47	*	(556) Income taxes on ordinary income: (a) Federal income taxes			47
48	*	(b) State income taxes			48
49	*	(c) Other income taxes			49
50	*	(557) Provision for deferred taxes			50
51		TOTAL PROVISION FOR INCOME TAXES (lines 47 through 52)			51
52		Income from continuing operations (line 46 minus line 51)			52
		DISCONTINUED OPERATIONS			
53		(560) Income or loss from operations of discontinued segments (less applicable income taxes of $)			53
54		(562) Gain or loss on disposal of discontinued segments (less applicable income taxes of $)			54
55		Income before extraordinary items (lines 52 through 54)			55
		EXTRAORDINARY ITEMS AND ACCOUNTING CHANGES			
56		(570) Extraordinary items (Net)			56
57		(590) Income taxes on extraordinary items			57
58		(591) Provision for deferred taxes - Extraordinary items			58
59		TOTAL EXTRAORDINARY ITEMS (lines 56 through 58)			59
60		(592) Cumulative effect of changes in accounting principles (less applicable income taxes of $)			60
61	*	Net income (Loss) (lines 55 + 59 + 60)			61
62		Less: Net income attributable to non-controlling interest			62
63		Net income attributable to reporting railroad			63
64		Earnings Per Share, basic and diluted			64
		RECONCILIATION OF NET RAILWAY OPERATING INCOME (NROI)			
65	*	Net revenues from railway operations			65
66	*	(556) Income taxes on ordinary income (-)			66
67	*	(557) Provision for deferred income taxes (-)			67
68		Income from lease of road and equipment (-)			68
69		Rent for leased roads and equipment (+)			69
70		Net railway operating income (loss)			70

Notes and Remarks For Schedules 210 and 220

Railroad Annual Report R-1

19 Road Initials: Year:

210 A. CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Dollars in Thousands)

1. This schedule applies only to entities with items of Other Comprehensive Income (OCI)

Cross-Checks: Schedule 210 Line 61, col b — Schedule 210 A = Line 1, col b

2. Entities must present comprehensive income in two separate but consecutive financial statements.

3. Entities must present reclassification adjustments and the effects of those adjustments on net income and OCI on the face of the financial statements.

4. All contra entries should be shown in parenthesis.

Line No.	Cross Check	Item	Amount for current year	Amount for preceding year	Freight-related revenue & expenses	Passenger-related revenue & expenses	Line No.
		(a)	(b)	(c)	(d)	(e)	
1		Net Income					1
2		Other Comprehensive Income, net of tax Foreign currency translation adjustments					2
3		Unrealized gains on securities: Unrealized holding gains arising during period					3
4		Less: reclassification adjustment for gains included in net income					4
5		Defined benefit pension plans: Prior service cost arising during period					5
6		Net loss arising during period					6

7		Less: amortization of prior service cost included in net periodic pension cost					7
8		Other Comprehensive Income (lines 62+63-64-65-66+67)					8
		Comprehensive Income (Line 61 + 68)					
9		Less: comprehensive income attributable to non-controlling interest					9
10		Comprehensive income attributable to reporting railroad (line 69-70)					10
Notes:							
							Railroad Annual Report R-1

Appendix B

Information Collection

Title: Class I Railroad Annual Report
OMB Control Number: 2140–0009.
Form Number: R1.
Type of Review: Revision of a currently approved collection.
Respondents: Class I railroads.
Number of Respondents: 7.
Estimated Time per Response: The railroads currently spend no more than 800 hours preparing this report, including time spent reviewing instructions; searching existing data sources; gathering and maintaining the data needed; completing and reviewing the collection of information; and converting the data from the carrier's individual accounting system to the Board's Uniform System of Accounts (USOA), which ensures that the information will be presented in a consistent format across all reporting railroads, *see* 49 U.S.C. 11141–43, 11161–64, 49 CFR parts 1200 and 1201. The proposed modifications would not increase the hourly burden.
Frequency of Response: Annual.
Total Annual Hour Burden: No more than 5,600 hours.
Total Annual ''Non-Hour Burden'' Cost: Respondents are currently required to submit a signed hard copy of this report. We estimate a total annual cost for all respondents of $28. The proposed modifications would not increase the cost burden.
Needs and Uses: Annual reports are required to be filed by Class I railroads under 49 U.S.C. 11145. The reports show operating expenses and operating statistics of the carriers. Operating expenses include costs for right-of-way and structures, equipment, train and yard operations, and general and administrative expenses. Operating statistics include such items as car-miles, revenue-ton-miles, and gross ton-miles. The reports are used by the Board, other Federal agencies, and industry groups to monitor and assess railroad industry growth, financial stability, traffic, and operations, and to identify industry changes that may affect national transportation policy. Information from this report is also entered into the Board's Uniform Rail Costing System (URCS), which is a cost measurement methodology. URCS, which was developed by the Board pursuant to 49 U.S.C. 11161, is used as a tool in rail rate proceedings, in accordance with 49 U.S.C. 10707(d), to calculate the variable costs associated with providing a particular service. The Board also uses this information to more effectively carry out other of its regulatory responsibilities, including: acting on railroad requests for authority to engage in Board-regulated financial transactions such as mergers, acquisitions of control, and consolidations, *see* 49 U.S.C. 11323–11324; analyzing the information that the Board obtains through the annual railroad industry waybill sample, *see* 49 CFR part 1244; measuring off-branch costs in railroad abandonment proceedings, in accordance with 49 CFR 1152.32(n); developing the ''rail cost adjustment factors,'' in accordance with 49 U.S.C. 10708; and conducting investigations and rulemakings.

Information from certain schedules contained in these reports is compiled and published on the Board's Web site, *http://www.stb.dot.gov*. Information in these reports is not available from any other source.

[FR Doc. 2015–15402 Filed 7–7–15; 8:45 am]

BILLING CODE 4915–01–C

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Parts 1241, 1242, 1243, 1244, 1245, 1246, 1247, and 1248

[Docket No. EP 701]

Accelerating Reporting Requirements for Class I Railroads

AGENCY: Surface Transportation Board.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Surface Transportation Board (Board or STB) proposes to revise its regulations to accelerate the filing deadlines for eight reports submitted by Class I railroads: Schedule 250 (required under the Annual Report Form R–1); Quarterly Condensed Balance Sheet Forms (CBS); Quarterly Revenue, Expenses, and Income Reports (RE&I); Quarterly and Annual Wage Forms A&B; Quarterly Reports of Fuel Cost, Consumption, and Surcharge Revenue; Quarterly and Annual Freight Commodity Statistics Report Forms (QCS); Annual Report of Cars Loaded and Terminated (Form STB–54); and Monthly Report of Number of Employees (Form C).

DATES: Comments on this proposed rulemaking are due on or before August 7, 2015; reply comments are due by September 8, 2015.

ADDRESSES: Comments may be submitted either via the Board's e-filing format or in the traditional paper format. Any person using e-filing should attach a document and otherwise comply with the instructions at the E-FILING link on the Board's Web site, at *http://www.stb.dot.gov.* Any person submitting a filing in the traditional paper format should send an original and 10 copies to: Surface Transportation Board, Attn: Docket No. EP 701, 395 E Street SW., Washington, DC 20423–0001.

Copies of written comments received by the Board will be posted to the Board's Web site at *http://www.stb.dot.gov* and will be available for viewing and self-copying in the Board's Public Docket Room, Suite 131, 395 E Street SW., Washington, DC. Copies of the comments will also be available (for a fee) by contacting the Board's Chief Records Officer at (202) 245–0238 or 395 E Street SW., Washington, DC 20423–0001.

FOR FURTHER INFORMATION CONTACT: Pedro Ramirez, (202) 245–0333. Assistance for the hearing impaired is available through Federal Information Relay Service (FIRS) at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The Board has authority to collect financial and statistical data from Class I railroads as necessary for the economic oversight of the industry. 49 U.S.C. 721(b), 11145. To this end, the Board's regulations require Class I railroads to submit annual, quarterly, and monthly reports containing financial and operating statistics, including employment and traffic data. 49 U.S.C. 11145; 49 CFR parts 1241 through 1248. The data collected is used by the Board in various decisions as well as by other governmental agencies and interested parties in evaluating the railroad industry.

The proposed changes to filing deadlines would further facilitate the

Board's oversight of Class I railroads. Earlier reporting of financial information would also allow the Board and the public to more quickly identify and evaluate emerging trends, business conditions, and issues related to Class I railroads. The Board's decisions concerning revenue and expenses of the railroads would be based on more current information.

Many of the current reporting deadlines have not been revised for over four decades. For example, the filing dates for Form RE&I and Form CBS have not been modified since March 16, 1972. Since then, reporting and information technology has improved, allowing data to be more easily compiled.

Proposed Filing Deadlines. The proposed regulations would provide for more timely filing deadlines:

(1) Schedule 250 would be required to be filed with the Annual Report Form R–1 by March 31 of the year following the report year (49 CFR 1241.11), instead of by April 30;

(2) Quarterly Report Forms RE&I (49 CFR 1243.1), CBS (49 CFR 1243.2), and Report of Fuel Cost, Consumption, and Surcharge Revenue (49 CFR 1243.3) would be required to be filed within 15 days, instead of 30 days, after the end of each quarter;

(3) Quarterly Wage Forms A & B would be required to be filed 15 days after the end of each quarter, instead of 30 days, and Annual Wage Forms A & B would be required to be filed 30 days after the end of each year, instead of 45 days (49 CFR 1245.2);[1]

(4) Quarterly and Annual Form QCS would be required to be filed 30 days after the end of each period for which they are compiled, instead of 60 days (49 CFR 1248.5);

(5) Form C would be required to be filed 10 days after the end of each month, instead of the current practice of 15 days (49 CFR 1246.1); [2] and

(6) Form STB–54 would be filed 60 days, instead of 90 days, after the end of each year (49 CFR 1247.1).

The proposed regulations would also amend the language in 49 CFR 1245.3(b) to clarify that the number of employees reported on Forms A & B should be consistent with the number reported on Form C, pursuant to part 1246.

[1] The form titles currently provided in 49 CFR 1245.2, ''Form QRSC'' and ''Form ARSC'' are outdated. The form titles will be updated if the Board adopts final rules in this proceeding.

[2] The current regulations at 49 CFR 1246.1 state that these reports are due ''by the end of the month to which it applies.'' In practice, the Board has accepted the report 15 days after the end of the month. The form title, ''Form MRRE'' is also outdated. The form title will be updated if the Board adopts final rules in this proceeding.

Similarly, the proposal would amend the language in 49 CFR 1246.1 to clarify the method by which carriers arrive at the monthly average number of employees. These changes codify the current settled practice of the reporting railroads. References to the ''Interstate Commerce Act'' would be replaced with ''part A of subtitle IV of title 49, United States Code'' [3] between 49 CFR parts 1241 and 1248 to accurately describe the current controlling statute. We are also proposing to eliminate the requirement of railroads to file ''duplicate'' copies of reports. Because railroads currently submit their reports electronically, this eliminates the need for hard copies to be filed. We are proposing to remove this requirement, with the exception of the Annual Report Form R–1, which still requires hard copies to be filed.

Only negligible additional burdens to respondent railroads would be expected as a result of the expedited deadlines being proposed. Due to the availability of more robust financial and statistical reporting technology since the adoption of the current Class I railroad reporting requirements, the information requested should be readily available for timely filing under the proposed deadlines. In addition, it is standard practice for companies to compile and summarize accounting transactions and financial data on a monthly basis, if not more frequently. Therefore, we anticipate that more timely reporting of the required information could be accomplished with negligible additional burden on the railroads.

Paperwork Reduction Act. Pursuant to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3549, and Office of Management and Budget (OMB) regulations at 5 CFR 1320.8(d)(3), the Board seeks comments regarding: (1) Whether the revisions to the collections of information proposed here are necessary for the proper performance of the functions of the Board, including whether the collection has practical utility; (2) the accuracy of the Board's burden assessment; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burdens of the collections of information on the respondents, including the use of automated collection techniques or other forms of information technology, when appropriate. The proposed revisions described in this notice are being submitted to OMB for review as required under the PRA, 44 U.S.C. 3507(d) and OMB regulations at 5 CFR 1320.11. Comments received by the Board regarding the information collection will also be forwarded to OMB for its review when the final rule is published.

[3] These are the rail provisions of the Interstate Commerce Act, as amended by the ICC Termination Act of 1995.

Regulatory Flexibility Act Certification. Pursuant to 5 U.S.C. 605(b), the Board certifies that this action will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act. These proposed rules will provide revised reporting deadlines for financial and statistical data for Class I railroads (carriers having annual carrier operating revenues of $250 million or more as defined by 49 CFR part 1201, General Instruction 1–1(a)). Based on the Small Business Administration's regulations at 13 CFR 121.201, none of the current Class I railroads qualify as a small business (1,500 or fewer employees for line-haul railroads). Therefore, no small entities would be subject to these requirements. A copy of this decision is being provided to the Chief Counsel for Advocacy, Small Business Administration.

This action will not significantly affect the quality of the human environment or the conservation of energy resources.

It is ordered:

1. Comments on this proposal are due by August 7, 2015; reply comments are due by September 8, 2015.

2. A copy of this decision will be served upon the Chief Counsel for Advocacy, Office of Advocacy, U.S. Small Business Administration.

3. Notice of this decision will be published in the **Federal Register**.

4. This decision is effective on its service date.

List of Subjects

49 CFR Part 1241

Railroads, Reporting and recordkeeping requirements.

49 CFR Part 1242

Railroad and taxes.

49 CFR Part 1243

Railroads, Reporting and recordkeeping requirements.

49 CFR Part 1244

Freight, Railroads, Reporting and recordkeeping requirements.

49 CFR Part 1245

Railroad employees, Reporting and recordkeeping requirements, Wages.

49 CFR Part 1246

Railroad employees, Reporting and recordkeeping requirements.

49 CFR Part 1247

Freight, Railroads, Reporting and recordkeeping requirements.

49 CFR Part 1248

Freight, Railroads, Reporting and recordkeeping requirements, Statistics.

Decided: June 18, 2015.

By the Board, Acting Chairman Miller and Vice Chairman Begeman.

Jeffrey Herzig,

Clearance Clerk.

For the reasons set forth in the preamble, the Surface Transportation Board proposes to amend parts 1241, 1242, 1243, 1244, 1245, 1246, 1247, and 1248 of title 49, chapter X, of the Code of Federal Regulations as follows:

PART 1241—ANNUAL, SPECIAL, OR PERIODIC REPORTS—CARRIERS SUBJECT TO PART A OF SUBTITLE IV OF TITLE 49, UNITED STATES CODE

■ 1. The authority citation for part 1241 continues to read as follows:

Authority: 49 U.S.C. 11145.

■ 2. Revise § 1241.1 to read as follows:

§ 1241.1 Common carriers.

All common carriers subject to the provisions of part A of subtitle IV of title 49, United States Code, and the owners of all railroads engaged in interstate commerce as therein defined, are required to file in the office of the Board on or before the 31st day of March in each year, reports covering the preceding year that is being reported, giving the particulars called for in the annual reports required by the Board of said carriers and owners of railroads.

■ 3. Amend § 1241.11 by revising paragraph (a) to read as follows:

§ 1241.11 Annual reports of Class I railroads.

(a) All line-haul railroad companies of Class I, as defined in part 1201 of this chapter, subject to part A of subtitle IV of title 49, United States Code, are required to file annual reports in accordance with Railroad Annual Report Form R–1. Such annual report shall be filed in duplicate in the Office of Economics, Surface Transportation Board, Washington, DC 20423–0001, on or before March 31 of the year following the year which is being reported.

* * * * *

PART 1242—SEPARATION OF COMMON OPERATING EXPENSES BETWEEN FREIGHT SERVICE AND PASSENGER SERVICE FOR RAILROADS

■ 4. The authority citation for part 1242 continues to read as follows:

Authority: 49 U.S.C. 721, 11142.

■ 5. Amend § 1242.00 by revising paragraph (a) to read as follows:

§ 1242.00 Separation of common operating expenses.

(a) All Class I railroad companies including Class I switching and terminal companies subject to part A of subtitle IV of title 49, United States Code, shall separate operating expenses common to both freight service and passenger service in accordance with the regulation in this part.

* * * * *

PART 1243—QUARTERLY OPERATING REPORTS—RAILROADS

■ 6. The authority citation for part 1243 continues to read as follows:

Authority: 49 U.S.C. 721, 11145.

■ 7. Revise § 1243.1 to read as follows:

§ 1243.1 Revenues, expenses and income.

All Class I railroads, except switching and terminal companies, subject to the provisions of part A of subtitle IV of title 49, United States Code, are required to compile and file quarterly reports of revenues, expenses and income in accordance with Form RE&I, and instructions thereon. Such quarterly reports shall be electronically submitted or filed in the Office of Economics, Surface Transportation Board, Washington, DC 20423–0001, within 15 days after the end of each quarter to which they relate.

■ 8. Revise § 1243.2 to read as follows:

§ 1243.2 Condensed balance sheet.

All Class I railroads, except switching and terminal companies, subject to the provisions of part A of subtitle IV of title 49, United States Code, are required to compile and file quarterly reports of balance sheet items in accordance with Form CBS, and instructions thereon. Such quarterly reports shall be electronically submitted or filed with the Office of Economics, Surface Transportation Board, Washington, DC 20423–0001, within 15 days after the end of each quarter to which they relate.

■ 9. Revise § 1243.3 to read as follows:

§ 1243.3 Report of fuel cost, consumption, and surcharge revenue.

All Class I railroads are required to file quarterly a Report of Fuel Cost, Consumption, and Surcharge Revenue, in accordance with the Board's reporting form. Such reports shall be electronically submitted or filed with the Office of Economics, Surface Transportation Board, Washington, DC 20423–0001, within 15 days after the end of each quarter reported.

PART 1244—WAYBILL ANALYSIS OF TRANSPORTATION OF PROPERTY—RAILROADS

■ 10. The authority citation for part 1244 continues to read as follows:

Authority: 49 U.S.C. 721, 10707, 11144, 11145.

■ 11. Revise § 1244.1(a) to read as follows:

§ 1244.1 Definitions.

(a) *Railroad*–an individual railroad or terminal company subject to part A of subtitle IV of title 49, United States Code, and every receiver, trustee, executor, administrator or assignee of any such railroad. If a railroad and its railroad subsidiaries report to the Board on a consolidated basis, they would collectively be considered as a *railroad.*

* * * * *

PART 1245—CLASSIFICATION OF RAILROAD EMPLOYEES; REPORTS OF SERVICE AND COMPENSATION

■ 12. The authority citation for part 1245 continues to read as follows:

Authority: 49 U.S.C. 721, 11145.

■ 13. Revise § 1245.2 to read as follows:

§ 1245.2 Reports of railroad employees, service and compensation.

All Class I railroads are required to file a Quarterly Report of Railroad Employees, Service, and Compensation, (Quarterly Forms A & B). In addition, such carriers shall also file an Annual Report of Railroad Employees, Service, and Compensation, (Annual Forms A & B) for each calendar year. Both reports shall be electronically submitted or filed with the Office of Economics, Surface Transportation Board, Washington, DC 20423–0001. The quarterly report shall be filed within 15 days after the end of each calendar quarter. The annual report shall be filed within 30 days after the end of each reporting year.

■ 14. Revise § 1245.3(b) to read as follows:

§ 1245.3 Employees; definition, service hours, and compensation.

* * * * *

(b) *Counting employees.* Because the number of employees fluctuates, carriers are required to classify and count all of their employees on a monthly basis,

consistent with the data reported in accordance with § 1246.1 of this chapter.

* * * * *

PART 1246—NUMBER OF RAILROAD EMPLOYEES

■ 15. The authority citation for part 1246 continues to read as follows:

Authority: 49 U.S.C. 721, 11145.

■ 16. Revise § 1246.1 to read as follows:

§ 1246.1 Monthly report of number of railroad employees.

Each Class I railroad shall file a Monthly Report of Number of Railroad Employees (Form C) each month. The number reported should represent the average of the actual count at the beginning of the reported month and the actual count at the end of the month. The report should be electronically submitted or mailed to Office of Economics, Surface Transportation Board, Washington, DC 20423–0001, 10 days after the end of each month to which it applies.

PART 1247—REPORT OF CARS LOADED AND CARS TERMINATED

■ 17. The authority citation for part 1247 continues to read as follows:

Authority: 49 U.S.C. 721, 10707, 11144, 11145.

■ 18. Revise § 1247.1 to read as follows:

§ 1247.1 Annual Report of Cars Loaded and Cars Terminated.

Each Class I railroad shall file Form STB–54, Annual Report of Cars Loaded and Cars Terminated, together with the accompanying certification, with the Office of Economics (OE), Surface Transportation Board, Washington, DC 20243–0001, within 60 days after the end of each reporting year. Blank forms and instructions are available on the Board's Web site (*http://www.stb.dot.gov*) or can be obtained by contacting OE.

PART 1248—FREIGHT COMMODITY STATISTICS

■ 19. The authority citation for part 1248 continues to read as follows:

Authority: 49 U.S.C. 721, 11144, and 11145.

■ 20. Revise § 1248.1 to read as follows:

§ 1248.1 Freight commodity statistics.

All Class I railroads, as described in part 1201 of this chapter, subject to part A of subtitle IV of title 49, United States Code, shall compile and report freight commodity statistics on the basis of the commodity codes named in § 1248.101. Carriers shall report quarterly and annually on the basis of the 3, 4 and 5-digit commodity codes named in that section. Such reports shall be made in conformity with the outline of terms set forth in §§ 1248.2 through 1248.5, as supplemented by instructions included in the appropriate report form to be supplied to the reporting railroads.

■ 21. Revise § 1248.5 to read as follows:

§ 1248.5 Report forms and date of filing.

(a) Reports required from Class I carriers by this section shall be electronically submitted or filed with the Office of Economics, Surface Transportation Board, Washington, DC 20423–0001, on forms which will be furnished to the carriers. Data required under § 1248.2 shall be filed on Form QCS on or before the 30th day succeeding the close of each period for which they are compiled.

(b) [Reserved]

Note to § 1248.5: The outline of Report Form QCS follows the tenor of the order.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix—Collection Number 1

Title: Class I Railroad Annual Report.
OMB Control Number: 2140–0009.
Form Number: R1.
Type of Review: Revision of a currently approved collection.
Respondents: Class I railroads.
Number of Respondents: 7.
Estimated Time Per Response: The railroads currently spend no more than 800 hours preparing the Annual Report Form R–1, including time spent reviewing instructions; searching existing data sources; gathering and maintaining the data needed; completing and reviewing the collection of information; and converting the data from the carrier's individual accounting system to the Board's Uniform System of Accounts (USOA), which ensures that the information will be presented in a consistent format across all reporting railroads, *see* 49 U.S.C. 11141–43, 11161–64, 49 CFR parts 1200 and 1201. The proposed modification would be limited to a change in the due date for the Report's Schedule 250 and would not increase the hourly burden.
Frequency of Response: Annual.
Total Annual Hour Burden: No more than 5,600 hours.
Total Annual ''Non-Hour Burden'' Cost: Respondents are currently required to submit a signed hard copy of this report. We estimate a total annual cost for all respondents of $28. The proposed modification will not increase the cost burden.
Needs and Uses: Annual reports are required to be filed by Class I railroads under 49 U.S.C. 11145. The reports show operating expenses and operating statistics of the carriers. Operating expenses include costs for right-of-way and structures, equipment, train and yard operations, and general and administrative expenses. Operating statistics include such items as car-miles, revenue-ton-miles, and gross ton-miles. The reports are used by the Board, other Federal agencies, and industry groups to monitor and assess railroad industry growth, financial stability, traffic, and operations, and to identify industry changes that may affect national transportation policy. The annual reports also contain multiple schedules. One of these schedules is the Schedule 250 (required under the Annual Report Form R–1). The Schedule 250 data is used to compute the rate of return on net investment (ROI) for the Class I Railroads, which is used in annual determination of railroad revenue adequacy. *See* 49 U.S.C. 10704(a)(3); *Standards for Railroad Revenue Adequacy,* 364 I.C.C. 803 (1981); *Standards for Railroad Revenue Adequacy,* 3 I.C.C. 2d 261 (1986); and *Supplemental Reporting of Consolidated Information for Revenue Adequacy,* 5 I.C.C. 2d 65 (1988). The only modification being made to the annual report is the modification of the due date for Schedule 250. Receiving this data at the earlier date would enable the Board to expedite the Board's revenue-adequacy determinations. This change in due date was made possible by the improvements in technology. No other changes to this collection are being made.

Information from certain schedules contained in these reports is compiled and published on the Board's Web site, *http://www.stb.dot.gov/stb/industry/econ_reports.html.* Information in these reports is not available from any other source.

Collection Number 2

Title: Quarterly Report of Revenues, Expenses, and Income—Railroads (Form RE&I).
OMB Control Number: 2140–0013.
Form Number: None.
Type of Review: Revision of a currently approved collection.
Respondents: Class I railroads.
Number of Respondents: 7.
Estimated Time per Response: 6 hours.
Frequency of Response: Quarterly.
Total Annual Hour Burden: 168 hours.
Total Annual ''Non Hour Burden'' Cost: No ''non-hour cost'' burdens associated with this collection have been identified.
Needs and Uses: This collection is a report of railroad operating revenues, operating expenses and income items; it is a profit and loss statement, disclosing net railway operating income on a quarterly and year-to-date basis for the current and prior years. *See* 49 CFR 1243.1. The Board uses the information in this report to ensure competitive, efficient, and safe transportation through general oversight programs that monitor and forecast the financial and operating condition of railroads, and through regulation of railroad rate and service issues and rail restructuring proposals, including railroad mergers, consolidations, acquisitions of control, and abandonments. Information from these reports is used by the Board, other Federal agencies, and industry groups to monitor and assess industry growth and operations, detect changes in carrier financial stability, and identify trends that may affect the national transportation system. Some of

the information from these reports is compiled by the Board in our quarterly Selected Earnings Data Report, which is published on the Board's Web site, *http://www.stb.dot.gov.* The information contained in these reports is not available from any other source.

Collection Number 3

Title: Quarterly Condensed Balance Sheet—Railroads (Form CBS).
OMB Control Number: 2140–0012.
Form Number: None.
Type of Review: Revision of a currently approved collection.
Respondents: Class I railroads.
Number of Respondents: 7.
Estimated Time per Response: 6 hours.
Frequency of Response: Quarterly.
Total Annual Hour Burden: 168 hours.
Total Annual ''Non-Hour Burden'' Cost: No ''non-hour cost'' burdens associated with this collection have been identified.
Needs and Uses: This collection shows the balance (quarterly and cumulative) for the current and prior year of the carrier's assets and liabilities, gross capital expenditures, and revenue tons carried. *See* 49 CFR 1243.2. The Board uses the information in this report to ensure competitive, efficient, and safe transportation through general oversight programs that monitor and forecast the financial and operating condition of railroads, and through specific regulation of railroad rate and service issues and rail restructuring proposals, including railroad mergers, consolidations, acquisitions of control, and abandonments. Information from these reports is used by the Board, other Federal agencies, and industry groups to assess industry growth and operations, detect changes in carrier financial stability, and identify trends that may affect the national transportation system. Revenue ton-miles, which are reported in these reports, are compiled and published by the Board in its quarterly Selected Earnings Data Report, which is published on the Board's Web site, *http://www.stb.dot.gov.* The information contained in these reports is not available from any other source.

Collection Number 4

Title: Report of Railroad Employees, Service and Compensation (Wage Forms A and B).
OMB Control Number: 2140–0004.
Form Number: None.
Type of Review: Revision of a currently approved collection.
Respondents: Class I railroads.
Number of Respondents: 8.
Estimated Time per Response: No more than 30 hours per quarterly report and 40 hours per annual summation.
Frequency of Response: Quarterly, with an annual summation.
Total Annual Hour Burden: No more than 1280 hours.
Total Annual ''Non-Hour Burden'' Cost: No ''non-hour cost'' burdens associated with this collection have been identified.
Needs and Uses: This collection shows the number of employees, service hours, and compensation, by employee group (*e.g.,* executive, professional, maintenance-of-way and maintenance of equipment, and transportation), of the reporting railroads. *See* 49 CFR part 1245. The information is used by the Board to forecast labor costs and measure the efficiency of the reporting railroads. The information is also used by the Board to evaluate proposed regulated transactions that may impact rail employees, including mergers and consolidations, acquisitions of control, purchases, and abandonments. Other Federal agencies and industry groups, including the Railroad Retirement Board, Bureau of Labor Statistics, and Association of American Railroads, use the information contained in the reports to monitor railroad operations. Certain information from these reports is compiled and published on the Board's Web site, *http://www.stb.dot.gov.* The information contained in these reports is not available from any other source.

Collection Number 5

Title: Monthly Report of Number of Employees of Class I Railroads (Form C).
OMB Control Number: 2140–0007.
Form Number: None.
Type of Review: Revision of a currently approved collection.
Respondents: Class I railroads.
Number of Respondents: 8.
Estimated Time per Response: 1.25 hours.
Frequency of Response: Monthly.
Total Annual Hour Burden: 120 hours.
Total Annual ''Non-Hour Burden'' Cost: No ''non-hour cost'' burdens associated with this collection have been identified.
Needs and Uses: This collection shows, for each reporting carrier, the average number of employees at mid-month in the six job-classification groups that encompass all railroad employees. *See* 49 CFR part 1246. The information is used by the Board to forecast labor costs and measure the efficiency of the reporting railroads. The information is also used by the Board to evaluate the impact on rail employees of proposed regulated transactions, including mergers and consolidations, acquisitions of control, purchases, and abandonments. Other Federal agencies and industry groups, including the Railroad Retirement Board, Bureau of Labor Statistics, and Association of American Railroads, use the information contained in these reports to monitor railroad operations. Certain information from these reports is compiled and published on the Board's Web site, *http://www.stb.dot.gov.* The information contained in these reports is not available from any other source.

Collection Number 6

Title: Annual Report of Cars Loaded and Cars Terminated.
OMB Control Number: 2140–0011.
Form Number: Form STB–54.
Type of Review: Revision of a currently approved collection.
Number of Respondents: 7.
Estimated Time per Response: 4 hours.
Frequency of Response: Annual.
Total Annual Hour Burden: 28 hours.
Total Annual ''Non Hour Burden'' Cost: No ''non-hour cost'' burdens associated with this collection have been identified.
Needs and Uses: This collection reports the number of cars loaded and cars terminated on the reporting carrier's line. *See* 49 CFR part 1247. Information in this report is entered into the Board's URCS, the uses of which are explained under Collection Number 1. There is no other source for the information contained in this report.

Collection Number 7

Title: Quarterly Report of Freight Commodity Statistics (Form QCS).
OMB Control Number: 2140–0001.
Form Number: None.
Type of Review: Revision of a currently approved collection.
Respondents: Class I railroads.
Number of Respondents: 7.
Estimated Time per Response: 217 hours.
Frequency of Response: Quarterly, with an annual summation.
Total Annual Hour Burden: 7,595 hours annually.
Total Annual ''Non-Hour Burden'' Cost: No ''non-hour cost'' burdens associated with this collection have been identified.
Needs and Uses: This collection, which is based on information contained in carload waybills used by railroads in the ordinary course of business, reports car loadings and total revenues by commodity code for each commodity that moved on the railroad during the reporting period. *See* 49 CFR part 1248. Information in this report is entered into the Board's URCS, the uses of which are explained under Collection Number 1. There is no other source for the information contained in this report.

Collection Number 8

Title: Report of Fuel Cost, Consumption, and Surcharge Revenue.
OMB Control Number: 2140–0014.
STB Form Number: None.
Type of Review: Revision of a currently approved collection.
Respondents: Class I railroads.
Number of Respondents: 7.
Estimated Time per Response: 1 hour.
Frequency: Quarterly.
Total Burden Hours (annually including all respondents): 28 hours.
Total ''Non-hour Burden'' Cost: None identified.
Needs and Uses: Under 49 U.S.C. 10702, the Surface Transportation Board has the authority to address the reasonableness of a rail carrier's practices. The proposed information collection is intended to permit the Board to monitor the current fuel surcharge practices of the Class I carriers. Failure to collect this information would impede the Board's ability to monitor the current fuel surcharge practices of Class I carriers. The Board has authority to collect information about rail costs and revenues under 49 U.S.C. 11144 and 11145.

[FR Doc. 2015–15407 Filed 7–7–15; 8:45 am]
BILLING CODE 4915–01–P

Notices

Federal Register
Vol. 80, No. 130
Wednesday, July 8, 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

Submission for OMB Review; Comment Request

July 1, 2015.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 7, 2015 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725–17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Debt Settlement Policies and Procedures.

OMB Control Number: 0560–0146.

Summary of Collection: The Federal Claims Collection Standards provides at 4 CFR 102, that whenever feasible, debts owed to the United States should be collected in full in one lump sum. The Debt Collection Improvement Act (DCIA) of 1996 further emphasizes, as one of its goals, to maximize collections of delinquent debt owed to the Government, by ensuring quick action is taken to enforce recovery of debts and the use of all appropriate collection tools, while ensuring that the public is fully informed of the Federal Government's debt collection policies and the debtors are fully cognizant of their financial obligations to repay amounts owed to the Federal Government. Provisions under the Federal Claims Collection Standards and the DCIA allow the debtor upon receiving a notification letter and unable to pay debt owed to the Federal Government in one lump sum, to forward a written request and financial statement to Farm Service Administration (FSA) and Commodity Credit Corporation (CCC) for establishing an agreed repayment plan in the promissory note using form CCC–279, Promissory Note.

Need and Use of the Information: When a debtor requests to enter into an installment agreement to settle their debt, FSA will collect information on the debtor's assets, liabilities, income and expenses. Based on that information a determination can be made on whether the debtor can pay the debt in one lump sum or an installment is necessary. Without this financial information FSA/CCC would have no method of allowing debtor's to pay their debts in installments while still ensuring that the government's financial interests are protected.

Description of Respondents: Individuals or households.

Number of Respondents: 100.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 200.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2015–16650 Filed 7–7–15; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 1, 2015.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 7, 2015 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725–17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such

persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Agricultural Research Service

Title: Meeting the Information Requirements of the Animal Welfare Act Workshop Registration Form.

OMB Control Number: 0518–0033.

Summary of Collection: The U.S. Department of Agriculture, National Agricultural Library (NAL), Animal Welfare Information Center conducts a workshop titled ''Meeting the Information Requirements of the Animal Welfare Act.'' The registration form collects information from interested parties necessary to register them for the workshop. The information includes: Workshop data preferences, signature, name, title, organization name, mailing address, phone and fax numbers and email address. The information will be collected using online and printed versions of the form. Also forms can be fax or mailed.

Need and Use of the Information: NAL will collect information to register participants, contact them regarding schedule changes, control the number of participants due to limited resources and training space, and compile and customize class materials to meet the needs of the participants. Failure to collect the information would prohibit the delivery of the workshop and significantly inhibit NAL's ability to provide up-to-date information on the requirements of the Animal Welfare Act.

Description of Respondents: Not-for-Profit Institutions; Business or Other for-profit; Government; State, Local, or Tribal Government.

Number of Respondents: 200.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 17.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2015–16649 Filed 7–7–15; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Forest Service

Idaho Roadless Area Boundary Modification; Caribou-Targhee National Forest

AGENCY: Forest Service, USDA.

ACTION: Notice of proposed Idaho Roadless Area boundary modification; request for comment.

SUMMARY: The Forest Service, U.S. Department of Agriculture (USDA), proposes to modify the West Mink Idaho Roadless Area boundary on the Caribou-Targhee National Forest to relocate and expand the Gibson Jack Trailhead. The Chief of the Forest Service proposes to modify the boundary after a 45-day public notice and opportunity to comment.

DATES: Comments must be received in writing by August 24, 2015.

ADDRESSES: Written comments concerning this notice should be addressed to Doug Herzog, Caribou-Targhee National Forest, 1405 Hollipark Drive, Idaho Falls, ID 83401. Comments may also be sent via email to *comments-intermtn-caribou-targhee-westside@fs.fed.us,* or via facsimile to (208) 557–5826. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at 1405 Hollipark Drive, Idaho Falls, ID 83401. Visitors are encouraged to call ahead to (208) 524–7511 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Doug Herzog, Forest Planner, at (208) 557–5826. Additional information concerning this boundary modification and trailhead relocation, including the proposed modified map, may be obtained on the Internet at *http://www.fs.usda.gov/detail/roadless/idahoroadlessrule/?cid=stelprdb5382399 and at http://data.ecosystem-management.org/nepaweb/nepa_project_exp.php?project=44396.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

The Idaho Roadless Rule permits the Chief of the Forest Service to modify Idaho Roadless Area boundaries based on changed circumstances or public need after providing public notice and a 45-day public comment period. Pursuant to 36 CFR 294.27(b), the Forest Service proposes to modify the West Mink Roadless Area boundary, located in the Caribou-Targhee National Forest, to allow for the relocation and expansion of the Gibson Jack trailhead.

The existing Gibson Jack trailhead outside of Pocatello, Idaho does not provide adequate parking to accommodate the trail's high level of use. Vehicles must park along the trailhead's access road on adjacent private lands. Expansion of the trailhead in its existing location is not feasible because of the presence of steep and erodible slopes. The West Mink Roadless Area surrounds the trailhead on three sides.

A flat bench approximately 700 feet west of the existing trailhead and inside the roadless area would provide adequate space to accommodate trailhead parking and for vehicles pulling trailers. Moving the trailhead to this location requires removing 11.4 acres from the roadless area and reconstructing approximately 700 feet of a closed Forest Service road that currently serves as a non-motorized trail.

The Forest Service also proposes to eliminate an 18.8-acre area (or ''cherry stem'') that has been carved out of the same roadless area. This 18.8-acre area follows a closed Forest Service road which has since been converted to a motorized trail. The Forest Service will add these 18.8 acres to the Roadless Area and remove the previously mentioned 11.4 acres to accommodate the new trailhead, resulting in a net increase of 7.4 acres to the West Mink Roadless Area. The boundary modification would improve the area's manageability for the Caribou-Targhee National Forest. The trailhead relocation would provide improved access and safety for trail users and meet current and projected recreation demand. A map of the proposed modifications is available at: *http://www.fs.usda.gov/detail/roadless/idahoroadlessrule/?cid=stelprdb5382399.*

The Forest Service prepared an environmental assessment to analyze the impacts of the trailhead relocation and roadless area boundary modifications. The Chief of the Forest Service is the responsible official for the boundary modification under the Idaho Roadless Rule. The Forest Supervisor, Caribou-Targhee National Forest, is the responsible official for the trailhead relocation project. The Forest Service will consider public comments on the proposed boundary modifications in coordination with the proposed trailhead relocation. The environmental assessment, finding of no significant impact, and draft decision notice for the trailhead relocation are available at the Caribou-Targhee National Forest Supervisor's Office, 1405 Hollipark Drive, Idaho Falls, ID 83401 or on the Internet at: *www.fs.usda.gov/projects/ctnf/landmanagement/projects.* The trailhead relocation project is subject to the objection process at 36 CFR part 218 and 219. Information on filing an objection on the trailhead relocation project is available at the Web site above.

Dated: June 30, 2015.

Thomas L. Tidwell

Chief, Forest Service.

[FR Doc. 2015–16657 Filed 7–7–15; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; Business and Professional Classification Report

AGENCY: U.S. Census Bureau.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: To ensure consideration, written comments must be submitted on or before September 8, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Scott Handmaker, Chief, Classification Processing Branch, U.S. Census Bureau, 8K149, Washington, DC 20233, Telephone 301–763–7107; Email: *Scott.P.Handmaker@census.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau conducts the Business and Professional Classification Report survey (SQ–CLASS) to collect information from new businesses to obtain proper industry classification for use in economic surveys and the Economic Census. The survey, conducted quarterly, samples businesses with newly assigned Employer Identification Numbers (EINs) from the Internal Revenue Service (IRS). Businesses can only be selected once for the survey. The survey collects data about a business in such areas as: Primary business activity, company structure, size, and business operations. This information is used to update the sampling frame for current business surveys, which ensures high quality economic estimates. Additionally, by ensuring proper industry classification, this survey reduces burden for the businesses in the five-year Economic Census, as the questions in the census are tailored to the industry in which the business operates.

The major change in this survey will be the way respondents report their primary business activity. In the past, respondents provided a brief description of their primary business activity. Respondents will now choose the economic sector of their business and then select from a list of business activities. If the respondent does not see their business activity listed, then they will provide a brief description of their business activity. This is the same methodology that the Census Bureau uses in the Economic Census to assign industry classification.

Additionally, there will no longer be a paper form on which to report. Respondents can report over the Internet or by telephone. However, we will work with the individual respondents if reporting on the Internet or by telephone presents difficulties.

Minimal changes will be made to the wording and organization of existing questions and instructions.

II. Method of Collection

We will collect this information over the Internet and by telephone follow-up. Respondents will receive a letter directing them to the Internet to report their information. After two weeks, respondents will receive a reminder letter about the survey. After the due date, the Census Bureau will conduct a telephone follow-up operation for nonresponse. Throughout the survey, telephone assistance is available for respondents with questions and for those that cannot report over the Internet.

III. Data

OMB Control Number: 0607–0189.

Form Number(s): SQ–CLASS.

Type of Review: Regular submission.

Affected Public: Business or other for profit and not-for-profit institutions.

Estimated Number of Respondents: 52,000.

Estimated Time per Response: 13 minutes.

Estimated Total Annual Burden Hours: 11,267 hours.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13, United States Code, sections 131, 182, 193, 224, and 225.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 2, 2015.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2015–16678 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Economic Analysis (BEA).

Title: Quarterly Survey of Insurance Transactions by U.S. Insurance Companies with Foreign Persons.

OMB Control Number: 0608–0066.

Form Number: BE–45.

Type of Request: Regular submission.

Number of Responses: 2,000 annually (500 filed each quarter; 475 reporting mandatory or voluntary data, and 25 that would not report data).

Average Hours per Response: 8 hours is the average for those reporting data and 1 hour is the average for those not reporting data, but hours may vary considerably among respondents because of differences in company size and complexity.

Estimated Total Annual Burden Hours: 15,300.

Needs and Uses: The Quarterly Survey of Insurance Transactions by U.S. Insurance Companies with Foreign

Persons (BE–45) is a survey that collects data on U.S. trade in insurance services. The information collected on this survey will be used to formulate U.S. international economic policy and analyze the impact of that policy, and the policies of foreign countries, on international trade in services. The data are used in estimating the insurance component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

Affected Public: Businesses or other for-profit organizations.

Frequency: Quarterly.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to OIRA *submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: July 1, 2015.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2015–16625 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Emerging Technology and Research Advisory Committee; Notice of Open Meeting

The Emerging Technology and Research Advisory Committee (ETRAC) will meet on July 23, 2015, 8:30 a.m., Room 3884, at the Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues NW., Washington, DC The Committee advises the Office of the Assistant Secretary for Export Administration on emerging technology and research activities, including those related to deemed exports.

Agenda

Thursday, July 23

Open Session

1. Welcome and Introductions
2. Opening Remarks by the Assistant Secretary for Export Administration
3. Review and discussion of new Export Control Reform Initiative Activities
4. Report on the June Conference by the Association of University Export Control Officials
5. Comments from the Public
6. Reports from ETRAC Committee members of their assigned Categories in reviewing the Export Administration Regulations
7. Report on Air Force Office of Scientific Research-recent international technologies exchange meeting & Emerging Technologies under consideration
8. Committee Administration matters

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov,* no later than July 16, 2015.

A limited number of seats will be available for the public session. Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate the distribution of public presentation materials to the Committee members, the Committee suggests that presenters forward the public presentation materials prior to the meeting to Ms. Springer via email.

For more information, call Yvette Springer at (202) 482–2813.

Dated: July 2, 2015.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2015–16671 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–337–804; A–533–813; A–560–802; A–570–851]

Certain Preserved Mushrooms from Chile, India, Indonesia and the People's Republic of China: Final Results of Expedited Third Sunset Reviews of the Antidumping Duty Orders

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

SUMMARY: As a result of these sunset reviews, the Department of Commerce (the Department) finds that revocation of the antidumping duty orders on certain preserved mushrooms (mushrooms) from Chile, India, Indonesia and the People's Republic of China (PRC) would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Reviews'' section of this notice.

DATES: *Effective Date:* July 8, 2015.

FOR FURTHER INFORMATION CONTACT: Terre Keaton Stefanova or Katherine Johnson, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1280 or (202) 482–4929, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 2, 2015, the Department published the notice of initiation of the third sunset reviews of the antidumping duty orders on mushrooms from Chile, India, Indonesia and the PRC pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[1] On March 15, 2015, the Department received a Notice of Intent to Participate in these reviews from the following domestic producers of mushrooms: L.K. Bowman Company, a division of Hanover Foods Corporation, Monterey Mushrooms, Inc., and The Mushroom Company (formerly Mushroom Canning Company) (collectively, ''the petitioners''), within the deadline specified in 19 CFR 351.218(d)(1)(i). The petitioners claimed interested party status under section 771(9)(C) of the Act, as manufacturers of a domestic like product in the United States. On April 1, 2015, we received a complete substantive response for each review from the petitioners within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[2] We received no substantive responses from any respondent interested parties. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), the Department conducted expedited (120-day) sunset reviews of these orders.

Scope of the Orders

The merchandise subject to the orders is certain preserved mushrooms. The merchandise subject to the orders is classifiable under subheadings: 2003.10.0127, 2003.10.0131, 2003.10.0137, 2003.10.0143, 2003.10.0147, 2003.10.0153, 0711.51.0000, 0711.90.4000, 2003.10.0027, 2003.10.0031, 2003.10.0037, 2003.10.0043 and 2003.10.0047 of the Harmonized Tariff Schedule of the United States (HTSUS).

[1] *See Initiation of Five-Year (''Sunset'') Review,* 80 FR 11164 (March 2, 2015).

[2] *See* April 1, 2015, letters from the petitioners regarding Five-Year (3rd Sunset) Review of the Antidumping Duty Orders on Certain Preserved Mushrooms from Chile, India, Indonesia, and the People's Republic of China.

Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this order is dispositive.[3]

Analysis of Comments Received

All issues raised in these reviews, including the likelihood of continuation or recurrence of dumping in the event of revocation and the magnitude of the margins likely to prevail if the orders were revoked, are addressed in the accompanying Issues and Decision Memorandum, which is hereby adopted by this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Sunset Reviews

Pursuant to sections 751(c)(1) and 752(c)(1),(2) and (3) of the Act, we determine that revocation of the antidumping duty orders on mushrooms from Chile, India, Indonesia and the PRC would be likely to lead to continuation or recurrence of dumping up to the following weighted-average margin percentages:

Country	Weighted-average margin (percent)
Chile	148.51
India	243.87
Indonesia	16.24
PRC	198.63

Notification to Interested Parties

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: June 30, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2015–16747 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–DS–P

[3] A full description of the scope of the orders is contained in the memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, ''Issues and Decision Memorandum for the Final Results of the Expedited Third Sunset Reviews of the Antidumping Duty Orders on Certain Preserved Mushrooms from Chile, India, Indonesia and the People's Republic of China'' (Issues and Decision Memorandum), dated concurrently with these results and hereby adopted by this notice.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–059]

Pressure Sensitive Plastic Tape from Italy: Final Results of Expedited Fourth Sunset Review of the Antidumping Duty Finding

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

SUMMARY: As a result of this review, the Department of Commerce (the Department) finds that revocation of the antidumping duty finding on pressure sensitive plastic tape (PSP tape) from Italy would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: *Effective Date:* July 8, 2015.

FOR FURTHER INFORMATION CONTACT: Terre Keaton Stefanova, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1280.

SUPPLEMENTARY INFORMATION

Background

On March 2, 2015, the Department published the notice of initiation of the fourth sunset review of the antidumping finding on PSP tape from Italy pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[1] On March 17, 2015, the Department received a notice of intent to participate in this review from the following domestic producers of PSP tape: 3M Company, Intertape Polymer Group Inc., and Shurtape Technologies LLC (collectively, the petitioners), within the deadline specified in 19 CFR 351.218(d)(1)(i). The petitioners claimed interested party status under section 771(9)(C) of the Act, as manufacturers, producers, or wholesalers of a domestic like product in the United States. On April 1, 2015, we received a complete substantive response from the petitioners within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[2] We received no substantive responses from any respondent interested parties. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), the Department conducted an expedited (120-day) sunset review of the finding.

Scope of the Finding

The merchandise subject to the finding is pressure sensitive plastic tape. The merchandise subject to the finding is classifiable under subheadings 3919.90.20 and 3919.90.50 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and for customs purposes, our written description of the scope of this finding is dispositive.[3]

Analysis of Comments Received

All issues raised in this review are addressed in the accompanying Issues and Decision Memorandum, which is hereby adopted by this notice, including the likelihood of continuation or recurrence of dumping in the event of

[1] *See Initiation of Five-Year (''Sunset'') Review,* 80 FR 11164 (March 2, 2015).

[2] *See* April 1, 2015, letter from the petitioners regarding Pressure Sensitive Plastic Tape from Italy: Substantive Response to Notice of Initiation.

[3] A full description of the scope of the finding is contained in the memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, ''Issues and Decision Memorandum for the Final Results of the Fourth Expedited Sunset Review of the Antidumping Duty Finding on Pressure Sensitive Plastic Tape from Italy'' (Issues and Decision Memorandum), dated concurrently with these results and hereby adopted by this notice.

revocation and the magnitude of the margins likely to prevail if the finding were revoked. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, we determine that revocation of the antidumping duty finding on PSP tape from Italy would be likely to lead to continuation or recurrence of dumping, and that the magnitude of the margin of dumping likely to prevail would be 3.70 percent for all producers and exporters [4] of subject merchandise.

Notification to Interested Parties

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: June 30, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Finding
IV. History of the Finding
V. Legal Framework
VI. Discussion of the Issues
A. Likelihood of Continuation or Recurrence of Dumping
B. Magnitude of the Margins of Dumping Likely to Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2015–16745 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–DS–P

[4] Plasturopa-SIPA S.a.S, Autodesivitalia, S.p.A and Boston S.p.A are excluded from the finding.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–836]

Light-Walled Rectangular Pipe and Tube from Mexico: Preliminary Results of Antidumping Duty Administrative Review; 2013–2014

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

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on light-walled rectangular pipe and tube (LWR pipe and tube) from Mexico. The period of review (POR) is August 1, 2013, through July 31, 2014. The review covers one producer/exporter of the subject merchandise, Perfiles y Herrajes LM, S.A. de C.V. (Perfiles).

We preliminarily determine that sales of subject merchandise by Perfiles were made at less than normal value during the POR. Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* July 8, 2015.

FOR FURTHER INFORMATION CONTACT: Ilissa Kabak Shefferman or Brian C. Davis, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4684 or (202) 482–7924, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The merchandise that is the subject of the order is certain welded carbon-quality light-walled steel pipe and tube, of rectangular (including square) cross section, having a wall thickness of less than 4 mm. The welded carbon-quality rectangular pipe and tube subject to the order is currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7306.61.50.00 and 7306.61.70.60. This tariff classification is provided for convenience and Customs purposes; however, the written description of the scope of the order is dispositive. A full description of the scope of the order is contained in the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, titled ''Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review: Light Walled Rectangular Pipe and Tube from Mexico'' (Preliminary Decision Memorandum), which is issued concurrent with and hereby adopted by this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). Access to ACCESS is available to registered users at *http://access.trade.gov* and is available to all parties in the Central Records Unit, Room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html.* A list of topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice. The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Methodology

The Department is conducting this review in accordance with section 751(a)(2) of the Tariff Act of 1930, as amended (the Act). For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

We preliminarily determine that, for the period August 1, 2013, through July 30, 2014, the following weighted-average dumping margin exists:

Manufacturer/Exporter	Weighted-average margin (percent)
Perfiles y Herrajes, L.M. SA de CV	4.15

Disclosure and Public Comment

The Department intends to disclose to interested parties to the proceeding any calculations performed in connection with these preliminary results of review within five days after the date of publication of this notice.[1] Interested

[1] *See* 19 CFR 351.224(b)

parties may submit case briefs to the Department in response to these preliminary results no later than 30 days after the publication of these preliminary results.[2] Rebuttal briefs, the content of which is limited to the issues raised in the case briefs, must be filed within five days from the deadline date for the submission of case briefs.[3] Parties who submit arguments in this proceeding are requested to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[4] Executive summaries should be limited to five pages total, including footnotes. Case and rebuttal briefs should be filed using ACCESS.[5] In order to be properly filed, ACCESS must successfully receive an electronically-filed document in its entirety by 5 p.m. Eastern Time. Case and rebuttal briefs must be served on interested parties.[6]

Within 30 days of the date of publication of this notice, interested parties may request a public hearing on arguments raised in the case and rebuttal briefs.[7] Unless the Department specifies otherwise, the hearing, if requested, will be held two days after the date for submission of rebuttal briefs.[8] Written argument and hearing requests should be electronically submitted to the Department via ACCESS.[9] The Department's electronic records system, ACCESS, must successfully receive an electronically-filed document in its entirety by 5:00 p.m. Eastern Daylight Time within 30 days after the date of publication of this notice.[10] Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. Parties will be notified of the time and location of the hearing.

The Department intends to publish the final results of this administrative review, including the results of its analysis of issues addressed in any case or rebuttal brief, no later than 120 days after publication of the preliminary results, unless extended.[11]

[2] *See* 19 CFR 351.309(c)(1)(ii).

[3] *See* 19 CFR 351.309(d)(1) and (2).

[4] *See* 19 CFR 351.309(c)(2) and (d)(2).

[5] *See generally* 19 CFR 351.303.

[6] *See* 19 CFR 351.303(f).

[7] *See* 19 CFR 351.310(c).

[8] *See* 19 CFR 351.310(d)(1).

[9] *See generally* 19 CFR 351.303.

[10] *See* 19 CFR 351.310(c).

[11] *See* section 751(a)(3)(A) of the Act; 19 CFR 351.213(h).

Assessment Rates

Upon completion of this administrative review, the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries.[12] If Perfiles' weighted-average dumping margin is not zero or *de minimis* in the final results of this review, we will calculate importer-specific assessment rates on the basis of the ratio of the total amount of antidumping duties calculated for an importer's examined sales and the total entered value of such sales in accordance with 19 CFR 351.212(b)(1). The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

We intend to issue liquidation instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Perfiles will be that established in the final results of this administrative review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or in the less-than-fair-value investigation but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be the all-others rate of 3.76 percent, which is the all-others rate established in the investigation.[13] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h)(1).

Dated: July 1, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2015–16724 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–DS–P

[12] *See* 19 CFR 351.212(b)(1)

[13] *See Orders,* 73 FR at 45404.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–821]

Polyethylene Retail Carrier Bags From Thailand: Final Results of Antidumping Duty Administrative Review; 2013–2014

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

SUMMARY: On May 7, 2015, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on polyethylene retail carrier bags (PRCBs) from Thailand.[1] For these final results, we continue to find that subject

[1] *See Polyethylene Retail Carrier Bags from Thailand: Preliminary Results of Antidumping Duty Administrative Review and Rescission of Review in Part; 2013–2014,* 80 FR 26224 (May 7, 2015) (*Preliminary Results*) and accompanying Preliminary Decision Memorandum, dated May 1, 2015 (Preliminary Decision Memorandum).

merchandise has been sold at less than normal value by Beyond Packaging Co., Ltd. (Beyond Packaging) during the period of review (POR).

DATES: *Effective Date:* July 8, 2015.

FOR FURTHER INFORMATION CONTACT: Dmitry Vladimirov or Minoo Hatten, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0665, and (202) 482–1690, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 7, 2015, the Department published the *Preliminary Results.* The POR is August 1, 2013, through July 31, 2014. We invited interested parties to comment on the *Preliminary Results.* We received no comments.

The Department conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise subject to the antidumping duty order is PRCBs, which may be referred to as t-shirt sacks, merchandise bags, grocery bags, or checkout bags. The subject merchandise is defined as non-sealable sacks and bags with handles (including drawstrings), without zippers or integral extruded closures, with or without gussets, with or without printing, of polyethylene film having a thickness no greater than 0.035 inch (0.889 mm) and no less than 0.00035 inch (0.00889 mm), and with no length or width shorter than 6 inches (15.24 cm) or longer than 40 inches (101.6 cm). The depth of the bag may be shorter than 6 inches but not longer than 40 inches (101.6 cm).

PRCBs are typically provided without any consumer packaging and free of charge by retail establishments, *e.g.,* grocery, drug, convenience, department, specialty retail, discount stores, and restaurants, to their customers to package and carry their purchased products. The scope of the order excludes (1) polyethylene bags that are not printed with logos or store names and that are closeable with drawstrings made of polyethylene film and (2) polyethylene bags that are packed in consumer packaging with printing that refers to specific end-uses other than packaging and carrying merchandise from retail establishments, *e.g.,* garbage bags, lawn bags, trash-can liners.

As a result of changes to the Harmonized Tariff Schedule of the United States (HTSUS), imports of the subject merchandise are currently classifiable under statistical category 3923.21.0085 of the HTSUS. Furthermore, although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Final Results of the Review

For the final results of this review, in accordance with sections 776(a) and (b) of the Tariff Act of 1930, as amended (the Act), we continued to rely on facts available with an adverse inference to establish a rate of 122.88 percent as the weighted-average dumping margin for Beyond Packaging. As the Department explained in the Preliminary Decision Memorandum, the 122.88 percent rate is derived from the petition in the underlying investigation, and the Department determined that for purposes of this review, the rate is corroborated, in accordance with section 776(c) of the Act.[2]

Assessment Rates

The Department will instruct U.S. Customs and Border Protection (CBP) to apply an *ad valorem* assessment rate of 122.88 percent to all entries of subject merchandise during the POR which were produced and/or exported by Beyond Packaging.

We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Beyond Packaging will be 122.88 percent, the weighted-average dumping margin established in the final results of this administrative review; (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation but the manufacturer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the manufacturer of the merchandise; (4) if neither the exporter nor the manufacturer has its own rate, the cash deposit rate will be 4.69 percent.[3] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

The Department is issuing and publishing these final results of administrative review in accordance with sections 751(a)(1), and 777(i) of the Act and 19 CFR 351.213(h).

Dated: June 30, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–16723 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–DS–P

[2] *See* Preliminary Decision Memorandum at 8.

[3] *See Notice of Implementation of Determination Under Section 129 of the Uruguay Round Agreements Act and Partial Revocation of the Antidumping Duty Order on Polyethylene Retail Carrier Bags From Thailand,* 75 FR 48940 (August 12, 2010).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–405–803]

Purified Carboxymethylcellulose From Finland: Initiation and Preliminary Results of Changed Circumstances Review and Consideration of Revocation of the Antidumping Duty Order

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

SUMMARY: In response to a request by Ashland Specialty Ingredients, G.P. (Ashland), and pursuant to section 782(h)(2) of the Tariff Act of 1930, as amended (the Act), 19 CFR 351.222(g)(1)(i) and 19 CFR 351.221(c)(3)(ii), the Department of Commerce (the Department) is initiating a changed circumstances review (CCR) of the antidumping duty (AD) order on purified carboxymethylcellulose (CMC) from Finland. Based on the information received, we preliminarily intend to revoke the *Order*.[1] Interested parties are invited to comment on these preliminary results.

DATES: Effective Date: July 8, 2015.

FOR FURTHER INFORMATION CONTACT: Victoria Cho, or Robert James, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5075 or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 11, 2005, the Department published in the **Federal Register** the AD order on CMC from Finland.[2] On May 15, 2015, in accordance with sections 751(b) and 751(d)(1) of the Act, 19 CFR 351.216(b), and 19 CFR 351.222(g)(1), Ashland, the petitioner and sole domestic producer of CMC, requested revocation of the *Order* with respect to Finland as part of a CCR. Ashland requested that the Department conduct the CCR on an expedited basis pursuant to 19 CFR 351.221(c)(3)(ii). On June 8, 2015, CP Kelco Oy and its U.S. affiliate, CP Kelco U.S. Inc., (collectively, CP Kelco), interested parties as a U.S. importer of CMC and sole manufacturer of CMC in Finland, also requested that the outcome of Ashland's CCR request should be the revocation of the AD order on CMC from Finland, due to the lack of interest in continuation of the *Order.*

Scope of the Order

The merchandise covered by these orders is all purified CMC, sometimes also referred to as purified sodium CMC, polyanionic cellulose, or cellulose gum, which is a white to off-white, non-toxic, odorless, biodegradable powder, comprising sodium CMC that has been refined and purified to a minimum assay of 90 percent. Purified CMC does not include unpurified or crude CMC, CMC Fluidized Polymer Suspensions, and CMC that is cross-linked through heat treatment. Purified CMC is CMC that has undergone one or more purification operations which, at a minimum, reduce the remaining salt and other by-product portion of the product to less than ten percent.

The merchandise subject to this order is classified in the Harmonized Tariff Schedule of the United States at subheading 3912.31.00. This tariff classification is provided for convenience and customs purposes; however, the written description of the scope of the order is dispositive.

Initiation and Preliminary Results of Changed Circumstances Review

Section 782(h)(2) of the Act and 19 CFR 351.222(g)(1)(i) provide that the Department may revoke an order (in whole or in part) if it determines that producers accounting for substantially all of the production of the domestic like product have no further interest in the order, in whole or in part. In addition, in the event the Department determines that expedited action is warranted, 19 CFR 351.221(c)(3)(ii) permits the Department to combine the notices of initiation and preliminary results.

On May 15, 2015, Ashland requested that the Department conduct the CCR on an expedited basis. On June 8, 2015, CP Kelco filed a letter in support of Ashland's CCR request. Ashland stated that, as the sole U.S. producer of CMC, it accounts for substantially all of the production of the domestic like product. Ashland also stated that it has no interest in the continuation of the *Order.*[3]

Therefore, at the request of Ashland and in accordance with sections 751(b)(1) and 751(d)(1) of the Act, 19 CFR 351.216, 19 CFR 351.222(g)(1), and 19 CFR 351.221(c)(3)(ii), we are initiating this CCR on CMC from Finland to determine whether revocation of the *Order* is warranted with respect to this product. In addition, we determine that expedited action is warranted. In accordance with 19 CFR 351.222(g)(1), we find that the petitioner's affirmative statement of no interest constitutes good cause to conduct this review. Additionally, our decision to expedite this review by combining the notice of initiation and the preliminary results in a single notice pursuant to 19 CFR 351.221(c)(3)(ii), stems from the domestic industry's lack of interest in applying the *Order.* If the final results of this changed circumstances review result in the revocation of the *Order,* the Department intends that such revocation will be effective the first day of the most recent period not subject to administrative review, which is currently July 1, 2014.

Public Comment

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 14 days of publication of this notice.[4] Parties will be notified of the time and date of any hearing if requested. Interested parties may submit case briefs and/or written comments not later than 14 days after the publication of this notice. Rebuttal briefs, and rebuttals to written comments, which must be limited to issues raised in such briefs or comments, may be filed not later than 21 days after the date of publication of this notice. Parties who submit case briefs or rebuttal briefs in this changed circumstance review are requested to submit with each argument: (1) A statement of the issue; and (2) a brief summary of the argument; and (3) a table of authorities. Interested parties who wish to comment on the preliminary results must file briefs electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* An electronically-filed document must be received successfully in its entirety by ACCESS by 5 p.m. Eastern Time on the date the document is due.

If final revocation occurs, we will instruct U.S. Customs and Border Protection to end the suspension of liquidation for the merchandise covered by the revocation on the effective date of the notice of revocation and to release any cash deposit or bond. The current requirement for a cash deposit of estimated AD duties on all subject merchandise will continue unless and

[1] *See Notice of Antidumping Duty Orders: Purified Carboxymethylcellulose from Finland, Mexico, the Netherlands and Sweden,* 70 FR 39734 (July 11, 2005) (the *Order*).

[2] *Id.*

[3] *See* Ashland's May 15, 2015, submission to the Department.

[4] *See* 19 CFR 351.303 for general filing requirements.

until it is modified pursuant to the final results of this changed circumstances review.

This initiation and preliminary results of review notice is published in accordance with sections 751(b)(1) and 777(i)(1) of the Act and 19 CFR 351.216, 351.221(b)(1), (4), and 351.222(g).

Dated: July 1, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–16722 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Docket No. 150416372–5569–02]

DEPARTMENT OF STATE

DEPARTMENT OF TRANSPORTATION

Information on Assertions Raised About State-Owned Airlines in Qatar and the UAE

AGENCY: International Trade Administration, U.S. Department of Commerce; Bureau of Economic and Business Affairs, U.S. Department of State; Office of Aviation and International Affairs, U.S. Department of Transportation.

ACTION: Supplemental notice.

SUMMARY: This notice supplements the **Federal Register** notice published on May 5, 2015 by the Departments of Commerce, State, and Transportation announcing their interest in obtaining information and views on assertions that three foreign airlines—Emirates Airline, Etihad Airways, and Qatar Airways—have received and are benefitting from subsidies from their respective governments that are distorting the global aviation market. This notice establishes deadlines for submission of information and provides additional guidance for submission of information that the submitter believes to be exempt from disclosure under the Freedom of Information Act (FOIA) (hereafter ''Confidential Information'') (such as trade secrets and commercial or financial information obtained from a person that is privileged or confidential).

DATES: The Departments request that information provided in response to the Departments' May 5, 2015 **Federal Register** notice be submitted to the dockets by 11:59 p.m. Eastern Daylight Time (EDT) on August 3, 2015. The Departments further request that additional materials commenting on information submitted to the dockets be submitted by 11:59 p.m. EDT on August 24, 2015. The Departments may, at their discretion, establish additional deadlines for submission of further materials to the dockets.

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

- *Electronic Submission:* Submit all electronic comments via the Federal e-Rulemaking Portal at *http://www.regulations.gov*. The materials in the dockets will not be edited to remove identifying or contact information, and the Departments caution against including any information in an electronic submission that the submitter does not want publicly disclosed. You may submit comments in any (or all) of the three docket numbers open for comment:
  - DOT–OST–2015–0082
  - DOS–2015–0016
  - DOC–2015–0001
- *Hard copy submission for Confidential Information:* Any submissions containing Confidential Information must be delivered to each of the three Departments in the following manner:
  - Deliver the submission in a sealed envelope marked ''confidential treatment requested'';
  - Provide an index listing the document(s) or information that the submitter would like the Departments to withhold. The index should include information such as numbers used to identify the relevant document(s) or information, document title and description, and relevant pages numbers and/or section numbers within a document; and
  - Provide a statement explaining the submitter's grounds for objecting to disclosure of the information to the public.

The Departments also request that submitters of Confidential Information, including those who have previously submitted Confidential Information, include a non-confidential version (either redacted or summarized) of those confidential submissions in the public dockets. In the event that the submitter cannot provide a non-confidential version of its submission, the Departments request that the submitter post a notice in the dockets stating that it has provided the Departments with Confidential Information. Should a submitter fail to docket either a non-confidential version of its submission or to post a notice that Confidential Information has been provided, the Departments will note the receipt of the submission on the dockets, including for submissions already received, with the submitter's organization or name (to the degree permitted by law) and the date of submission.

FOR FURTHER INFORMATION CONTACT: Eugene Alford, Office of Supply Chain, Professional & Business Services, International Trade Administration (Phone: (202) 482–5071 or Email: *airservices@trade.gov*). Robert Newsome, Transportation Affairs, Bureau of Economic and Business Affairs, U.S. Department of State (Phone: (202) 647–7540 or Email: *newsomerc@state.gov*). Claire McKenna, Office of Operations, Office of the General Counsel, U.S. Department of Transportation (Phone: (202) 366–0365 or Email: *Claire.McKenna@dot.gov*).

SUPPLEMENTARY INFORMATION:

Background

The U.S. Departments of Commerce, State, and Transportation are reviewing assertions that three foreign airlines—Emirates Airline, Etihad Airways, and Qatar Airways—have received and are benefitting from subsidies from their respective governments of the United Arab Emirates (UAE) and Qatar that are distorting the global aviation market. The three Departments announced by **Federal Register** notice on May 5, 2015 (80 FR 25671), the establishment of an open forum by which any interested stakeholder may submit information regarding its views on this subject and have access to such information submitted by other interested stakeholders. The Departments are publishing this supplemental notice to establish deadlines for the submission of information to the dockets and to provide additional guidance for submission of Confidential Information. See the deadlines listed in the **DATES** section, and procedures listed in the **ADDRESSES** section above. To ensure that their views are considered, stakeholders should provide a written submission to the Departments.

In reviewing Freedom of Information Act (FOIA) requests submitted to the Departments for information related to this matter that may include Confidential Information, the Departments are applying the FOIA, 5 U.S.C. 552, and their respective FOIA regulations, including the submitter notice process outlined in Executive Order 12,600. The Departments also are supplementing the Questions & Answers for Information Docket posted at *http://www.regulations.gov* to further clarify the procedures and policies the Departments are applying regarding

information submitted to the Departments in this matter.

Dated: July 1, 2015.

Marcus Jadotte,

Assistant Secretary for Industry and Analysis, Department of Commerce.

Dated: July 1, 2015.

Thomas Engle,

Deputy Assistant Secretary for Transportation Affairs, Department of State.

Dated: July 1, 2015.

Brandon Belford,

Deputy Assistant Secretary for Aviation and International Affairs, Department of Transportation.

Supplemental Questions & Answers for Information Docket

1) Q. The Departments say that review of the new material will begin towards the end of May. What do the three Departments intend to do with this material?

A. We are asking for stakeholder input on this matter to supplement the information that we are already reviewing and considering. No decision has been made on next steps.

2) Q. When will the joint docket on www.regulations.gov close for submissions?

A. Information provided in response to the Departments' May 5, 2015 notice must be submitted to the dockets by 11:59 p.m. Eastern Daylight Time (EDT) on August 3, 2015. Additional materials commenting on information submitted to the dockets must be submitted by 11:59 p.m. EDT on August 24, 2015. The Departments may, at their discretion, establish additional deadlines for submission of further materials to the dockets. To ensure that their views are considered, stakeholders should provide a written submission to the Departments.

3) Q. The April 10 press release refers to the Administration's Open Government Initiative. Does the open and transparent character of this forum mean that anyone can file anything?

A. The Departments are not interested in limiting the scope of what the public may offer in terms of submissions. There is no specific constraint on the material that interested stakeholders may submit. Of course, we expect that the submissions will be relevant, and we encourage thoughtful insights and analysis.

4) Q. I understand that the docket on the www.regulations.gov will be accessible to the public. Is the public docket the only means by which I can provide information?

A. While the preference is for written submissions to be made available to the public, the establishment of the joint docket is not intended to foreclose other means of communication with the three Departments and U.S. government officials. Please note that the materials in the dockets will not be edited to remove identifying or contact information, and the Departments caution against including any information in an electronic submission that one does not want publicly disclosed.

5) Q. How do I submit information that I believe to be confidential information?

A. Please refer to the **Federal Register** notice for the procedure. The Departments request that submitters of information that the submitter believes to be exempt from disclosure under the Freedom of Information Act (FOIA) (hereafter ''Confidential Information'') (such as trade secrets and commercial or financial information obtained from a person that is privileged or confidential), *including those who have previously submitted Confidential Information,* include a non-confidential version (either redacted or summarized) of those confidential submissions in the public dockets. In the event that the submitter cannot provide a non-confidential version of its submission, the Departments request that the submitter post a notice in the dockets stating that it has provided the Departments with Confidential Information. Should a submitter fail to docket either a non-confidential version of its submission or to post a notice that Confidential Information has been provided, the Departments will note the receipt of the submission on the dockets, *including for submissions already received,* with the submitter's organization or name (to the degree permitted by law) and the date of submission.

6) Q. How will the Departments handle Freedom of Information (FOIA) requests for materials provided by stakeholders and identified as ''Confidential Information''?

A. As noted in the **Federal Register** notice, the Departments will process FOIA requests for information submitted regarding the Gulf Carriers matter and marked ''Confidential Information'' in accordance with the FOIA and the Departments' respective FOIA regulations, including the submitter notice process outlined in Executive Order 12,600. Each Department will follow its normal FOIA procedures as to requests received.

7) Q. In the May 5, 2015 notice, the Departments did not establish a deadline for comments, but said that materials should be submitted as soon as is practicable. Why has this changed and how will materials submitted after the new deadlines be treated?

A. The Departments have received considerable information from stakeholders to date. In order to be responsive to all stakeholders, the Departments are proceeding with review of submissions but are providing further opportunity for stakeholders to submit materials for the Departments' review. Please refer to the **Federal Register** notice for deadlines.

[FR Doc. 2015–16648 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–898]

Chlorinated Isocyanurates From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2013–2014

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

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on chlorinated isocyanurates (chlorinated isos) from the People's Republic of China (PRC). The period of review (POR) is June 1, 2013, through May 31, 2014. This administrative review covers three producers/exporters: (1) Heze Huayi Chemical Co. Ltd. (Heze Huayi); (2) Hebei Jiheng Chemical Co., Ltd.(Jiheng); and (3) Juancheng Kangtai Chemical Co., Ltd. (Kangtai). We preliminarily determine that Jiheng made sales in the United States at prices below normal value (NV), and that Heze Huayi and Kangtai did not. Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* July 8, 2015.

FOR FURTHER INFORMATION CONTACT: Sean Carey, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW.,

Washington, DC 20230; telephone: (202) 482–3964.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The products covered by the order are chlorinated isos, which are derivatives of cyanuric acid, described as chlorinated s-triazine triones.[1] Chlorinated isos are currently classifiable under subheadings 2933.69.6015, 2933.69.6021, 2933.69.6050, 3808.40.50, 3808.50.40 and 3808.94.5000 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheadings are provided for convenience and customs purposes only; the written product description of the scope of the order is dispositive.

Methodology

The Department is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). Export and Constructed Export prices have been calculated in accordance with section 772 of the Act. Because the PRC is a non-market economy within the meaning of section 771(18) of the Act, normal value has been calculated in accordance with section 773(c) of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum, which is hereby adopted by this notice. A list of the topics included in the Preliminary Decision Memorandum is included as an appendix to this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''). ACCESS is available to registered users at *http://access.trade.gov* and in the Department's Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html*. The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Preliminary Results of Review

The Department preliminarily determines that the following weighted-average dumping margins exist for the period of June 1, 2013 through May 31, 2014:

Exporter	Weight-average dumping margin percentage
Heze Huayi Chemical Co., Ltd.	0.00
Hebei Jiheng Chemical Co., Ltd.	1.38
Juancheng Kangtai Chemical Co., Ltd.	0.00

Disclosure and Public Comment

The Department intends to disclose calculations performed for these preliminary results to the parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Because, as noted above, the Department intends to verify the information upon which we will rely in making our final determination, the Department will establish the briefing schedule at a later time, and will notify parties of the schedule in accordance with 19 CFR 351.309. Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[2]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, within 30 days of the date of publication of this notice.[3] Requests should contain: (1) The party's name, address and telephone number; (2) The number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.[4]

Assessment Rates

Upon issuing the final results of this review, the Department shall determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries covered by this review.[5] The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of this review.

In accordance with 19 CFR 351.212(b)(1), we are calculating importer- (or customer-) specific assessment rates for the merchandise subject to this review. For any individually examined respondent whose weighted-average dumping margin is above *de minimis* (*i.e.,* 0.50 percent), the Department will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales and the total entered value of sales.[6] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate is above *de minimis*. Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For entries that were not reported in the U.S. sales database submitted by an exporter individually examined during this review, the Department will instruct CBP to liquidate such entries at the PRC-wide rate. Additionally, if the Department determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number will be liquidated at the PRC-wide rate.[7]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be the rate established

[1] For a complete description of the Scope of the Order, *see* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Decision Memorandum for the Preliminary Results of the 2013–2014 Antidumping Duty Administrative Review: Chlorinated Isocyanurates from the People's Republic of China,'' dated concurrently with this notice (Preliminary Decision Memorandum).

[2] *See* 19 CFR 351.309(c) and (d); *see also* 19 CFR 351.303 (for general filing requirements).

[3] *See* 19 CFR 351.310(c).

[4] *See* 19 CFR 351.310(d).

[5] *See* 19 CFR 351.212(b)(1).

[6] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[7] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

in the final results of this review (except, if the rate is zero or *de minimis,* a zero cash deposit rate will be required for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the existing producer/exporter-specific combination rate published for the most recent period; (3) for all PRC exporters of subject merchandise that have not been found to be eligible for a separate rate, the cash deposit rate will be the PRC-wide rate of 285.63 percent; [8] and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213 and 19 CFR 351.221(b)(4).

Dated: June 30, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Non-Market Economy Country Status
5. Separate Rates
6. Surrogate Country
7. Date of Sale
8. Fair Value Comparisons
9. Factor Valuation Methodology
10. Surrogate Values
11. Comparisons to Normal Value
12. Adjustments for Countervailable Subsidies
13. Currency Conversion

[FR Doc. 2015–16733 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–DS–P

[8] *See Notice of Final Determination of Sales at Less Than Fair Value: Chlorinated Isocyanurates From the People's Republic of China,* 70 FR 24502, 24505 (May 10, 2005).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title:

OMB Control Number: 0648–0228.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 1.

Average Hours per Response: 30 minutes.

Burden Hours: 1.

Needs and Uses: This request is for extension of a currently approved information collection.

Regulations at 50 CFR part 300, subpart J, govern U.S. fishing in the Economic Zone of the Russian Federation. Russian authorities may permit U.S. fishermen to fish for allocations of surplus stocks in the Russian Economic Zone. Permit application information is sent to the National Marine Fisheries Service (NMFS) for transmission to Russia. If Russian authorities issue a permit, the vessel owner or operator must submit a permit abstract report to NMFS, and also report 24 hours before leaving the U.S. Exclusive Economic Zone (EEZ) for the Russian Economic Zone and 24 hours before re-entering the U.S. EEZ after being in the Russian Economic Zone.

The permit application information is used by Russian authorities to determine whether to issue a permit. NMFS uses the other information to help ensure compliance with Russian and U.S. fishery management regulations.

Affected Public: Business or other for-profit organizations.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–16670 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD870

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Shallow Geohazard Survey in the Beaufort Sea, Alaska

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

ACTION: Notice; issuance of an incidental take authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA) regulations, notification is hereby given that NMFS has issued an Incidental Harassment Authorization (IHA) to Hilcorp Alaska, LLC (Hilcorp) to take, by harassment, small numbers of marine mammals incidental to a shallow geohazard survey in the Beaufort Sea, Alaska, during the 2015 Arctic open-water season.

DATES: Effective July 1, 2015, through September 30, 2015.

ADDRESSES: Inquiry for information on the incidental take authorization should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East West Highway, Silver Spring, MD 20910. A copy of the application containing a list of the references used in this document, NMFS' Environmental Assessment (EA) and Finding of No Significant Impact (FONSI), and the IHA may be obtained by writing to the address specified above, telephoning the contact listed below (see **FOR FURTHER INFORMATION CONTACT**), or visiting the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications.*

Documents cited in this notice may be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Shane Guan, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Summary of Request

On December 1, 2014, NMFS received an application from Hilcorp for the taking of marine mammals incidental to shallow geohazard surveys in the Beaufort Sea. After receiving NMFS comments, Hilcorp submitted a revised IHA application on January 5, 2015. In addition, Hilcorp submitted a marine mammal mitigation and monitoring plan (4MP) on January 21, 2015. NMFS determined that the application was adequate and complete on February 9, 2015.

The proposed activity would occur between July 1 and September 30, 2015. The actual survey is expected to be complete in 45 days, including weather and equipment downtime. Underwater noises generated from the sonar used for the survey are likely to result Level B harassment of individuals of 6 species of marine mammals.

Description of the Specified Activity

Detailed descriptions of Hilcorp's shallow geohazard survey are provided in the **Federal Register** notice for the proposed IHA (80 FR 27901; May 15, 2015). No change has been made in the action described in the **Federal Register** notice. Please refer to that document for detailed information about the activities involved in the shallow geohazard survey program.

Comments and Responses

A notice of NMFS' proposal to issue an IHA to Hilcorp was published in the **Federal Register** on May 15, 2015 (80 FR 27901). That notice described in detail Hilcorp's activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals and the availability of marine mammals for subsistence uses. During the 30-day public comment period, NMFS received comment letters from the Marine Mammal Commission (Commission) and a private citizen. All comments are addressed in this section of the **Federal Register** notice.

Comment 1: The Commission states that the sub-bottom profiler, echosounder, and other sonars are non-impulsive acoustic sources and that NMFS should use the behavioral harassment threshold of 120 dB re 1 μPa instead of 160 dB, which is the threshold for impulse sound. Further, the Commission recommends that NMFS require Hilcorp to monitor the larger 120-dB re 1 μPa harassment zone of 450 m for the purpose of enumerating marine mammal takes associated with the use of the sub-bottom profiler.

Response: NMFS does not agree with the Commission's statement that signals from a sub-bottom profiler, echosounder, and other sonar equipment proposed to be used by Hilcorp are non-impulsive. In classifying underwater noise types, NMFS recognizes two categories: continuous sounds and intermittent sounds. Continuous sounds are those whose sound pressure level remains above that of the ambient sound, with negligibly small fluctuations in level (NIOSH, 1998; ANSI, 2005), while intermittent sounds are defined as sounds with interrupted levels of low or no sound (NIOSH, 1998). Thus, signals from sub-bottom profiler, echosounder, and other sonar equipment to be used by Hilcorp are not continuous sounds but rather intermittent sounds. Intermittent sounds can further be defined as either impulsive or non-impulsive. Impulsive sounds have been defined as sounds that are typically transient, brief (< 1 sec), broadband, and consist of a high peak pressure with rapid rise time and rapid decay (ANSI, 1986; NIOSH, 1998). Signals from these sources to be used by Hilcorp also have durations that are typically very brief (< 1 sec), with temporal characteristics that more closely resemble those of impulsive sounds than non-impulsive sounds, which typically have more gradual rise times and longer decays (ANSI, 1995; NIOSH, 1998). With regard to behavioral thresholds, we therefore consider the temporal and spectral characteristics of signals from the sub-bottom profiler, echosounder, and other sonar equipment to be used by Hilcorp to more closely resemble those of an impulse sound than a continuous sound.

Therefore, NMFS considers that using the 160 dB re 1 μPa threshold for Level B harassment for marine mammal noise exposure by Hilcorp's sub-bottom profiler is more appropriate than the continuous threshold of 120 dB re 1 μPa. Subsequently, the Level B zone of influence (ZOI) is established as the isopleths where the received level is 160 dB re 1 μPa and higher, which will be monitored by the protected species observers (PSOs).

Comment 2: A private citizen states that the **Federal Register** notice (80 FR 27901; May 15, 2015) for the proposed IHA fails to provide adequate information concerning the purpose of Hilcorp's shallow geohazard survey. The person states that the notice refers only obliquely to acquiring data ''along the subsea pipeline corridor area'' and ''a 300 m corridor around the centerline of the proposed pipeline area will be covered''. The person states that the notice should be withdrawn until NMFS is able to provide the public with the purpose for the proposed survey and how it would contribute to any future project, pipeline or otherwise, in the Beaufort Sea.

Response: NMFS does not agree with the private citizen's assessment. The **Federal Register** notice for the proposed IHA may not have provided detail on the purpose of Hilcorp's shallow geoharzard survey; however the purpose is described in Hilcorp's IHA application (ERM Alaska, Inc. 2014), which is referenced by the notice. As stated in Hilcorp's IHA application, the purpose of the survey is to evaluate

development of the Liberty field, with a potential plan of building a gravel island situated over the Liberty reservoir. The proposed shallow geohazard survey is to obtain subsurface information for the potential development of a subsea pipeline. The proposed IHA did not include this detail because NMFS does not believe that this information is critical for NMFS to make a determination of the survey's potential effects to marine mammals. Instead, the **Federal Register** notice provided a detailed description of the activity Hilcorp is proposing to undertake for the shallow geohazard survey in the Beaufort Sea. Hilcorp's plans related to any future project, pipeline or otherwise in the Beaufort Sea are speculative and do not affect NMFS' analysis of the potential impacts on marine mammals as a result of Hilcorp's shallow geohazard survey.

Description of Marine Mammals in the Area of the Specified Activity

The Beaufort Sea supports a diverse assemblage of marine mammals. Table 1 lists the 12 marine mammal species under NMFS jurisdiction with confirmed or possible occurrence in the proposed project area.

TABLE 1—MARINE MAMMAL SPECIES WITH CONFIRMED OR POSSIBLE OCCURRENCE IN THE PROPOSED SHALLOW GEOHAZARD SURVEY AREA

Common name	Scientific name	Occurrence	Seasonality	Range	Abundance
Odontocetes					
Beluga whale (Beaufort Sea stock).	*Delphinapterus leucas*	Common	Mostly spring and fall with some in summer.	Mostly Beaufort Sea	39,258
Beluga whale (eastern Chukchi Sea stock).		Common	Mostly spring and fall with some in summer.	Mostly Chukchi Sea	3,710
Killer whale**	*Orcinus orca*	Extralimital	Mostly summer and early fall.	California to Alaska	552
Harbor porpoise**	*Phocoena phocoena*	Extralimital	Mostly summer and early fall.	California to Alaska	48,215
Narwhal**	*Monodon monoceros*	Extralimital	Year round	Arctic Ocean	45,358
Mysticetes					
Bowhead whale*	*Balaena mysticetus*	Common	Mostly spring and fall with some in summer.	Russia to Canada	19,534
Gray whale	*Eschrichtius robustus*	Somewhat common	Mostly summer	Mexico to the U.S. Arctic Ocean.	19,126
Minke whale**	*Balaenoptera acutorostrata*.	Extralimital	Mostly summer	North Pacific Ocean	810–1,003
Humpback whale (Central North Pacific stock)***.	*Megaptera novaeangliae*.	Extralimital	Mostly summer	North Pacific Ocean	21,063
Pinnipeds					
Bearded seal (Beringia distinct population segment).	*Erigathus barbatus*	Common	Spring and summer	Bering, Chukchi, and Beaufort Seas.	155,000
Ringed seal (Arctic stock)*.	*Phoca hispida*	Common	Year round	Arctic Ocean	300,000
Spotted seal	*Phoca largha*	Common	Summer	Japan to U.S. Arctic Ocean.	141,479
Ribbon seal**	*Histriophoca fasciata*	Occasional	Summer	Arctic Ocean	49,000

* Endangered, threatened, or species of concern under the Endangered Species Act (ESA); Depleted under the MMPA.
** These species are so rarely sighted in the proposed project area that take is unlikely.

Minke whales are relatively common in the Bering and southern Chukchi Seas and have recently also been sighted in the northeastern Chukchi Sea (Aerts *et al.,* 2013; Clarke *et al.,* 2013). Minke whales are rare in the Beaufort Sea. They have not been reported in the Beaufort Sea during the Bowhead Whale Aerial Survey Project/Aerial Surveys of Arctic Marine Mammals (BWASP/ASAMM) surveys (Clarke *et al.,* 2011, 2012; 2013; Monnet and Treacy, 2005), and there was only one observation in 2007 during vessel-based surveys in the region (Funk *et al.,* 2010). Humpback whales have not generally been found in the Arctic Ocean. However, subsistence hunters have spotted humpback whales in low numbers around Barrow, and there have been several confirmed sightings of humpback whales in the northeastern Chukchi Sea in recent years (Aerts *et al.,* 2013; Clarke *et al.,* 2013). The first confirmed sighting of a humpback whale in the Beaufort Sea was recorded in August 2007 (Hashagen *et al.,* 2009), when a cow and calf were observed 54 mi east of Point Barrow. No additional sightings have been documented in the Beaufort Sea. Narwhal are common in the waters of northern Canada, west Greenland, and in the European Arctic, but rarely occur in the Beaufort Sea (COSEWIC, 2004). Only a handful of sightings have occurred in Alaskan waters (Allen and Angliss, 2013). These three species are not considered further in this document. Both the walrus and the polar bear could occur in the U.S. Beaufort Sea; however, these species are managed by the U.S. Fish and Wildlife Service (USFWS) and are not considered further in this document.

The Beaufort Sea is a main corridor of the bowhead whale migration route. The main migration periods occur in spring from April to June and in fall from late August/early September through October to early November. During the fall migration, several locations in the U.S. Beaufort Sea serve as feeding grounds for bowhead whales. Small numbers of bowhead whales that remain in the U.S. Arctic Ocean during summer also feed in these areas. The U.S. Beaufort Sea is not a main feeding or calving area for any other cetacean species. Ringed seals breed and pup in the Beaufort Sea; however, this does not occur during the summer or early fall. Further information on the biology and local distribution of these species can be

found in Hilcorp's application (see **ADDRESSES**) and the NMFS Marine Mammal Stock Assessment Reports, which are available online at: *http://www.nmfs.noaa.gov/pr/species/.*

Potential Effects of the Specified Activity on Marine Mammals

Operating active acoustic sources such as sub-bottom profilers, echosounders, and other civilian sonar equipment, and vessel activities has the potential for adverse effects on marine mammals. Potential effects from Hilcorp's shallow geohazard survey on marine mammals in the U.S. Beaufort Sea are discussed in the ''Potential Effects of the Specified Activity on Marine Mammals'' section of the **Federal Register** notice for the proposed IHA (80 FR 27901; May 15, 2015). No changes have been made to the discussion contained in this section of the **Federal Register** notice for the proposed IHA.

Anticipated Effects on Habitat

The primary potential impacts to marine mammal habitat are associated with elevated sound levels produced by sonar equipment and vessels and their effects on marine mammal prey species. These potential effects from Hilcorp's shallow geohazard survey are discussed in the ''Anticipated Effects on Marine Mammal Habitat'' section of the **Federal Register** notice for the proposed IHA (80 FR 27901; May 15, 2015). No changes have been made to the discussion contained in this section of the **Federal Register** notice for the proposed IHA.

Mitigation Measures

In order to issue an incidental take authorization under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses.

For the Hilcorp's open-water shallow geohazard survey in the Beaufort Sea, NMFS is requiring Hilcorp to implement the following mitigation measures to minimize the potential impacts to marine mammals in the project vicinity as a result of its survey activities. The primary purpose of these mitigation measures is to detect marine mammals within or about to enter designated exclusion zones and to initiate immediate shutdown or power down of the sonar equipment. There is no change made to the mitigation measures prescribed in the IHA issued to Hilcorp from the **Federal Register** notice (80 FR 27901; May 15, 2015) for the proposed IHA.

Vessel Related Mitigation Measures

The general mitigation measures apply to all vessels that are part of the Foggy Island Bay sonar survey. The source vessel will operate under an additional set of specific mitigation measures during operations.

- To minimize collision risk with marine mammals, vessels shall not be operated at speeds that would make collisions likely. When weather conditions require, such as when visibility drops, vessels shall adjust speed accordingly to avoid the likelihood of marine mammal collisions.
- Vessel operators shall check the waters immediately adjacent to a vessel to ensure that no marine mammals will be injured when the vessel's propellers (or screws) are engaged.
- Vessel operators shall avoid concentrations or groups of whales and vessels shall not be operated in a way that separates members of a group. In proximity of feeding whales or aggregations, vessel speed shall be less than 10 knots.
- When within 900 ft. (300 m) of whales vessel operators shall take every effort and precaution to avoid harassment of these animals by:
  - Reducing speed and steering around (groups of) whales if circumstances allow, but never cutting off a whale's travel path;
  - Avoiding multiple changes in direction and speed.
- In general, the survey design will start in shallow water and work deeper to mitigate the potential ''herding'' effect.

Establishing Exclusion and Disturbance Zones

Under current NMFS guidelines, the ''exclusion zone'' for marine mammal exposure to impulse sources is customarily defined as the area within which received sound levels are ≥180 dB (rms) re 1 μPa for cetaceans and ≥190 dB (rms) re 1 μPa for pinnipeds. These safety criteria are based on an assumption that SPL received at levels lower than these will not injure these animals or impair their hearing abilities, but at higher levels might have some such effects. Disturbance or behavioral effects to marine mammals from underwater sound may occur after exposure to sound at distances greater than the exclusion zones (Richardson *et al.* 1995). Currently, NMFS uses 160 dB (rms) re 1 μPa as the threshold for Level B behavioral harassment from impulse noise.

The sounds generated by the multibeam echosounder and sidescan sonar are outside the hearing range of marine mammals. Sounds generated by the sub-bottom profiler are within the hearing range of all marine mammal species occurring in the area. The distance to 160 dB re 1 μPa (rms) zone of influence (ZOI) is estimated at 30 m (Warner & McCrodan 2011). However, Hilcorp will establish a ZOI of 50 m around all sonar sources for more protective measures. The exclusion zones of all sonar equipment are less than 30 m from the sources.

Mitigation Measures for Sonar Equipment

(1) Ramp Up Procedure

A ramp up of the sub-bottom profiler provides a gradual increase in sound levels, and involves a step-wise increase in the number and incremental levels of the sub-bottom profiler firing until the maximum level is achieved. The purpose of a ramp up (or ''soft start'') is to ''warn'' cetaceans and pinnipeds in the vicinity of the survey and to provide time for them to leave the area and thus reducing startling responses from marine mammals.

(2) Shutdown Measures

Although there is no exclusion zone expected from the sonar source operated by Hilcorp during its proposed shallow geohazard survey, Hilcorp proposes to implement shutdown measures when a marine mammals is sighted within the 50 m ZOI during the operation of the sub-bottom profiler.

After shutdown for more than 10 minutes, ramp-up shall not start until after the marine mammal is visually seen having left the ZOI; or 15 minutes have passed after the last detection of the marine mammal with shorter dive durations (pinnipeds and small odontocetes); or 30 minutes have passed after the last detection of the marine mammal with longer dive durations (mysticetes and large odontocetes, including beluga whales).

(3) Poor Visibility Conditions:

If during foggy conditions, heavy snow or rain, or darkness, the full 160 dB ZOI is not visible, sonar equipment cannot commence a ramp-up procedure from a full shut-down. If the sub-bottom profiler has been operational before nightfall or before the onset of poor visibility conditions, it can remain operational throughout the night or poor visibility conditions.

Mitigation Conclusions

NMFS has carefully evaluated Hilcorp's mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measures are expected to minimize adverse impacts to marine mammals;
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and
- The practicability of the measure for applicant implementation.

Any mitigation measure(s) prescribed by NMFS should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

1. Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).
2. A reduction in the numbers of marine mammals (total number or number at biologically important time or location) exposed to received levels of sub-bottom profiler, or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).
3. A reduction in the number of times (total number or number at biologically important time or location) individuals would be exposed to received levels of sub-bottom profiler or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).
4. A reduction in the intensity of exposures (either total number or number at biologically important time or location) to received levels of sub-bottom profiler or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing the severity of harassment takes only).
5. Avoidance or minimization of adverse effects to marine mammal habitat, paying special attention to the food base, activities that block or limit passage to or from biologically important areas, permanent destruction of habitat, or temporary destruction/disturbance of habitat during a biologically important time.
6. For monitoring directly related to mitigation—an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on our evaluation of these measures, NMFS has determined that the mitigation measures provide the means of effecting the least practicable impact on marine mammals species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance. Mitigation measures to ensure availability of such species or stock for taking for certain subsistence uses are discussed later in this document (see ''Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses'' section).

Monitoring and Reporting

In order to issue an ITA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth, ''requirements pertaining to the monitoring and reporting of such taking.'' The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Hilcorp submitted a marine mammal monitoring plan as part of the IHA application. The plan may be modified or supplemented based on comments or new information received from the public during the public comment period or from the peer review panel (see the ''*Monitoring Plan Peer Review''* section later in this document).

There is no change in the monitoring prescribed in the IHA issued to Hilcorp from the **Federal Register** notice (80 FR 27901; May 15, 2015) for the proposed IHA.

Monitoring measures prescribed by NMFS should accomplish one or more of the following general goals:

1. An increase in our understanding of the likely occurrence of marine mammal species in the vicinity of the action, *i.e.,* presence, abundance, distribution, and/or density of species.
2. An increase in our understanding of the nature, scope, or context of the likely exposure of marine mammal species to any of the potential stressor(s) associated with the action (*e.g.* sound or visual stimuli), through better understanding of one or more of the following: the action itself and its environment (*e.g.* sound source characterization, propagation, and ambient noise levels); the affected species (*e.g.* life history or dive pattern); the likely co-occurrence of marine mammal species with the action (in whole or part) associated with specific adverse effects; and/or the likely biological or behavioral context of exposure to the stressor for the marine mammal (*e.g.* age class of exposed animals or known pupping, calving or feeding areas).
3. An increase in our understanding of how individual marine mammals respond (behaviorally or physiologically) to the specific stressors associated with the action (in specific contexts, where possible, *e.g.,* at what distance or received level).
4. An increase in our understanding of how anticipated individual responses, to individual stressors or anticipated combinations of stressors, may impact either: the long-term fitness and survival of an individual; or the population, species, or stock (*e.g.* through effects on annual rates of recruitment or survival).
5. An increase in our understanding of how the activity affects marine mammal habitat, such as through effects on prey sources or acoustic habitat (*e.g.,* through characterization of longer-term contributions of multiple sound sources to rising ambient noise levels and assessment of the potential chronic effects on marine mammals).
6. An increase in understanding of the impacts of the activity on marine mammals in combination with the impacts of other anthropogenic activities or natural factors occurring in the region.
7. An increase in our understanding of the effectiveness of mitigation and monitoring measures.
8. An increase in the probability of detecting marine mammals (through improved technology or methodology), both specifically within the safety zone (thus allowing for more effective implementation of the mitigation) and in general, to better achieve the above goals.

Monitoring Measures

Monitoring will provide information on the numbers of marine mammals potentially affected by the exploration operations and facilitate real-time mitigation to prevent injury of marine mammals by industrial sounds or activities. These goals will be accomplished in the Beaufort Sea during 2015 by conducting vessel-based monitoring and passive acoustic monitoring to document marine mammal presence and distribution in the vicinity of the survey area.

Visual monitoring by Protected Species Observers (PSOs) during shallow geohazard survey operations, and periods when these surveys are not occurring, will provide information on the numbers of marine mammals potentially affected by these activities and facilitate real-time mitigation to prevent impacts to marine mammals by industrial sounds or operations. Vessel-based PSOs onboard the survey vessels will record the numbers and species of marine mammals observed in the area and any observable reaction of marine mammals to the survey activities in the Beaufort Sea.

(1) Vessel-based Monitoring

(A) Protected Species Observers (PSOs)

Vessel-based monitoring for marine mammals will be done by trained PSOs throughout the period of survey activities. The observers will monitor the occurrence of marine mammals near the survey vessel during all daylight periods during operation, and during most daylight periods when operations are not occurring. PSO duties will include watching for and identifying marine mammals; recording their numbers, distances, and reactions to the survey operations; and documenting ''take by harassment.''

Two PSOs will be present on the main sonar vessel. The smaller skiff may only accommodate one at a time. Of these two PSOs, one will be on watch at all times, except during darkness.

PSO teams will consist of Inupiat observers and experienced field biologists. Each vessel will have an experienced field crew leader to supervise the PSO team.

Visual monitoring by the PSOs will be required to meet the following criteria:

- 100% monitoring coverage during all periods of survey operations in daylight;
- Maximum of 4 consecutive hours on watch per PSO; and
- Maximum of 12 hours of watch time per day per PSO.

(B) PSO Qualifications and Training

Lead PSOs will be individuals with experience as observers during recent seismic, site clearance and shallow hazards, and other monitoring projects in Alaska or other offshore areas in recent years. New or inexperienced PSOs will be paired with an experienced PSO or experienced field biologist so that the quality of marine mammal observations and data recording is kept consistent.

Resumes for candidate PSOs will be provided to NMFS for review and acceptance of their qualifications. Inupiat observers will be experienced in the region and familiar with the marine mammals of the area. All observers will complete a training course designed to familiarize individuals with monitoring and data collection procedures.

(C) Marine Mammal Observer Protocol

The PSOs will watch for marine mammals during all periods of source operations and for a minimum of 30 minutes prior to the planned start of sonar operations after an extended shutdown. Marine mammal monitoring shall continue throughout sonar operations and last for 30 minutes after the finish of sonar operations during daylight hours. Hilcorp vessel crew and operations personnel will also watch for marine mammals, as practical, to assist and alert the PSOs for the sub-bottom profiler to be shut down if marine mammals are observed in or about to enter the 50-m ZOI.

PSOs will also perform vessel-based marine mammal monitoring during vessel transit when the shallow geohazard survey is not being conducted. Marine mammal sighting data collected during the non-survey period will be compared with those during the survey to analyze the effects of the activities.

The PSOs will watch for marine mammals from the best available vantage point on the vessels. The PSOs will scan the area around the vessel systematically with reticle binoculars (*e.g.,* 7×50 and $16–40 \times 80$) and with the naked eye. GPS unit and laptop computer(s) will also be available for PSOs onboard survey vessels.

The observers will give particular attention to the areas within the marine mammal exclusion zones around the source vessels.

When a marine mammal is seen approaching or within the 50-m ZOI, the survey crew will be notified immediately so that mitigation measures called for in the applicable authorization(s) can be implemented.

Information to be recorded by PSOs will include:

- Species, group size, age/size/sex categories (if determinable), physical description of features that were observed or determined not to be present in the case of unknown or unidentified animals;
- Behavior when first sighted and after initial sighting;
- Heading (if consistent), bearing and distance from observer;
- Apparent reaction to activities (*e.g.,* none, avoidance, approach, paralleling, etc.), closest point of approach, and behavioral pace;
- Time, location, speed, and activity of the vessel, sea state, ice cover, visibility, and sun glare; and
- Positions of other vessel(s) (if present) in the vicinity of the observer location.

The vessel's position, speed, water depth, sea state, ice cover, visibility, and sun glare will also be recorded at the start and end of each observation watch, every 30 minutes during a watch, and whenever there is a change in any of those variables.

(2) Acoustic Monitoring

Passive acoustic monitoring (PAM) will be conducted to document ambient noise conditions, to examine the spatial and temporal distribution of marine mammals based on acoustic detections of their vocalizations, and to characterize the long-range propagation of sounds produced during the geohazard survey. The goal of the program is to address knowledge gaps about ambient sound levels and the distributions and migration paths of several marine mammal species including bowhead whales, beluga whales, and seals.

The acoustic data will be collected with Autonomous Multichannel Acoustic Recorder (AMAR) systems deployed on the seabed for an extended period. Two AMARs with different sampling rates will be deployed on the seabed for 3 months. An AMAR with a sampling rate of 64 kHz (24 bits) will be deployed at 500 m from the offshore end of the survey line and will record continuously. A high-frequency AMAR with a sampling rate of 380 kHz (16 bits) will be deployed at 5,000 m from the offshore end of the survey line. This high-frequency AMAR will be operated at 380 kHz (16 bits) for 2 minutes each hour and the rest of the time at 64 kHz (24 bits). The AMARs will be calibrated using pistonphone calibrators immediately before and after each deployment. These calibrations are accurate to less than 0.5 dB absolute.

Monitoring Plan Peer Review

The MMPA requires that monitoring plans be independently peer reviewed ''where the proposed activity may affect the availability of a species or stock for taking for subsistence uses'' (16 U.S.C. 1371(a)(5)(D)(ii)(III)). Regarding this requirement, NMFS' implementing regulations state, ''Upon receipt of a complete monitoring plan, and at its discretion, [NMFS] will either submit the plan to members of a peer review panel for review or within 60 days of receipt of the proposed monitoring plan, schedule a workshop to review the plan'' (50 CFR 216.108(d)).

NMFS has established an independent peer review panel to review Hilcorp's 4MP for the proposed shallow geohazard survey in the Beaufort Sea. The panel has met in early March 2015, and provided comments and recommendations to NMFS in April 2015. The full panel report can be viewed on the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.*

NMFS provided the panel with Hilcorp's IHA application and monitoring plan and asked the panel to answer the following questions:

1. Will the applicant's stated objectives effectively further the understanding of the impacts of their activities on marine mammals and otherwise accomplish the goals stated above? If not, how should the objectives be modified to better accomplish the goals above?

2. Can the applicant achieve the stated objectives based on the methods described in the plan?

3. Are there technical modifications to the proposed monitoring techniques and methodologies proposed by the applicant that should be considered to better accomplish their stated objectives?

4. Are there techniques not proposed by the applicant (*i.e.,* additional monitoring techniques or methodologies) that should be considered for inclusion in the applicant's monitoring program to better accomplish their stated objectives?

5. What is the best way for an applicant to present their data and results (formatting, metrics, graphics, etc.) in the required reports that are to be submitted to NMFS (*i.e.,* 90-day report and comprehensive report)?

The peer-review panel report contains recommendations that the panel members felt were applicable to the Hilcorp' monitoring plans. The panel believes that the objectives for both vessel-based and passive acoustic monitoring are appropriate, and agrees that the objective of real-time mitigation of potential disturbance of marine mammals would be met through visual monitoring. Nevertheless, the panel is concerned that there may also be behavioral effects resulting from the use of single and multi-beam echosounders and side-scan sonar that may warrant real-time mitigation to avoid disturbance, and provide a series of recommendations to improve efficiencies and effectiveness of monitoring and mitigation measures.

Specific recommendations provided by the peer review panel to enhance marine mammal monitoring and reporting measures are:

(1) Deploying an additional observer on the source vessel such that at least two observers are on watch during all daylight hours;

(2) Monitoring for marine mammals also be conducted during non-survey activities to assist in the collection of baseline information from which to analyze the effects of the activities;

(3) Deploying a third autonomous multichannel acoustic recorder (AMAR) and arrange the AMARs in a triangular array, as depicted in Figure 1 of the panel report, with the 500 m AMAR being a high-frequency AMAR, for marine mammal monitoring;

(4) Using AMAR to collect data on cumulative sound exposure level over 24 hours ($cSEL_{24}$), in particular during the use of the two sub-bottom profilers;

(5) Ground-truthing data collected by AMARs in consultation with biologists experienced in Arctic species vocalizations and to include error rates for automatic detection to ensure the accurate classification of vocalizations by species;

(6) Collaborating with other entities collecting data on marine mammal vocalizations in the Beaufort Sea to improve auto-detection and manual capabilities for identifying species in which acoustic data are limited or lacking (*e.g.,* spotted seals); and

(7) Including information from high frequency acoustic recordings in reports to provide a better understanding of source levels and other acoustic characteristics of the active acoustics survey equipment, such as spectral content, and received levels in root-mean-squared (RMS) dB, sound exposure level (SEL), dB peak to peak and 1/3 octave bands.

In addition, although not requested by NMFS under the MMPA, the panel also provided several mitigation measures. These recommendations are:

(1) Hilcorp limit operations at night or during periods of low visibility so that marine mammals do not enter the safety zone undetected;

(2) Hilcorp specify that the delay for ramp-up and after a shut-down should be 15 minutes for species with short dive durations (small odontocetes and pinnipeds) and 30 minutes for species with longer diver durations (mysticetes and large odontocetes, including beluga whales);

(3) Additional sound source information from the various active acoustic equipment proposed for the survey be obtained by maneuvering the source vessels over the high frequency AMARs; and

(4) Hilcorp conduct the survey starting closest to shore and proceeding offshore to avoid any potential ''herding'' effect of marine mammals into shallow waters, as was implicated in a mass stranding of melon headed whales off Madagascar during a multi-beam echosounder survey (Southall *et al.* 2013).

NMFS discussed these recommendations with Hilcorp to improve its monitoring and reporting measures, and to some extent, as well as mitigation measures. As a result, Hilcorp agrees to implement the following recommendations:

(1) Hilcorp will perform vessel-based marine mammal monitoring by protected species observers (PSOs) during vessel transit when the shallow geohazard survey is not being conducted. Marine mammal sighting data collected during the non-survey period will be compared with those during the survey to analyze the effects of the activities.

(2) Hilcorp and its contractor JASCO will deploy a high-frequency AMAR at the 5000 m site for detecting beluga clicks. The high-frequency AMAR would be operated at 380 kHz (16 bits) for about 2 minutes each hour and the rest of the time at 64 kHz (24 bits) for the 3 months deployment. The reason for deploying the high-frequency AMAR at 5000 m location, which NMFS concurs, is that there is a higher likelihood of detecting marine mammal acoustics in the deeper water father from the island.

(3) Hilcorp will work with JASCO to use AMAR to collect data on cumulative sound exposure level over 24 hours ($cSEL_{24}$), in particular during the use of the two sub-bottom profilers.

(4) Hilcorp will work with JASCO to ground-truth data collected by AMARs in consultation with biologists experienced in Arctic species vocalizations and to include error rates for automatic detection to ensure the accurate classification of vocalizations by species.

(5) Hilcorp is open to sharing data and work with its contractor JASCO to collaborate with other researchers. In addition, Hilcorp and JASCO will make the passive acoustic recording data, including data on marine mammal vocalizations, publically available for researchers. These data sharing/collaboration efforts will enable scientists to purse a variety of studies concerning the acoustic environment, marine mammal bioacoustics, and potential activity effects on marine mammals in the survey area.

(6) Hilcorp will including information from high frequency acoustic recordings in reports to provide a better understanding of source levels and other acoustic characteristics of the

active acoustics survey equipment, such as spectral content, and received levels in root-mean-squared (RMS) dB, sound exposure level (SEL), dB peak to peak and 1/3 octave bands.

Furthermore, Hilcorp agrees to implement the following mitigation recommendation and provided additional information in regard to the peer-review panel report:

(1) Hilcorp will specify that the delay for ramp-up and after a shut-down should be 15 minutes for species with short dive durations (small odontocetes and pinnipeds) and 30 minutes for species with longer diver durations (mysticetes and large odontocetes, including beluga whales).

(2) Regarding sound source information from the various active acoustic equipment proposed for Hilcorp's shallow geohazard survey, acoustic characteristics of these equipment or its equivalents were previously measured by JASCO. The measurement results in the following reports that are posted on NMFS Web site:

• Statoil 2011 Shallow Hazards Survey 90-day Report (Chapter 3) (*http://www.nmfs.noaa.gov/pr/pdfs/permits/statoil_90day_report2011.pdf*).

• Shell 2013 Shallow Hazards Survey 90-day Report (Chapter 2) (*http://www.nmfs.noaa.gov/pr/permits/incidental/oilgas/2013_shell_monitoringreport.pdf*).

(3) Regarding the panel's recommendation on Hilcorp's survey transect design, Hilcorp states that it can start in shallow water and work deeper to mitigate the potential ''herding'' effect. Hilcorp's plan is to divide the corridor into multiple sub-sections based on depth and work each section independently. This method is necessary for side scan sonar operations as each subsection will have a different range setting and line spacing that is related to depth.

All these aforementioned recommendations from the peer-review panel are included in the prescribed mitigation and monitoring measures for Hilcorp's 2015 open-water shallow geohazard survey in the Beaufort Sea.

However, Hilcorp will not be able to increase the number of vessel-based PSOs onboard the survey vessel. The number of PSOs onboard the vessel is limited by the available berth space. The survey vessels used for the proposed shallow geohazard survey can only accommodate maximum of 2 PSOs. Nevertheless, NMFS considers that due to the exceptionally small ensonified zones (no exclusion zone, with the radius of ZOI at 30 m from the source), one PSO on watch onboard the survey vessel is adequate.

In regard to an additional AMAR to be deployed in the vicinity of the survey area, NMFS worked with Hilcorp and determined that deployment of three AMARs would be cost prohibitive to Hilcorp, given the small project budget of the shallow geohazard survey. In addition, due to the short duration and minimal impact of the proposed shallow geohazard survey, the currentpassive acoustic monitoring, improved with a high-frequency AMAR, is adequate to provide needed information to assess potential environmental effects from the proposed project.

Finally, NMFS does not agree with one of the panel's recommendations that Hilcorp limit operations at night or during periods of low visibility so that marine mammals do not enter the safety zone undetected. As mentioned previously, there is no safety zone (exclusion zone) because of the low intensity high-frequency sonar equipment being employed in the proposed shallow geohazard survey. In addition, limiting the survey at night or during periods of low visibility would increase the survey duration, thus extend the noise output from survey vessels in the area. NMFS believes that as long as the 50-m ZOI is cleared of marine mammals before the ramp-up of sonar equipment during daylight hours with good visibility, shallow hazard survey can be carried out with minimum adverse effects to marine mammals.

Reporting Measures

(1) Technical Report

The results of Hilcorp's 2015 vessel-based monitoring, including estimates of ''take'' by harassment, will be presented in a ''90-day'' draft Technical Report, to be submitted to NMFS within 90 days after the end of the shallow geohazard survey, and then in a final Technical Report, which will address any comments NMFS had on the draft. The Technical Report will include:

(a) Summaries of monitoring effort (*e.g.,* total hours, total distances, and marine mammal distribution through the study period, accounting for sea state and other factors affecting visibility and detectability of marine mammals);

(b) Analyses of the effects of various factors influencing detectability of marine mammals (*e.g.,* sea state, number of observers, and fog/glare);

(c) Species composition, occurrence, and distribution of marine mammal sightings, including date, water depth, numbers, age/size/gender categories (if determinable), group sizes, and ice cover;

(d) Data analysis separated into periods when a sonar source is operating and when it is not, to better assess impacts to marine mammals—the final and comprehensive report to NMFS should summarize and plot:

• Data for periods when a sonar source is active and when it is not; and

• The respective predicted received sound conditions over fairly large areas (tens of km) around operations;

(e) Sighting rates of marine mammals during periods with and without sonar activities (and other variables that could affect detectability), such as:

• Initial sighting distances versus sonar activity state;

• Closest point of approach versus sonar activity state;

• Observed behaviors and types of movements versus sonar activity state;

• Numbers of sightings/individuals seen versus sonar activity state;

• Distribution around the survey vessel versus sonar activity state; and

• Estimates of take by harassment;

(f) Results from all hypothesis tests, including estimates of the associated statistical power, when practicable;

(g) Estimates of uncertainty in all take estimates, with uncertainty expressed by the presentation of confidence limits, a minimum-maximum, posterior probability distribution, or another applicable method, with the exact approach to be selected based on the sampling method and data available; and

(h) A clear comparison of authorized takes and the level of actual estimated takes.

In addition, the technical report will include analysis on acoustic monitoring such as:

(a) Cumulative sound exposure level over 24 hours ($cSEL_{24}$), in particular during the use of the two sub-bottom profilers;

(b) Ground-truth of data collected by AMARs in consultation with biologists experienced in Arctic species vocalizations with error rates for automatic detection to ensure the accurate classification of vocalizations by species; and

(c) Information of source levels and other acoustic characteristics of the active acoustics survey equipment, such as spectral content, and received levels in root-mean-squared (RMS) dB, sound exposure level (SEL), dB peak to peak and 1/3 octave bands.

Finally, Hilcorp will share data and work with its contractor JASCO to collaborate with other researchers. The passive acoustic recording data, including data on marine mammal

vocalizations, will be made publically available for researchers. These data sharing/collaboration efforts will enable scientists to purse a variety of studies concerning the acoustic environment, marine mammal bioacoustics, and potential activity effects on marine mammals in the survey area.

(5) Notification of Injured or Dead Marine Mammals

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA, such as a serious injury, or mortality (*e.g.,* ship-strike, gear interaction, and/or entanglement), Hilcorp would immediately cease the specified activities and immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinators. The report would include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with Hilcorp to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Hilcorp would not be able to resume its activities until notified by NMFS via letter, email, or telephone.

In the event that Hilcorp discovers a dead marine mammal, and the lead PSO determines that the cause of the death is unknown and the death is relatively recent (*i.e.,* in less than a moderate state of decomposition as described in the next paragraph), Hilcorp would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinators. The report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with Hilcorp to determine whether modifications in the activities are appropriate.

In the event that Hilcorp discovers a dead marine mammal, and the lead PSO determines that the death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Hilcorp would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinators, within 24 hours of the discovery. Hilcorp would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network. Hilcorp can continue its operations under such a case.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]. Only take by Level B behavioral harassment is anticipated as a result of the proposed shallow geohazard survey. Noise propagation from subbottom profilers is expected to harass, through behavioral disturbance, affected marine mammal species or stocks.

The full suite of potential impacts to marine mammals from various industrial activities was described in detail in the ''Potential Effects of the Specified Activity on Marine Mammals'' section found earlier in the **Federal Register** notice (80 FR 27901; May 15, 2015) for the proposed IHA. The potential effects of sound from the proposed shallow geohazard survey without any mitigation might include one or more of the following: tolerance; masking of natural sounds; behavioral disturbance; non-auditory physical effects; and, at least in theory, temporary or permanent hearing impairment (Richardson *et al.,* 1995a). As discussed in the following sections in this document, NMFS estimates that Hilcorp's activities will most likely result in behavioral disturbance, including avoidance of the ensonified area or changes in speed, direction, and/or diving profile of one or more marine mammals. For reasons discussed previously in this document, hearing impairment (TTS and PTS) is highly unlikely to occur based on the fact that most of the equipment to be used during Hilcorp's proposed shallow geohazard survey does not have source levels high enough to elicit even mild TTS and/or the fact that certain species are expected to avoid the ensonified areas close to the operations. Additionally, non-auditory physiological effects are anticipated to be minor, if any would occur at all.

For impulsive sounds, such as the signals produced by the subbottom profiler sources during the shallow geohazard survey, NMFS uses a received level of 160-dB (rms) to indicate the onset of Level B harassment. Hilcorp provided calculations of the 160-dB isopleth produced by the subbottom profiler and then used that isopleth to estimate takes by harassment. Hilcorp provides a full description of the methodology used to estimate takes by harassment in its IHA application (see **ADDRESSES**), which is also provided in the following sections.

Hilcorp has requested authorization to take bowhead, gray, humpback, minke, killer, and beluga whales, harbor porpoise, and ringed, spotted, bearded, and ribbon seals incidental to shallow geohazard survey in the Beaufort Sea. However, as stated previously in this document, humpback, minke, and killer whales, harbor porpoise, and ribbon seal are considered extralimital in the proposed shallow geohazard survey area. Therefore, NMFS is not proposing to authorize take of these species. In addition, NMFS made a minor adjustment to the take number issued to Hilcorp from the proposed IHA published in the **Federal Register** notice (80 FR 27901; May 15, 2015). In the notice for the proposed IHA, the proposed take numbers were based on Hilcorp's requested takes, which were higher than the estimated takes based on calculation. The takes authorized in the IHA issued to Hilcorp are estimated takes based on calculation, without upward adjustments, except for beluga whales (explained below). No other changes were made from the proposed IHA.

Basis for Estimating ''Take by Harassment''

''Take by Harassment'' is described in this section and was calculated in Hilcorp's application by multiplying the expected densities of marine mammals that may occur near the shallow geohazard survey areas where received noise levels are higher than 160 dB re 1 µPa (rms) created by the subbottom profiler during the survey.

Marine Mammal Density Estimates

Whale species are migratory and therefore show a seasonal distribution, with different densities for the summer period (covering July and August) and the fall period (covering September and October). Seal species in the Beaufort Sea do not show a distinct seasonal distribution during the open water period between July and October. Data acquisition of the proposed sonar survey will only take place in summer (before start of Nuiqsut whaling); therefore only estimates of marine mammal densities for the summer are included in the take calculation. Whale and seal densities in the Beaufort Sea will further depend on the presence of sea ice. However, if ice cover within or close to the sonar survey area is more than approximately 10%, sonar survey activities may not start or be halted for safety reasons. Densities related to ice conditions are therefore not included in the take estimates.

Spatial differentiation is another important factor for marine mammal densities, both in latitudinal and longitudinal gradient. Taking into account the shallow water operations of the proposed sonar survey area and the associated area of influence, data from the nearshore zone of the Beaufort Sea is used for the calculation of densities, if available.

Density estimates are based on best available data. Because available data did not always cover the area of interest, estimates are subject to large temporal and spatial variation. Though correction factors for perception and availability bias have been calculated for certain coastal areas they were not always known for this study area. There is some uncertainty in the 2014 raw data and assumptions were used in the estimated number of exposures. To provide allowance for these uncertainties, maximum density estimates have been provided in addition to average density estimates.

A summary of marine mammal density in the proposed Hilcorp survey area is provided in Table 2.

TABLE 2—ESTIMATED SUMMER DENSITIES OF WHALES AND SIGHTING RATES OF SEALS (AVERAGE AND MAXIMUM) FOR THE PROPOSED NORTH PRUDHOE BAY SURVEY. DENSITIES ARE PROVIDED IN NUMBER OF INDIVIDUALS PER KM^2 (IND/KM^2), SIGHTING RATES IN NUMBER OF INDIVIDUALS PER HOUR (INDV/HR.)

Species	Summer densities (INDV/km^2)	
	Average	Maximum
Bowhead whale	0.0088	0.0200
Beluga	0.0008	0.0078
	Summer sighting rates (INDV/hr.)	
	Average	Maximum
Ringed seal	0.122	0.397
Bearded seal	0.033	0.107
Spotted seal	0.039	0.126

Level B Harassment Zone Distance

As discussed earlier in this document, the operating frequencies of the multibeam, single-beam, and sidescan sonar equipment in Hilcorp's proposed shallow geohazard survey are above the hearing range of all marine mammals and therefore are not expected to have take of marine mammals. Estimated distance to sound pressure levels of 160 dB re 1 µPa, generated by the proposed sub-bottom equipment is 30 m from the source. However, as stated in this document earlier, Hilcorp proposes to implement a 50 m shutdown zone for the Level B behavioral harassment. Therefore, the calculation of marine mammal take is based on the number of animals exposed within the 50 m radius.

Potential Number of ''Takes by Harassment''

This section provides estimates of the number of individuals potentially exposed to pulsed sound levels ≥160 dB re 1 µPa rms by shallow geohazard survey using a subbottom profiler. The estimates are based on a consideration of the number of marine mammals that might be affected by operations in the Beaufort Sea during 2015 and the anticipated area exposed to those sound levels.

The potential number of bowhead whales and belugas that might be exposed to the 160 dB re 1 µPa (rms) sound pressure level was calculated by multiplying:

- The expected bowhead and beluga density as provided in Table 3;
- The total 160 dB re 1 µPa (rms) ensonified area in a single hour by the vessel travelling at 3 knots; and
- The estimated number of hours that the source vessels are operating.

The calculated area (0.0079 km^2) expected to be ensonified is determined based on the maximum distance to the 160 dB re 1 µPa (rms) sound pressure level for the Sub-bottom profiler, which is 0.05 km.

The estimated number of 24-hr days of sonar operations was determined by assuming a 25% downtime during the planned 45-day time span of the sonar survey period. Downtime is related to weather, equipment maintenance, mitigation implementation, and other circumstances. The total number of full 24-hr days that data acquisition is expected to occur is ~34 days or 816 hours.

The total 160 dB re 1 µPa (rms) ensonified area in a single hour by the vessel is calculated as 0.556 km^2/hr.

The average and maximum number of bowhead whales potentially exposed to sonar sound levels of 160 dB re 1µPa (rms) or more is estimated at 4 and 9 respectively. The limited number of exposures is due to the low estimated density of bowheads in Foggy Island Bay during July and August, the short duration of the survey, and the small acoustic footprint. For the requested authorization, the maximum number was increased by three to account for unexpected bowhead occurrences.

The average and maximum number of potential beluga exposures to 160 dB is <1. Belugas are known to show aggregate behavior and can occur in large numbers in nearshore zones, as evidenced by the sighting from Endicott in August 2013. Although beluga whales are not expected to frequent the vicinity of the Liberty Unit shallow geohazard survey area, their occurrence is still a possibility. To account for the potential average take of 1 beluga whale per day during the 45-day survey period, NMFS proposed a take authorization of 45 beluga whales for Hilcorp's shallow geohazard survey. Chance encounters with small numbers of other whale species are possible, but exposures to 160 dB or more are very unlikely for these species.

Although gray whale density is not known, this species has been occasionally sited in the Arctic, and Hilcorp is requesting takes of 3 individuals of gray whales by Level B behavioral harassment (Table 3).

The estimated number of seals that might be exposed to pulsed sounds of 160 dB re 1 µPa (rms) is calculated by multiplying:

- The expected species specific sighting rate as provided in Table 2; and
- The total number of hours that each source vessel will be operating during the data acquisition period.

The estimated number of hours that the sonar equipment will operate was determined by assuming a 25% downtime during a 45-day survey period, which is a total of 816 hours (34 days of 24 hour operations).

These estimated exposures do not take into account the mitigation measures that will be implemented, such as marine mammal observers watching for animals, shutdowns or power downs of the equipment when marine mammals are seen within defined ranges. These measures will further reduce the number of exposures and expected short-term reactions, and minimize any effects on hearing sensitivity.

A summary of the estimated takes and percent take among the population is provided in Table 3.

TABLE 3—THE TOTAL NUMBER OF POTENTIAL EXPOSURES OF MARINE MAMMALS TO SOUND LEVELS ≥160 DB RE 1 µPA RMS DURING THE HILCORP'S PROPOSED SHALLOW GEOHAZARD SURVEY IN THE BEAUFORT SEA, ALASKA, 2015. ESTIMATES ARE ALSO SHOWN AS A PERCENT OF EACH POPULATION

Species	Abundance	Authorized level B take	% Estimated population
Beluga whale (Beaufort Sea stock)	39,258	45	0.11
Bowhead whale	19,534	9	0.05
Gray whale	19,126	3	0.02
Bearded seal	155,000	87	0.06
Ringed seal	300,000	324	0.11
Spotted seal	141,479	103	0.07

Analysis and Determinations

Negligible Impact

Negligible impact is ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival'' (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of Level B harassment takes, alone, is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through behavioral harassment, NMFS must consider other factors, such as the likely nature of any responses (their intensity, duration, etc.), the context of any responses (critical reproductive time or location, migration, etc.), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, effects on habitat, and the status of the species.

To avoid repetition, this introductory discussion of our analyses applies to all the species listed in Table 3, given that the anticipated effects of Hilcorp's shallow geohazard survey project on marine mammals are expected to be relatively similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, they are described independently in the analysis below.

No injuries or mortalities are anticipated to occur as a result of Hilcorp's proposed shallow geohazard survey, and none are authorized. Additionally, animals in the area are not expected to incur hearing impairment (*i.e.,* TTS or PTS) or non-auditory physiological effects. The takes that are anticipated and authorized are expected to be limited to short-term Level B behavioral harassment. While the sonar sources are expected to be operated for approximately 45 days, the project timeframe will occur when cetacean species are typically not found in the project area or are found only in low numbers. While pinnipeds are likely to be found in the proposed project area more frequently, their distribution is dispersed enough that they likely will not be in the Level B harassment zone continuously.

Most of the marine mammals encountered will likely show overt disturbance (avoidance) only if they receive sonar sounds with levels ≥ 160 dB re 1 µPa. However, the estimated 160 dB zone is only 30 m from the source, which means that the animals have to be very close to the source vessel to be exposure to noise levels that could cause Level B harassment. In addition, Hilcorp will implement shutdown measures if a marine mammal is sighted within or is moving towards the 160 dB isopleths.

Taking into account the mitigation measures that are planned, effects on marine mammals are generally expected to be restricted to avoidance of a limited area around Hilcorp's proposed open-water activities and short-term changes in behavior, falling within the MMPA definition of ''Level B harassment.'' Mitigation measures, such as controlled vessel speed, dedicated marine mammal observers, non-pursuit, ramp up procedures, and shut downs or power downs when marine mammals are seen within or approaching the ZOI, will further reduce short-term reactions. In all cases, the effects are expected to be short-term, with no lasting biological consequence.

Of the six marine mammal species likely to occur in the proposed marine

survey area, bowhead whale and ringed seal are listed as endangered and threatened under the ESA, respectively. These species are also designated as ''depleted'' under the MMPA. None of the other species that may occur in the project area are listed as threatened or endangered under the ESA or designated as depleted under the MMPA.

Bowhead Whales

The Bering-Chukchi-Beaufort stock of bowheads has been increasing at a rate of 3.4 percent annually for nearly a decade (Allen and Angliss 2010). Additionally, during the 2001 census, 121 calves were counted, which was the highest yet recorded. The calf count provides corroborating evidence for a healthy and increasing population (Allen and Angliss 2010). There is no critical habitat designated in the U.S. Arctic for the bowhead whales.

Bowhead whales are designated as low-frequency cetacean. Although the hearing sensitivity of low-frequency cetacean is thought to reach 25 kHz based on vocalizations from humpback whales, in general they are not expected to be very sensitive to sound frequencies above several kHz. Therefore, noise impacts on bowhead whales from Hilcorp's sonar equipment are expected to be very mild. Potential impacts to bowhead whales from Hilcorp's shallow geohazard survey would be limited to brief behavioral disturbances and temporary avoidance of the ensonified areas and survey vessels. It is estimated that a maximum of 9 bowhead whales (0.11%) could be taken by Level B harassment.

Bowhead whales are less likely to occur in the proposed project area in July and early August, as they are found mostly in the Canadian Beaufort Sea at this time. The animals are more likely to occur later in the season (late-August through September), as they head west towards Chukchi Sea.

In their westward migration route, bowhead whales have been observed to feed in the vicinity of the survey area in the Beaufort Sea. Most of the feedings are observed in the September to October period as more bowhead whales are moving through the migratory corridor in the Beaufort Sea. Therefore, the areas in offshore Beaufort Sea are considered as biologically important areas (BIAs) for bowhead whales in September and October (Clarke *et al.* 2015). However, most, if not all of their BIAs are in relatively deeper waters outside the barrier islands, while almost all of Hilcorp's survey area is waters <31 m within the barrier islands.

The proposed survey area is also mostly outside BIAs where bowhead whale mother/calf pairs are sighted in the summer and fall and BIAs of bowhead whale fall migration (Clarke *et al.,* 2015).

Gray Whales

Gray whales are not expected to frequent the proposed shallow geohazard survey area in the Beaufort Sea, although occasional sightings of this species occurred in the past several years. Being a member of low-frequency cetacean, the potential acoustic impacts to gray whales are the same to those to bowhead whales as discussed above. It is estimated that a maximum of 3 gray whales (0.02%) could be taken by Level B harassment. There is no BIA for gray whales within Hilcorp's proposed shallow geohazard survey area.

Beluga Whales

Although the acoustic effects on beluga whale, a mid-frequency cetacean species, are expected to be more noticeable compared to bowhead and gray whales, the adverse effects are still considered minor due to the low intensity sonar equipment being used by Hilcorp's shallow geohazard survey. Potential impacts to beluga whales would be limited to brief behavioral disturbances and temporary avoidance of the ensonified areas and survey vessels.

In addition, beluga whales in Beaufort Sea are typically distributed in deeper waters offshore from Hilcorp's survey area. It is estimated that a maximum of 45 beluga whales (0.05%) could be taken by Level B harassment. There is no BIA for beluga whales within Hilcorp's proposed shallow geohazard survey area.

Pinnipeds

Ringed, spotted, and bearded are expected to be encountered in the Hilcorp's shallow geohazard survey area. However, as stated in the **Federal Register** notice (80 FR 21901; May 15, 2015) for the proposed IHA, they appear to be more tolerant of anthropogenic sound, especially at lower received levels, than other marine mammals, such as mysticetes. Hilcorp's proposed activities would occur at a time of year when these seal species found in the region are not molting, breeding, or pupping. Therefore, these important life functions would not be impacted by Hilcorp's activities. The exposure of pinnipeds to sounds produced by Hilcorp's shallow geohazard survey operations in the Beaufort Sea is not expected to result in more than Level B harassment of individuals from pinnipeds.

It is estimated that maxima of 324 ringed seals (0.11%), 103 spotted seals (0.07%), and 87 bearded seals (0.06%) could be taken by Level B harassment. Level B behavioral harassment to these species from Hilcorp's shallow geohazard survey activity include brief behavioral disturbances and temporary avoidance of the ensonified areas.

No biologically important area exists for seals in the vicinity of Hilcorp's shallow geohazard survey activities.

Although some disturbance of food sources of marine mammals is possible, any impacts are anticipated to be minor enough as to not affect rates of recruitment or survival of marine mammals in the area. The marine survey activities would occur in a localized area, and given the vast area of the Arctic Ocean where feeding by marine mammals occurs, any missed feeding opportunities in the direct project area could be offset by feeding opportunities in other available feeding areas.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the prescribed monitoring and mitigation measures, NMFS finds that the total marine mammal take from Hilcorp's shallow geohazard survey in the Beaufort Sea, Alaska, will have a negligible impact on the affected marine mammal species or stocks.

Small Numbers

The requested takes represent less than 0.11% of all populations or stocks potentially impacted (see Table 3 in this document). These take estimates represent the percentage of each species or stock that could be taken by Level B behavioral harassment if each animal is taken only once. The numbers of marine mammals estimated to be taken are small proportions of the total populations of the affected species or stocks. In addition, the mitigation and monitoring measures (described previously in this document) prescribed in the IHA are expected to reduce even further any potential disturbance to marine mammals.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, NMFS finds that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

Relevant Subsistence Uses

Marine mammals are legally hunted in Alaskan waters by coastal Alaska Natives and represent between 60% and 80% of their total subsistence harvest. The species regularly harvested by subsistence hunters in and around the Beaufort Sea are bowhead and beluga whales, and ringed, spotted, and bearded seals. The importance of each of the subsistence species varies among the communities and is mainly based on availability and season.

The communities closest to the project area are, from west to east, the villages of Barrow, Nuiqsut and Kaktovik. Barrow is located >200 mi west from the Hilcorp's survey area. It is the largest community on the Alaska's Beaufort Sea coast. Important marine subsistence resources for Barrow include bowhead and beluga whales, and ice seals. Nuiqsut is located near the mouth of the Colville River, about 55 mi southwest of the project area. The most important marine subsistence resource for Nuiqsut is the bowhead whale, and to a lesser extent belugas and seals. Nuiqsut hunters use Cross Island, (~20 mi northwest of the project area) as a base to hunt for bowhead whales during the fall migration and have historically hunted bowhead whales as far east as Flaxman Island. Kaktovik is located on Barter Island, about 120 mi east of the project area. Major marine subsistence resources include bowhead and beluga whales, and seals.

(1) Bowhead Whale

The bowhead whale is a critical subsistence and cultural resource for the North Slope communities of Barrow, Nuiqsut, and Kaktovik. The level of allowable harvest is determined under a quota system in compliance with the International Whaling Commission (IWC 1980; Gambell 1982). The quota is based on the nutritional and cultural needs of Alaskan Natives as well as on estimates of the size and growth of the Bering-Chukchi-Beaufort seas stock of bowhead whales (Donovan 1982; Braund 1992). The AEWC allots the number of bowhead whales that each community is permitted to harvest. Contemporary whaling in Kaktovik dates from 1964 and in Nuiqsut from 1973 (EDAW/AECOM 2007; Galginaitis and Koski 2002). The number of boats used or owned in 2011 by the subsistence whaling crew of the villages of Kaktovik, Nuiqsut, and Barrow was 8, 12, and 40, respectively. These numbers presumably change from year to year.

Bowhead harvesting in Barrow occurs both during the spring (April-May) and fall (September-October) when the whales migrate relatively close to shore (ADNR 2009). During spring bowheads migrate through open ice leads close to shore. The hunt takes place from the ice using umiaks (bearded seal skin boats). During the fall, whaling is shore-based and boats may travel up to 30 mi a day (EDAW/AECOM 2007). In Barrow, most whales were historically taken during spring whaling. More recently, however, the efficiency of the spring harvest appeared to be lower than the autumn harvest due to ice and weather conditions as well as struck whales escaping under the ice (Suydam *et al.* 2010). In the past few years the bowhead fall hunt has become increasingly important.

Nuiqsut and Kaktovik hunters harvest bowhead whales only during the fall. The bowhead spring migration in the Beaufort Sea occurs too far from shore for hunting because ice leads do not open up nearshore (ADNR 2009). In Nuiqsut, whaling takes place from early September through mid-to-late September as the whales migrate west (EDAW/AECOM 2007). Three to five whaling crews base themselves at Cross Island, a barrier island approximately 20 mi northwest of the Liberty Unit shallow geohazard survey area. Nuiqsut whalers harvest an average of 2 bowheads each year. Whaling from Kaktovik also occurs in the fall, primarily from late August through late September or early October (EDAW/AECOM 2007). Kaktovik whalers hunt from the Okpilak and Hulahula rivers east to Tapkaurak Point (ADNR 2009). Whaling activities are staged from the community rather than remote camps; most whaling takes place within 12 mi of the community (ADNR 2009). Kaktovik whalers harvest an average of 2–3 bowhead whales each year.

(2) Beluga

The harvest of belugas is managed cooperatively through an agreement between NMFS and the Alaska Beluga Whale Committee (ABWC). From 2005–2009, between 5 and 48 belugas were harvested annually from the Beaufort Sea stock (Allen and Angliss 2014); with a mean annual take of 25.8 animals. Both Nuiqsut and Kaktovik harvest few belugas, mostly opportunistically during the fall bowhead hunt.

(3) Seals

Seals represent an important subsistence resource for the North Slope communities. Harvest of bearded seals usually takes place during the spring and summer open water season from Barrow (EDAW/AECOM 2007) with only a few animals taken by hunters from Kaktovik or Nuiqsut. Seals are also taken during the ice-covered season, with peak hunting occurring in February (ADNR 2009). In 2003, Barrow-based hunters harvested 776 bearded seals, 413 ringed seals and 12 spotted seals (ADNR 2009). Nuiqsut hunters harvest seals in an area from Cape Halkett to Foggy Island Bay. For the period 2000–2001, Nuiqsut hunters harvested one bearded seal and 25 ringed seals (ADNR 2009). Kaktovik hunters also hunt seals year-round. In 2002–2003, hunters harvested 8 bearded seals and 17 ringed seals.

Potential Impacts to Subsistence Uses

NMFS has defined ''unmitigable adverse impact'' as an impact resulting from the specified activity. The definition and activities can be found in 50 CFR 216.103.

The shallow geohazard survey will take place between July 1 and September 30, 2015, with data acquisition occurring in July and August. The project area is located >200 mi east from Barrow, approximately 55 mi northeast from Nuiqsut (20 mi southeast of Cross Island), and 120 mi west from Kaktovik. Potential impact on the subsistence hunt from the planned activities is expected mainly from sounds generated by sonar equipment. Due to the timing of the project and the distance from the surrounding communities, there will be no effects on spring harvesting and little or no effects on the occasional summer harvest of beluga and subsistence seal hunts (ringed and spotted seals are primarily harvested in winter while bearded seals are hunted during July-September in the Beaufort Sea). The community of Nuiqsut may begin fall whaling activities in late August to early September from Cross Island (northwest of the survey area).

Plan of Cooperation or Measures To Minimize Impacts to Subsistence Hunts

(1) Plan of Cooperation

Regulations at 50 CFR 216.104(a)(12) require IHA applicants for activities that take place in Arctic waters to provide a Plan of Cooperation (POC) or information that identifies what measures have been taken and/or will be taken to minimize adverse effects on the availability of marine mammals for subsistence purposes.

Hilcorp has prepared a POC and is currently establishing a dialogue to coordinate activities with the villages.

The POC includes the aforementioned mitigation measures and includes plans for and results of meetings with Alaska Native communities. In addition, Hilcorp has conducted the following meetings and visits to subsistence communities to discuss mitigation and monitoring measures to achieve no unmitigable impacts to subsistence activities.

- December 2, 2014: Open house at Kisik Community Center in Nuiqsut, Alaska.
- December 2, 2014: Kuukpik Subsistence Oversight Panel Leadership meeting at Kisik Community Center in Nuiqsut, Alaska.
- January 8, 2015: Meeting with Uum's Consulting, LLC in Anchorage, Alaska.
- January 12, 2015: Native Village of Barrow Meeting at the Native Village of Barrow Conference Room in Barrow, Alaska.
- January 12, 2015: North Slope Borough Mayor's Office Meeting in Barrow, Alaska.
- January 12, 2015: North Slope Borough Planning Department Meeting in Barrow, Alaska.
- January 12, 2015: North Slope Borough Wildlife Department and Barrow Whaling Captain's Meeting at the Top of the World Hotel in Barrow, Alaska.
- January 13, 2015: Alaska Eskimo Whaling Commission meeting at the Top of the World Hotel in Barrow, Alaska.
- January 13, 2015: Native Village of Nuiqsut meeting in Nuiqsut, Alaska.
- January 13, 2015: Nuiqsut Whaling Captain's meeting at Kuukpik Hotel in Nuiqsut, Alaska.
- January 13, 2015: Kuukpik Corporation meeting at Kuukpik Corporation Conference Room in Nuiqsut, Alaska.
- January 14, 2015: City of Kaktovik meeting at the City of Kaktovik Community Center in Kaktovik, Alaska.
- January 14, 2015: Kaktovik Inupiat Corporation meeting at the Kaktovik Inupiaq Corporation Conference Room in Kaktovik, Alaska.
- January 14, 2015: Kaktovik Whaling Captain's meeting at Marsh Creek Hotel in Kaktovik, Alaska.

Any subsistence discussions are documented along with meeting minutes, and are provided to the NMFS as part of the POC. Additional pre-season meetings maybe planned if needed to address additional requests for coordination.

(2) Stakeholder Engagement

Hilcorp has signed a Conflict Avoidance Agreement (CAA) intended to minimize potential interference with bowhead subsistence hunting. Hilcorp has attended and participated in the CAA meetings scheduled in 2015. The CAA describes measures to minimize any adverse effects on the availability of bowhead whales for subsistence uses.

The North Slope Borough Department of Wildlife Management (NSB–DWM) was consulted, and the project was also presented to the NSB Planning Commission in January 2015. The following are measures that Hilcorp will take to reduce impacts to the subsistence community:

- Hilcorp will comply with the CAA terms to address plans to meet with the affected community to resolve conflicts and notify the communities of any changes in the operation.
- Inupiat Marine Mammal Observers on board the vessels are tasked with looking out for whales and other marine mammals in the vicinity of the vessel to assist the vessel captain in avoiding harm to whales and other marine mammals.
- Vessels will be operated in a manner to avoid areas where species that are sensitive to noise or movement are concentrated at times when such species are concentrated.
- Communications and conflict resolution are detailed in the CAA. Hilcorp is planning to participate in the Communications Center that is operated annually during the bowhead subsistence hunt.
- Communications with the villages of Barrow, Kaktovik, and Nuiqsut—discuss community questions or concerns including all subsistence hunting activities.

(3) Future Plan of Cooperation Consultations

Hilcorp plans to engage with the relevant subsistence communities regarding its future Beaufort Sea activities. With regard to the 2015 Liberty Unit shallow geohazard survey project, Hilcorp will present the data on marine mammal sightings and the results of the marine mammal monitoring and mitigation as part of our 90-day report to the regulatory authorities.

Unmitigable Adverse Impact Analysis and Determination

NMFS considers that these mitigation measures, including measures to reduce overall impacts to marine mammals in the vicinity of the proposed shallow geohazard survey area and measures to mitigate any potential adverse effects on subsistence use of marine mammals, are adequate to ensure subsistence use of marine mammals in the vicinity of Hilcorp's proposed survey in the Beaufort Sea.

Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the prescribed mitigation and monitoring measures, NMFS has determined that there will not be an unmitigable adverse impact on subsistence uses from Hilcorp's activities.

Endangered Species Act (ESA)

There are two marine mammal species listed as endangered under the ESA with confirmed or possible occurrence in the project area: the bowhead whale and ringed seal. NMFS' Permits and Conservation Division initiated consultation with NMFS' Endangered Species Division under section 7 of the ESA on the issuance of an IHA to Hilcorp under section 101(a)(5)(D) of the MMPA for this activity. In June 2015, NMFS finished conducting its section 7 consultation and issued a Biological Opinion concluding that the issuance of the IHA associated with Hilcorp's shallow geohazard survey in the Beaufort Sea during the 2015 open-water season is not likely to jeopardize the continued existence of the endangered bowhead, humpback and the threatened Arctic sub-species of ringed seal. No critical habitat has been designated for these species, therefore none will be affected.

National Environmental Policy Act (NEPA)

NMFS prepared an EA that includes an analysis of potential environmental effects associated with NMFS' issuance of an IHA to Hilcorp to take marine mammals incidental to conducting a shallow geohazard survey in the Beaufort Sea, Alaska. NMFS has finalized the EA and prepared a Finding of No Significant Impact for this action. Therefore, preparation of an Environmental Impact Statement is not necessary. NMFS' draft EA was available to the public for a 30-day comment period before it was finalized.

Authorization

As a result of these determinations, NMFS has issued an IHA to Hilcorp for the take of marine mammals, by Level B harassment, incidental to conducting a shallow geohazard survey in the Beaufort Sea during the 2015 open-water season, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: June 30, 2015.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–16521 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Science Advisory Board (SAB)

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC)

ACTION: Notice of open meeting.

SUMMARY: The Science Advisory Board (SAB) was established by a Decision Memorandum dated September 25, 1997, and is the only Federal Advisory Committee with responsibility to advise the Under Secretary of Commerce for Oceans and Atmosphere on strategies for research, education, and application of science to operations and information services. SAB activities and advice provide necessary input to ensure that National Oceanic and Atmospheric Administration (NOAA) science programs are of the highest quality and provide optimal support to resource management.

Time and Date: The meeting will be held Monday August 3 from 8:15 a.m. to 5:45 p.m. PDT and Tuesday August 4 from 8:15 a.m. to 1:00 p.m. PDT. These times and the agenda topics described below are subject to change. Please refer to the Web page *http://www.sab.noaa.gov/Meetings/meetings.html* for the most up-to-date meeting times and agenda.

Place: The meeting will be held at the NOAA Southwest Fisheries Science Center, 8901 La Jolla Shores Drive, La Jolla, California, 92037. Please check the SAB Web site *http://www.sab.noaa.gov/Meetings/meetings.html* for directions to the meeting location.

Status: The meeting will be open to public participation with a 15-minute public comment period on August 3 from 5:30–5:45 p.m. PDT (check Web site to confirm time). The SAB expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of two (2) minutes. Individuals or groups planning to make a verbal presentation should contact the Acting SAB Executive Director by July 27, to schedule their presentation. Written comments should be received in the Acting SAB Executive Director's, Office Room 146 Gregg Hall, 35 Colovos Road, Durham, NH 03824 by July 27, 2015, to provide sufficient time for SAB review. Written comments received by the Acting SAB Executive Director after July 27, 2015, will be distributed to the SAB, but may not be reviewed prior to the meeting date. Seating at the meeting will be available on a first-come, first-served basis.

Special Accommodations: These meetings are physically accessible to people with disabilities. Requests for special accommodations may be directed no later than 12:00 p.m. on July 27, 2015, to Dr. Elizabeth Turner, Acting SAB Executive Director, Room 146 Gregg Hall, 35 Colovos Road, Durham, NH 03824; Email: *Elizabeth.Turner@noaa.gov*.

Matters To Be Considered: The meeting will include the following topics: (1) NOAA Response to the SAB Ecosystem-Based Fisheries Management Report; (2) Review Report for the Cooperative Institute on Marine Resource Studies (CIMRS); (3) SAB strategy discussion; (4) Updates from the NOAA Administrator and Chief cientist; and (5) Working group updates.

FOR FURTHER INFORMATION CONTACT: Dr. Elizabeth Turner Acting Executive Director, Science Advisory Board, NOAA, Room 146 Gregg Hall, 35 Colovos Road, Durham, NH 03824. Email: *Elizabeth.Turner@noaa.gov;* or visit the NOAA SAB Web site at *http://www.sab.noaa.gov*.

Dated: June 30, 2015.

Jason Donaldson,

Chief Financial Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2015–16680 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Reporting of Sea Turtle Incidental Take in Virginia Chesapeake Bay Pound Net Operations.

OMB Control Number: 0648–0470.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 37.

Average Hours per Response: 10 minutes.

Burden Hours: 81.

Needs and Uses: This request is for extension of a current information collection.

This action would continue the reporting measure requiring all Virginia Chesapeake Bay pound net fishermen to report interactions with endangered and threatened sea turtles, found both live and dead, in their pound net operations. When a live or dead sea turtle is discovered during a pound net trip, the Virginia pound net fisherman is required to report the incidental take to National Marine Fisheries Service (NMFS) and, if necessary, the appropriate rehabilitation and stranding network. This information will be used to monitor the level of incidental take in the state-managed Virginia pound net fishery and ensure that the seasonal pound net leader restrictions (50 CFR 223.206(d)(10)) are adequately protecting listed sea turtles.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: July 2, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–16668 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Science Advisory Board (SAB); Charter Renewal

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of renewal of charter.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App., and after consultation with the General Services Administration, the Chief Financial Officer and Assistant Secretary for Administration has determined that renewal of the NOAA Science Advisory Board is in the public interest. The committee has been a successful undertaking and has provided advice to the Under Secretary for Oceans and Atmosphere on strategies for research, education, and application of science to operations and information services. The committee will continue to provide such advice and recommendations in the future. The structure and responsibilities of the Committee are unchanged from when it was originally established in September 1997. The Committee will continue to operate in accordance with the provisions of the Federal Advisory Committee Act.

FOR FURTHER INFORMATION CONTACT: Dr. Elizabeth Turner, Acting Executive Director, Science Advisory Board, NOAA, 35 Colovos Road, Durham, NH 03824. Email: *Elizabeth.Turner@noaa.gov;* or visit the NOAA SAB Web site at *http://www.sab.noaa.gov.*

Dated: July 2, 2015.

Jason Donaldson,

Chief Financial Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2015–16732 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD919

Notice of Availability of a Draft Programmatic Environmental Assessment (PEA) of Issuance of Scientific Research and Enhancement Permits for Use of Unmanned Vehicle Systems on Protected Species

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

ACTION: Notice; availability of draft environmental assessment.

SUMMARY: The National Marine Fisheries Service (NMFS) proposes to issue permits and permit amendments for take of protected species in the wild, pursuant to the Marine Mammal Protection Act of 1972, as amended; the Endangered Species Act of 1973; and the Fur Seal Act of 1966, as amended, as applicable. This may impact multiple species and taxa groups of protected species (marine mammals and sea turtles) by authorizing the use of unmanned vehicle systems (UVS), mainly small unmanned aircraft systems (UAS). The objectives of using UVS for research and enhancement may include determining the abundance, distribution, movement patterns, behavior, health and fitness, and stock structure of protected species found in U.S. territorial and international waters and coastal areas.

DATES: Written, telefaxed, or email comments must be received on or before August 7, 2015.

ADDRESSES: The draft PEA is available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376. Written comments must be postmarked by August 7, 2015, and should be mailed to: Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910–3226. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include ''Draft UVS PEA Comments'' in the subject line of the email.

FOR FURTHER INFORMATION CONTACT: Courtney Smith or Amy Sloan, (301) 427–8401.

SUPPLEMENTARY INFORMATION: NMFS is the federal agency responsible for management of sea turtles (in water), cetaceans, and pinnipeds (except walrus). NMFS' Office of Protected Resources administers a program that issues permits to various individuals and institutions to take these protected species in lands and waters under U.S. jurisdiction, and to U.S. citizens operating in international waters. Permits to take marine mammals are issued pursuant to the provisions of the MMPA, FSA (where applicable), and NMFS regulations governing the taking and importing of marine mammals (50 CFR part 216). For threatened and endangered species, permits are governed by the requirements of the ESA and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226). NMFS has prepared a draft PEA that evaluates the potential environmental impacts of scientific research or enhancement activities involving UVS, including UAS, on protected species. The purpose of the draft PEA is to assess impacts of UVS on protected species for issuance of future permits and permit amendments.

NMFS will consider all comments received during the comment period. NMFS requests that you include with your comments: (1) Your name and address; and (2) Any background documents to support your comments, as you feel necessary.

Dated: July 2, 2015.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–16669 Filed 7–7–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2015–OS–0067]

Manual for Courts-Martial; Publication of Supplementary Materials

AGENCY: Joint Service Committee on Military Justice (JSC), Department of Defense.

ACTION: Publication of Discussion and Analysis (Supplementary Materials) accompanying the Manual for Courts-Martial, United States (2012 ed.) (MCM).

SUMMARY: The JSC hereby publishes Supplementary Materials accompanying the MCM as amended by Executive Orders 13643, 13669, and 13696. The language of the Subsection or Subparagraph immediately preceding the new or amended Discussion has been inserted above each new or amended Discussion within this notice, and all new Analyses are located at the end of this notice. These changes have not been coordinated within the Department of Defense under DoD Directive 5500.1, ''Preparation, Processing and Coordinating Legislation, Executive Orders, Proclamations, Views Letters and Testimony,'' June 15, 2007, and do not constitute the official position of the Department of Defense, the Military Departments, or any other Government agency. These Supplementary Materials have been approved by the JSC and the General Counsel of the Department of Defense, and shall be applied in conjunction with the rule with which they are associated. The Discussions are effective insofar as the Rules they supplement are effective, but may not be applied earlier than the date of publication in the **Federal Register**.

DATES: The Analysis is effective as of July 8, 2015.

FOR FURTHER INFORMATION CONTACT: Capt. Harlye S. Carlton, USMC, (703) 963–9299 or *harlye.carlton@usmc.mil.* The JSC Web site is located at: *http://jsc.defense.gov.*

SUPPLEMENTARY INFORMATION:

Public Comments: The JSC solicited public comments for these changes to the MCM via the **Federal Register** on October 3, 2014 (79 FR 59938–59959, Docket ID: DoD–2014–OS–0140), held a public meeting at the Court of Appeals for the Armed Forces on December 2, 2014, and published the JSC response to public comments via the **Federal Register** on February 4, 2015 (80 FR 6057–6060, Docket ID: DoD–2014–OS–0140).

The amendments to the Discussion and Analysis of the MCM are as follows:

Annex

Section 1. Part II, Rules for Courts-Martial, is Amended as Follows:

(a) The Discussion section following R.C.M. 201(a)(2) is amended to read as follows:

(2) The code applies in all places.

Discussion

''Except insofar as required by the Constitution, the Code, or the Manual, such as jurisdiction over persons listed under Article 2(a)(10), jurisdiction of courts-martial does not depend on where the offense was committed.''

(b) A new Discussion section is added immediately after R.C.M. 201(f)(2)(D) to read as follows:

(D) *Certain Offenses under Articles 120, 120b, and 125.* Notwithstanding subsection (f)(2)(A), special courts-martial do not have jurisdiction over offenses under Article 120(a), 120(b), 120b(a), and 120b(b), forcible sodomy under Article 125, and attempts thereof under Article 80. Such offenses shall not be referred to a special court-martial.

Discussion

''Pursuant to the National Defense Authorization Act for Fiscal Year 2014, only a general court-martial has jurisdiction over penetrative sex offenses under subsections (a) and (b) of Article 120, subsections (a) and (b) of Article 120b, Article 125, and attempts to commit such penetrative sex offenses under Article 80.''

(c) A new Discussion section is added immediately after R.C.M. 305(i)(2)(A)(iv):

(iv) *Victim's right to be reasonably heard.* A victim of an alleged offense committed by the prisoner has the right to reasonable, accurate, and timely notice of the 7-day review; the right to confer with the representative of the command and counsel for the government, if any, and the right to be reasonably heard during the review. However, the hearing may not be unduly delayed for this purpose. The right to be heard under this rule includes the right to be heard through counsel. The victim of an alleged offense shall be notified of these rights in accordance with regulations of the Secretary concerned.

Discussion

''Personal appearance by the victim is not required. A victim's right to be reasonably heard at a 7-day review may also be accomplished telephonically, by video teleconference, or by written statement. The right to be heard under this rule includes the right to be heard through counsel.''

(d) A new Discussion section is added immediately after R.C.M. 305(j)(1)(C):

(C) The provisions of subsection (i)(1) or (2) of this rule have not been complied with and information presented to the military judge does not establish sufficient grounds for continued confinement under subsection (h)(2)(B) of this rule.

Discussion

''Upon a motion for release from pretrial confinement, a victim of an alleged offense committed by the prisoner has the right to reasonable, accurate, and timely notice of the motion and any hearing, the right to confer with counsel representing the government, and the right to be reasonably heard. Inability to reasonably afford a victim these rights shall not delay the proceedings. The right to be heard under this rule includes the right to be heard through counsel. *See* R.C.M. 906(b)(8).''

(e) A new Discussion section is added immediately after R.C.M. 305(n):

(n) *Notice to victim of escaped prisoner.* A victim of an alleged offense committed by the prisoner for which the prisoner has been placed in pretrial confinement has the right to reasonable, accurate, and timely notice of the escape of the prisoner, unless such notice may endanger the safety of any person.

Discussion

''For purposes of this rule, the term ''victim of an alleged offense'' means a person who has suffered direct physical, emotional, or pecuniary harm as a result of the commission of an offense under the UCMJ.''

(f) The Discussion section following R.C.M. 404(e) is amended to read as follows:

(e) Unless otherwise prescribed by the Secretary concerned, direct a preliminary hearing under R.C.M. 405, and, if appropriate, forward the report of preliminary hearing with the charges to a superior commander for disposition.

Discussion

''A preliminary hearing should be directed when it appears that the charges are of such a serious nature that trial by general court-martial may be warranted. *See* R.C.M. 405. If a preliminary hearing of the subject matter already has been conducted, *see* R.C.M. 405(b) and 405(e)(2).''

(g) A new Discussion section is added immediately after R.C.M. 404A(d):

(d) *Protective order if privileged information is disclosed.* If the government agrees to disclose to the accused information to which the protections afforded by Section V of Part III may apply, the convening authority, or other person designated by regulation of the Secretary concerned, may enter an appropriate protective order, in writing, to guard against the compromise of information disclosed to the accused. The terms of any such protective order may include prohibiting the disclosure of the information except as authorized by the authority issuing the protective order, as well as those terms specified by Mil. R. Evid. 505(g)(2)–(6) or 506(g)(2)–(5).

Discussion

''The purposes of this rule are to provide the accused with the documents used to make the determination to prefer charges and direct a preliminary hearing, and to allow the accused to prepare for the preliminary hearing. This rule is not intended to be a tool for discovery and does not impose the same discovery obligations found in R.C.M. 405 prior to amendments required by the National Defense Authorization Act for Fiscal Year 2014 or R.C.M. 701. Additional rules for disclosure of witnesses and other evidence in the preliminary hearing are provided in R.C.M. 405(g).''

(h) Discussions are added throughout the new R.C.M. 405 as follows:

Rule 405. Preliminary Hearing

(a) *In general.* Except as provided in subsection (k) of this rule, no charge or specification may be referred to a general court-martial for trial until completion of a preliminary hearing in substantial compliance with this rule. A preliminary hearing conducted under this rule is not intended to serve as a

means of discovery and will be limited to an examination of those issues necessary to determine whether there is probable cause to conclude that an offense or offenses have been committed and whether the accused committed it; to determine whether a court-martial would have jurisdiction over the offense(s) and the accused; to consider the form of the charge(s); and to recommend the disposition that should be made of the charge(s). Failure to comply with this rule shall have no effect on the disposition of the charge(s) if the charge(s) is not referred to a general court-martial.

Discussion

''The function of the preliminary hearing is to ascertain and impartially weigh the facts needed for the limited scope and purpose of the preliminary hearing. The preliminary hearing is not intended to perfect a case against the accused and is not intended to serve as a means of discovery or to provide a right of confrontation required at trial. Determinations and recommendations of the preliminary hearing officer are advisory.

Failure to substantially comply with the requirements of Article 32, which failure prejudices the accused, may result in delay in disposition of the case or disapproval of the proceedings. *See* R.C.M. 905(b)(1) and 906(b)(3) concerning motions for appropriate relief relating to the preliminary hearing.

The accused may waive the preliminary hearing. *See* subsection (k) of this rule. In such case, no preliminary hearing need be held. However, the convening authority authorized to direct the preliminary hearing may direct that it be conducted notwithstanding the waiver.''

(b) *Earlier preliminary hearing.* If a preliminary hearing of the subject matter of an offense has been conducted before the accused is charged with an offense, and the accused was present at the preliminary hearing and afforded the rights to counsel, cross-examination, and presentation of evidence required by this rule, no further preliminary hearing is required.

(c) *Who may direct a preliminary hearing.* Unless prohibited by regulations of the Secretary concerned, a preliminary hearing may be directed under this rule by any court-martial convening authority. That authority may also give procedural instructions not inconsistent with these rules.

(d) *Personnel.*

(1) *Preliminary hearing officer.* Whenever practicable, the convening authority directing a preliminary hearing under this rule shall detail an impartial judge advocate certified under Article 27(b), not the accuser, as a preliminary hearing officer, who shall conduct the preliminary hearing and make a report that addresses whether there is probable cause to believe that an offense or offenses have been committed and that the accused committed the offense(s); whether a court-martial would have jurisdiction over the offense(s) and the accused; the form of the charges(s); and a recommendation as to the disposition of the charge(s).

When the appointment of a judge advocate as the preliminary hearing officer is not practicable, or in exceptional circumstances in which the interest of justice warrants, the convening authority directing the preliminary hearing may detail an impartial commissioned officer, who is not the accuser, as the preliminary hearing officer. If the preliminary hearing officer is not a judge advocate, an impartial judge advocate certified under Article 27(b) shall be available to provide legal advice to the preliminary hearing officer.

When practicable, the preliminary hearing officer shall be equal or senior in grade to the military counsel detailed to represent the accused and the government at the preliminary hearing. The Secretary concerned may prescribe additional limitations on the appointment of preliminary hearing officers.

The preliminary hearing officer shall not depart from an impartial role and become an advocate for either side. The preliminary hearing officer is disqualified to act later in the same case in any other capacity.

Discussion

''The preliminary hearing officer, if not a judge advocate, should be an officer in the grade of O–4 or higher. The preliminary hearing officer may seek legal advice concerning the preliminary hearing officer's responsibilities from an impartial source, but may not obtain such advice from counsel for any party or counsel for a victim.''

(2) *Counsel to represent the United States.* A judge advocate, not the accuser, shall serve as counsel to represent the United States, and shall present evidence on behalf of the government relevant to the limited scope and purpose of the preliminary hearing as set forth in subsection (a) of this rule.

(3) *Defense counsel.*

(A) *Detailed counsel.* Except as provided in subsection (d)(3)(B) of this rule, military counsel certified in accordance with Article 27(b) shall be detailed to represent the accused.

(B) *Individual military counsel.* The accused may request to be represented by individual military counsel. Such requests shall be acted on in accordance with R.C.M. 506(b).

(C) *Civilian counsel.* The accused may be represented by civilian counsel at no expense to the United States. Upon request, the accused is entitled to a reasonable time to obtain civilian counsel and to have such counsel present for the preliminary hearing. However, the preliminary hearing shall not be unduly delayed for this purpose. Representation by civilian counsel shall not limit the rights to military counsel under subsections (d)(3)(A) and (B) of this rule.

(4) *Others.* The convening authority who directed the preliminary hearing may also, as a matter of discretion, detail or request an appropriate authority to detail:

(A) A reporter; and

(B) An interpreter.

(e) *Scope of preliminary hearing.*

(1) The preliminary hearing officer shall limit the inquiry to the examination of evidence, including witnesses, necessary to:

(A) Determine whether there is probable cause to believe an offense or offenses have been committed and whether the accused committed it;

(B) Determine whether a court-martial would have jurisdiction over the offense(s) and the accused;

(C) Consider whether the form of the charge(s) is proper; and

(D) Make a recommendation as to the disposition of the charge(s).

(2) If evidence adduced during the preliminary hearing indicates that the accused committed any uncharged offense(s), the preliminary hearing officer may examine evidence and hear witnesses relating to the subject matter of such offense(s) and make the findings and recommendations enumerated in subsection (e)(1) of this rule regarding such offense(s) without the accused first having been charged with the offense. The accused's rights under subsection (f)(2) of this rule, and, where it would not cause undue delay to the proceedings, subsection (g) of this rule, are the same with regard to both charged and uncharged offenses. When considering uncharged offenses identified during the preliminary hearing, the preliminary hearing officer shall inform the accused of the general nature of each uncharged offense considered, and otherwise afford the accused the same opportunity for representation, cross examination, and presentation afforded during the

preliminary hearing of any charged offense.

Discussion

''Except as set forth in subsection (h) of this rule, the Mil. R. Evid. do not apply at a preliminary hearing. Except as prohibited elsewhere in this rule, a preliminary hearing officer may consider evidence, including hearsay, which would not be admissible at trial.''

(f) *Rights of the accused.*

(1) Prior to any preliminary hearing under this rule the accused shall have the right to:

(A) Notice of any witnesses that the government intends to call at the preliminary hearing and copies of or access to any written or recorded statements made by those witnesses that relate to the subject matter of any charged offense;

(i) For purposes of this rule, a ''written statement'' is one that is signed or otherwise adopted or approved by the witness that is within the possession or control of counsel for the government; and

(ii) For purposes of this rule, a ''recorded statement'' is an oral statement made by the witness that is recorded contemporaneously with the making of the oral statement and contained in a digital or other recording or a transcription thereof that is within the possession or control of counsel for the government.

(B) Notice of, and reasonable access to, any other evidence that the government intends to offer at the preliminary hearing; and

(C) Notice of, and reasonable access to, evidence that is within the possession or control of counsel for the government that negates or reduces the degree of guilt of the accused for an offense charged.

(2) At any preliminary hearing under this rule the accused shall have the right to:

(A) Be advised of the charges under consideration;

(B) Be represented by counsel;

(C) Be informed of the purpose of the preliminary hearing;

(D) Be informed of the right against self-incrimination under Article 31;

(E) Except in the circumstances described in R.C.M. 804(c)(2), be present throughout the taking of evidence;

(F) Cross-examine witnesses on matters relevant to the limited scope and purpose of the preliminary hearing;

(G) Present matters in defense and mitigation relevant to the limited scope and purpose of the preliminary hearing; and

Discussion

''Unsworn statements by the accused, unlike those made under R.C.M. 1001(c)(2), shall be limited to matters in defense and mitigation.''

(H) Make a statement relevant to the limited scope and purpose of the preliminary hearing.

(g) *Production of Witnesses and Other Evidence.*

(1) *Military Witnesses.*

(A) Prior to the preliminary hearing, defense counsel shall provide to counsel for the government the names of proposed military witnesses whom the accused requests that the government produce to testify at the preliminary hearing, and the requested form of the testimony, in accordance with the timeline established by the preliminary hearing officer. Counsel for the government shall respond that either: (1) The government agrees that the witness's testimony is relevant, not cumulative, and necessary for the limited scope and purpose of the preliminary hearing and will seek to secure the witness's testimony for the hearing; or (2) the government objects to the proposed defense witness on the grounds that the testimony would be irrelevant, cumulative, or unnecessary based on the limited scope and purpose of the preliminary hearing.

(B) If the government objects to the proposed defense witness, defense counsel may request that the preliminary hearing officer determine whether the witness is relevant, not cumulative, and necessary based on the limited scope and purpose of the preliminary hearing.

(C) If the government does not object to the proposed defense military witness or the preliminary hearing officer determines that the military witness is relevant, not cumulative, and necessary, counsel for the government shall request that the commanding officer of the proposed military witness make that person available to provide testimony. The commanding officer shall determine whether the individual is available based on operational necessity or mission requirements, except that a victim, as defined in this rule, who declines to testify shall be deemed to be not available. If the commanding officer determines that the military witness is available, counsel for the government shall make arrangements for that individual's testimony. The commanding officer's determination of unavailability due to operational necessity or mission requirements is final. If there is a dispute among the parties, the military witness's commanding officer shall determine whether the witness testifies in person, by video teleconference, by telephone, or by similar means of remote testimony.

Discussion

''A commanding officer's determination of whether an individual is available, as well as the means by which the individual is available, is a balancing test. The more important the testimony of the witness, the greater the difficulty, expense, delay, or effect on military operations must be to deny production of the witness. Based on operational necessity and mission requirements, the witness's commanding officer may authorize the witness to testify by video teleconference, telephone, or similar means of remote testimony. Factors to be considered in making this determination include the costs of producing the witness; the timing of the request for production of the witness; the potential delay in the proceeding that may be caused by the production of the witness; and the likelihood of significant interference with operational deployment, mission accomplishment, or essential training.''

(2) *Civilian Witnesses.*

(A) Defense counsel shall provide to counsel for the government the names of proposed civilian witnesses whom the accused requests that the government produce to testify at the preliminary hearing, and the requested form of the testimony, in accordance with the timeline established by the preliminary hearing officer. Counsel for the government shall respond that either: (1) The government agrees that the witness's testimony is relevant, not cumulative, and necessary for the limited scope and purpose of the preliminary hearing and will seek to secure the witness's testimony for the hearing; or (2) the government objects to the proposed defense witness on the grounds that the testimony would be irrelevant, cumulative, or unnecessary based on the limited scope and purpose of the preliminary hearing.

(B) If the government objects to the proposed defense witness, defense counsel may request that the preliminary hearing officer determine whether the witness is relevant, not cumulative, and necessary based on the limited scope and purpose of the preliminary hearing.

(C) If the government does not object to the proposed civilian witness or the preliminary hearing officer determines that the civilian witness's testimony is relevant, not cumulative, and necessary, counsel for the government shall invite the civilian witness to provide

testimony and, if the individual agrees, shall make arrangements for that witness's testimony. If expense to the government is to be incurred, the convening authority who directed the preliminary hearing, or the convening authority's delegate, shall determine whether the witness testifies in person, by video teleconference, by telephone, or by similar means of remote testimony.

Discussion

''Factors to be considered in making this determination include the costs of producing the witness; the timing of the request for production of the witness; the potential delay in the proceeding that may be caused by the production of the witness; the willingness of the witness to testify in person; and, for child witnesses, the traumatic effect of providing in-person testimony. Civilian witnesses may not be compelled to provide testimony at a preliminary hearing. Civilian witnesses may be paid for travel and associated expenses to testify at a preliminary hearing. *See* Department of Defense Joint Travel Regulations.''

(3) *Other evidence.*

(A) *Evidence under the control of the government.*

(i) Prior to the preliminary hearing, defense counsel shall provide to counsel for the government a list of evidence under the control of the government the accused requests the government produce to the defense for introduction at the preliminary hearing. The preliminary hearing officer may set a deadline by which defense requests must be received. Counsel for the government shall respond that either: (1) The government agrees that the evidence is relevant, not cumulative, and necessary for the limited scope and purpose of the preliminary hearing and shall make reasonable efforts to obtain the evidence; or (2) the government objects to production of the evidence on the grounds that the evidence would be irrelevant, cumulative, or unnecessary based on the limited scope and purpose of the preliminary hearing.

(ii) If the government objects to production of the evidence, defense counsel may request that the preliminary hearing officer determine whether the evidence should be produced. The preliminary hearing officer shall determine whether the evidence is relevant, not cumulative, and necessary based on the limited scope and purpose of the hearing. If the preliminary hearing officer determines that the evidence shall be produced, counsel for the government shall make reasonable efforts to obtain the evidence.

(B) *Evidence not under the control of the government.*

(i) Evidence not under the control of the government may be obtained through noncompulsory means or by *subpoenas duces tecum* issued by counsel for the government in accordance with the process established by R.C.M. 703.

(ii) Prior to the preliminary hearing, defense counsel shall provide to counsel for the government a list of evidence not under the control of the government that the accused requests the government obtain. The preliminary hearing officer may set a deadline by which defense requests must be received. Counsel for the government shall respond that either: (1) the government agrees that the evidence is relevant, not cumulative, and necessary for the limited scope and purpose of the preliminary hearing and shall issue *subpoenas duces tecum* for the evidence; or (2) the government objects to production of the evidence on the grounds that the evidence would be irrelevant, cumulative, or unnecessary based on the limited scope and purpose of the preliminary hearing.

(iii) If the government objects to production of the evidence, defense counsel may request that the preliminary hearing officer determine whether the evidence should be produced. If the preliminary hearing officer determines that the evidence is relevant, not cumulative, and necessary based on the limited scope and purpose of the preliminary hearing and that the issuance of *subpoenas duces tecum* would not cause undue delay to the preliminary hearing, the preliminary hearing officer shall direct counsel for the government to issue *subpoenas duces tecum* for the defense-requested evidence. The preliminary hearing officer shall note in the report of preliminary hearing any failure on the part of counsel for the government to issue *subpoenas duces tecum* directed by the preliminary hearing officer.

Discussion

''A *subpoena duces tecum* to produce books, papers, documents, data, electronically stored information, or other objects for a preliminary hearing pursuant to Article 32 may be issued by counsel for the government. The preliminary hearing officer has no authority to issue a *subpoena duces tecum.* However, the preliminary hearing officer may direct counsel for the government to issue a *subpoena duces tecum* for defense-requested evidence.''

(h) *Military Rules of Evidence.* The Military Rules of Evidence do not apply in preliminary hearings under this rule except as follows:

(1) Mil. R. Evid. 301–303 and 305 shall apply in their entirety.

(2) Mil. R. Evid. 412 shall apply in any case that includes a charge defined as a sexual offense in Mil. R. Evid. 412(d), except that Mil. R. Evid. 412(b)(1)(C) shall not apply.

(3) Mil. R. Evid., Section V, Privileges, shall apply, except that Mil. R. Evid. 505(f)–(h) and (j); 506(f)–(h), (j), (k), and (m); and 514(d)(6) shall not apply.

(4) In applying these rules to a preliminary hearing, the term ''military judge,'' as used in these rules, shall mean the preliminary hearing officer, who shall assume the military judge's authority to exclude evidence from the preliminary hearing, and who shall, in discharging this duty, follow the procedures set forth in the rules cited in subsections (h)(1)–3) of this rule. However, the preliminary hearing officer is not authorized to order production of communications covered by Mil. R. Evid. 513 and 514.

Discussion

''The prohibition against ordering production of evidence does not preclude a preliminary hearing officer from considering evidence offered by the parties under Mil. R. Evid. 513 or 514.''

(5) Failure to meet the procedural requirements of the applicable rules of evidence shall result in exclusion of that evidence from the preliminary hearing, unless good cause is shown.

Discussion

''Before considering evidence offered under subsection (h)(2), the preliminary hearing officer must determine that the evidence offered is relevant for the limited scope and purpose of the hearing, that the evidence is proper under subsection (h)(2), and that the probative value of such evidence outweighs the danger of unfair prejudice to the alleged victim's privacy. The preliminary hearing officer shall set forth any limitations on the scope of such evidence. Evidence offered under subsection (h)(2) must be protected pursuant to the Privacy Act of 1974, 5 U.S.C. 552a. Although Mil. R. Evid. 412(b)(1)(C) allows admission of evidence of the victim's sexual behavior or predisposition at trial when it is constitutionally required, there is no constitutional requirement at an Article 32 hearing. There is likewise no constitutional requirement for a preliminary hearing officer to consider evidence under Mil. R. Evid. 514(d)(6)

at an Article 32 hearing. Evidence deemed admissible by the preliminary hearing officer should be made a part of the report of preliminary hearing. *See* subsection (j)(2)(C), of this Rule. Evidence not considered, and the testimony taken during a closed hearing, should not be included in the report of preliminary hearing but should be appropriately safeguarded or sealed. The preliminary hearing officer and counsel representing the government are responsible for careful handling of any such evidence to prevent unauthorized viewing or disclosure.''

(i) *Procedure.*

(1) *Generally.* The preliminary hearing shall begin with the preliminary hearing officer informing the accused of the accused's rights under subsection (f) of this rule. Counsel for the government will then present evidence. Upon the conclusion of counsel for the government's presentation of evidence, defense counsel may present matters in defense and mitigation consistent with subsection (f) of this rule. For the purposes of this rule, ''matters in mitigation'' are defined as matters that may serve to explain the circumstances surrounding a charged offense. Both counsel for the government and defense shall be afforded an opportunity to cross-examine adverse witnesses. The preliminary hearing officer may also question witnesses called by the parties. If the preliminary hearing officer determines that additional evidence is necessary to satisfy the requirements of subsection (e) of this rule, the preliminary hearing officer may provide the parties an opportunity to present additional testimony or evidence relevant to the limited scope and purpose of the preliminary hearing. The preliminary hearing officer shall not consider evidence not presented at the preliminary hearing. The preliminary hearing officer shall not call witnesses *sua sponte.*

Discussion

''A preliminary hearing officer may only consider evidence within the limited purpose of the preliminary hearing and shall ensure that the scope of the hearing is limited to that purpose. When the preliminary hearing officer finds that evidence offered by either party is not within the scope of the hearing, he shall inform the parties and halt the presentation of that information.''

(2) *Notice to and presence of the victim(s).*

(A) The victim(s) of an offense under the UCMJ has the right to reasonable, accurate, and timely notice of a preliminary hearing relating to the alleged offense and the reasonable right to confer with counsel for the government. For the purposes of this rule, a ''victim'' is a person who is alleged to have suffered a direct physical, emotional, or pecuniary harm as a result of the matters set forth in a charge or specification under consideration and is named in one of the specifications under consideration.

(B) A victim of an offense under consideration at the preliminary hearing is not required to testify at the preliminary hearing.

(C) A victim has the right not to be excluded from any portion of a preliminary hearing related to the alleged offense, unless the preliminary hearing officer, after receiving clear and convincing evidence, determines the testimony by the victim would be materially altered if the victim heard other testimony at the proceeding.

(D) A victim shall be excluded if a privilege set forth in Mil. R. Evid. 505 or 506 is invoked or if evidence is offered under Mil. R. Evid. 412, 513, or 514, for charges other than those in which the victim is named.

(3) *Presentation of evidence.*

(A) *Testimony.* Witness testimony may be provided in person, by video teleconference, by telephone, or by similar means of remote testimony. All testimony shall be taken under oath, except that the accused may make an unsworn statement. The preliminary hearing officer shall only consider testimony that is relevant to the limited scope and purpose of the preliminary hearing.

Discussion

''The following oath may be given to witnesses:

''Do you (swear) (affirm) that the evidence you give shall be the truth, the whole truth, and nothing but the truth (so help you God)?''

The preliminary hearing officer is required to include in the report of the preliminary hearing, at a minimum, a summary of the substance of all testimony. *See* subsection (j)(2)(B) of this rule.

All preliminary hearing officer notes of testimony and recordings of testimony should be preserved until the end of trial.

If during the preliminary hearing any witness subject to the Code is suspected of an offense under the Code, the preliminary hearing officer should comply with the warning requirements of Mil. R. Evid. 305(c), (d), and, if necessary, (e).

Bearing in mind that counsel are responsible for preparing and presenting their cases, the preliminary hearing officer may ask a witness questions relevant to the limited scope and purpose of the hearing. When questioning a witness, the preliminary hearing officer may not depart from an impartial role and become an advocate for either side.''

(B) *Other evidence.* If relevant to the limited scope and purpose of the preliminary hearing, and not cumulative, a preliminary hearing officer may consider other evidence, in addition to or in lieu of witness testimony, including statements, tangible evidence, or reproductions thereof, offered by either side, that the preliminary hearing officer determines is reliable. This other evidence need not be sworn.

(4) *Access by spectators.* Preliminary hearings are public proceedings and should remain open to the public whenever possible. The convening authority who directed the preliminary hearing or the preliminary hearing officer may restrict or foreclose access by spectators to all or part of the proceedings if an overriding interest exists that outweighs the value of an open preliminary hearing. Examples of overriding interests may include: preventing psychological harm or trauma to a child witness or an alleged victim of a sexual crime, protecting the safety or privacy of a witness or alleged victim, protecting classified material, and receiving evidence where a witness is incapable of testifying in an open setting. Any closure must be narrowly tailored to achieve the overriding interest that justified the closure. Convening authorities or preliminary hearing officers must conclude that no lesser methods short of closing the preliminary hearing can be used to protect the overriding interest in the case. Convening authorities or preliminary hearing officers must conduct a case-by-case, witness-by-witness, circumstance-by-circumstance analysis of whether closure is necessary. If a convening authority or preliminary hearing officer believes closing the preliminary hearing is necessary, the convening authority or preliminary hearing officer must make specific findings of fact in writing that support the closure. The written findings of fact must be included in the report of preliminary hearing.

(5) *Presence of accused.* The further progress of the taking of evidence shall not be prevented and the accused shall be considered to have waived the right to be present whenever the accused:

(A) After being notified of the time and place of the proceeding is voluntarily absent; or

(B) After being warned by the preliminary hearing officer that disruptive conduct will cause removal from the proceeding, persists in conduct that is such as to justify exclusion from the proceeding.

(6) *Recording of the preliminary hearing.* Counsel for the government shall ensure that the preliminary hearing is recorded by a suitable recording device. A victim, as defined by subsection (i)(2)(A) of this rule, may request access to, or a copy of, the recording of the proceedings. Upon request, counsel for the government shall provide the requested access to, or a copy of, the recording to the victim not later than a reasonable time following dismissal of the charges, unless charges are dismissed for the purpose of re-referral, or court-martial adjournment. A victim is not entitled to classified information or access to or a copy of a recording of closed sessions that the victim did not have the right to attend under subsections (i)(2)(C) or (i)(2)(D) of this rule.

Discussion

''Counsel for the government shall provide victims with access to, or a copy of, the recording of the proceedings in accordance with such regulations as the Secretary concerned may prescribe.''

(7) *Objections.* Any objection alleging a failure to comply with this rule shall be made to the convening authority via the preliminary hearing officer.

(8) *Sealed exhibits and proceedings.* The preliminary hearing officer has the authority to order exhibits, proceedings, or other matters sealed as described in R.C.M. 1103A.

(j) *Report of preliminary hearing.*

(1) *In general.* The preliminary hearing officer shall make a timely written report of the preliminary hearing to the convening authority who directed the preliminary hearing.

Discussion

''If practicable, the charges and the report of preliminary hearing should be forwarded to the general court-martial convening authority within 8 days after an accused is ordered into arrest or confinement. *See* Article 33. ''

(2) *Contents.* The report of preliminary hearing shall include:

(A) A statement of names and organizations or addresses of defense counsel and whether defense counsel was present throughout the taking of evidence, or, if not present, the reason why;

(B) The substance of the testimony taken on both sides;

(C) Any other statements, documents, or matters considered by the preliminary hearing officer, or recitals of the substance or nature of such evidence;

(D) A statement that an essential witness may not be available for trial;

(E) An explanation of any delays in the preliminary hearing;

(F) A notation if counsel for the government failed to issue a *subpoena duces tecum* that was directed by the preliminary hearing officer;

(G) The preliminary hearing officer's determination as to whether there is probable cause to believe the offense(s) listed on the charge sheet or otherwise considered at the preliminary hearing occurred;

(H) The preliminary hearing officer's determination as to whether there is probable cause to believe the accused committed the offense(s) listed on the charge sheet or otherwise considered at the preliminary hearing;

(I) The preliminary hearing officer's determination as to whether a court-martial has jurisdiction over the offense(s) and the accused;

(J) The preliminary hearing officer's determination as to whether the charge(s) and specification(s) are in proper form; and

(K) The preliminary hearing officer's recommendations regarding disposition of the charge(s).

Discussion

''The preliminary hearing officer may include any additional matters useful to the convening authority in determining disposition. The preliminary hearing officer may recommend that the charges and specifications be amended or that additional charges be preferred. *See* R.C.M. 306 and 401 concerning other possible dispositions.''

(3) *Sealed exhibits and proceedings.* If the report of preliminary hearing contains exhibits, proceedings, or other matters ordered sealed by the preliminary hearing officer in accordance with R.C.M. 1103A, counsel for the government shall cause such materials to be sealed so as to prevent unauthorized viewing or disclosure.

(4) *Distribution of the report.* The preliminary hearing officer shall cause the report to be delivered to the convening authority who directed the preliminary hearing. That convening authority shall promptly cause a copy of the report to be delivered to each accused.

(5) *Objections.* Any objection to the report shall be made to the convening authority who directed the preliminary hearing, via the preliminary hearing officer. Upon receipt of the report, the accused has 5 days to submit objections to the preliminary hearing officer. The preliminary hearing officer will forward the objections to the convening authority as soon as practicable. This subsection does not prohibit a convening authority from referring the charge(s) or taking other action within the 5-day period.

(k) *Waiver.* The accused may waive a preliminary hearing under this rule. However, the convening authority authorized to direct the preliminary hearing may direct that it be conducted notwithstanding the waiver. Failure to make a timely objection under this rule, including an objection to the report, shall constitute waiver of the objection. Relief from the waiver may be granted by the convening authority who directed the preliminary hearing, a superior convening authority, or the military judge, as appropriate, for good cause shown.

Discussion

''*See also* R.C.M. 905(b)(1); 906(b)(3).

The convening authority who receives an objection may direct that the preliminary hearing be reopened or take other action, as appropriate.''

(i) A new Discussion section is added immediately after R.C.M. 601(g):

(g) *Parallel convening authorities.* If it is impracticable for the original convening authority to continue exercising authority over the charges, the convening authority may cause the charges, even if referred, to be transmitted to a parallel convening authority. This transmittal must be in writing and in accordance with such regulations as the Secretary concerned may prescribe. Subsequent actions taken by the parallel convening authority are within the sole discretion of that convening authority.''

Discussion

''Parallel convening authorities are those convening authorities that possess the same court-martial jurisdiction authority. Examples of permissible transmittal of charges under this rule include the transmittal from a general court-martial convening authority to another general court-martial convening authority, or from one special court-martial convening authority to another special court-martial convening authority. It would be impracticable for an original convening authority to continue exercising authority over the charges, for example, when a command is being decommissioned or inactivated, or when deploying or redeploying and the accused is remaining behind. If charges have been referred, there is no requirement that the charges be

withdrawn or dismissed prior to transfer. *See* R.C.M. 604. In the event that the case has been referred, the receiving convening authority may adopt the original court-martial convening order, including the court-martial panel selected to hear the case as indicated in that convening order. When charges are transmitted under this rule, no recommendation as to disposition may be made.''

(j) The first sentence of the third paragraph of the Discussion section immediately after R.C.M. 702(a) is deleted.

(k) The Discussion section immediately following R.C.M. 702(c)(3)(A) is deleted.

(l) New Discussions sections are added throughout R.C.M. 801(a)(6) as follows:

(6) In the case of a victim of an offense under the UCMJ who is under 18 years of age and not a member of the armed forces, or who is incompetent, incapacitated, or deceased, designate in writing a family member, a representative of the estate of the victim, or another suitable individual to assume the victim's rights under the UCMJ.

(A) For the purposes of this rule, the individual is designated for the sole purpose of assuming the legal rights of the victim as they pertain to the victim's status as a victim of any offense(s) properly before the court.

Discussion

''The rights that a designee may exercise on behalf of a victim include the right to receive notice of public hearings in the case; the right to be reasonably heard at such hearings, if permitted by law; and the right to confer with counsel representing the government at such hearings. The designee may also be the custodial guardian of the child.

When determining whom to appoint under this rule, the military judge may consider the following: the age and maturity, relationship to the victim, and physical proximity of any proposed designee; the costs incurred in effecting the appointment; the willingness of the proposed designee to serve in such a role; the previous appointment of a guardian by another court of competent jurisdiction; the preference of the victim; any potential delay in any proceeding that may be caused by a specific appointment; and any other relevant information.''

(B) *Procedure to determine appointment of designee.*

(i) As soon as practicable, trial counsel shall notify the military judge, counsel for the accused, and the victim(s) of any offense(s) properly before the court when there is an apparent requirement to appoint a designee under this rule.

Discussion

''In the event a case involves multiple victims who are entitled to notice under this rule, each victim is only entitled to notice relating to his or her own designated representative.''

(ii) The military judge will determine if the appointment of a designee is required under this rule.

(iii) At the discretion of the military judge, victim(s), trial counsel, and the accused may be given the opportunity to recommend to the military judge individual(s) for appointment.

(iv) The military judge is not required to hold a hearing before determining whether a designation is required or making such an appointment under this rule.

(v) If the military judge determines a hearing pursuant to Article 39(a), UCMJ, is necessary, the following shall be notified of the hearing and afforded the right to be present at the hearing: trial counsel, accused, and the victim(s).

(vi) The individual designated shall not be the accused.

(C) At any time after appointment, a designee shall be excused upon request by the designee or a finding of good cause by the military judge.

(D) If the individual appointed to assume the victim's rights is excused, the military judge shall appoint a successor consistent with this rule.

Discussion

''The term ''victim of an offense under the UCMJ'' means a person who has suffered direct physical, emotional, or pecuniary harm as a result of the commission of an offense under the UCMJ. ''Good Cause'' means adequate or reasonable grounds to believe that the individual appointed to assume the victim's rights is not acting or does not intend to act in the best interest of the victim.''

(m) The Discussion section following R.C.M. 806(b)(1) is amended to read as follows:

(b) *Control of spectators and closure.*

(1) *Control of spectators.* In order to maintain the dignity and decorum of the proceedings or for other good cause, the military judge may reasonably limit the number of spectators in, and the means of access to, the courtroom, and exclude specific persons from the courtroom. When excluding specific persons, the military judge must make findings on the record establishing the reason for the exclusion, the basis for the military judge's belief that exclusion is necessary, and that the exclusion is as narrowly tailored as possible.

Discussion

''The military judge must ensure that the dignity and decorum of the proceedings are maintained and that the other rights and interests of the parties and society are protected. Public access to a session may be limited, specific persons may be excluded from the courtroom, and, under unusual circumstances, a session may be closed.

Exclusion of specific persons, if unreasonable under the circumstances, may violate the accused's right to a public trial, even though other spectators remain. Whenever specific persons or some members of the public are excluded, exclusion must be limited in time and scope to the minimum extent necessary to achieve the purpose for which it is ordered. Prevention of over-crowding or noise may justify limiting access to the courtroom. Disruptive or distracting appearance or conduct may justify excluding specific persons. Specific persons may be excluded when necessary to protect witnesses from harm or intimidation. Access may be reduced when no other means is available to relieve a witness' inability to testify due to embarrassment or extreme nervousness. Witnesses will ordinarily be excluded from the courtroom so that they cannot hear the testimony of other witnesses. *See* Mil. R. Evid. 615.

For purposes of this rule, the term ''victim of an alleged offense'' means a person who has suffered direct physical, emotional, or pecuniary harm as a result of the commission of an offense under the UCMJ.''

(n) The Discussion section following R.C.M. 807(b)(1)(B) is amended to read as follows:

(B) *Witnesses.* Each witness before a court-martial shall be examined on oath.

Discussion

''*See* R.C.M. 307 concerning the requirement for an oath in preferral of charges. *See* R.C.M. 405 and 702 concerning the requirements for an oath in Article 32 preliminary hearings and depositions.

An accused making an unsworn statement is not a ''witness.'' *See* R.C.M. 1001(c)(2)(C).

A victim of an offense for which the accused has been found guilty is not a ''witness'' when making an unsworn statement during the presentencing phase of a court-martial. *See* R.C.M. 1001A.''

(o) The Discussion section following R.C.M. 906(b)(9) is amended to read as follows:

(9) Severance of multiple accused, if it appears that an accused or the Government is prejudiced by a joint or common trial. In a common trial, a severance shall be granted whenever any accused, other than the moving accused, faces charges unrelated to those charged against the moving accused.

Discussion

''A motion for severance is a request that one or more accused against whom charges have been referred to a joint or common trial be tried separately. Such a request should be granted if good cause is shown. For example, a severance may be appropriate when: the moving party wishes to use the testimony of one or more of the coaccused or the spouse of a coaccused; a defense of a coaccused is antagonistic to the moving party; or evidence as to any other accused will improperly prejudice the moving accused.

If a severance is granted by the military judge, the military judge will decide which accused will be tried first. *See* R.C.M. 801(a)(1). In the case of joint charges, the military judge will direct an appropriate amendment of the charges and specifications.

See also R.C.M. 307(c)(5); 601(e)(3); 604; 812.''

(p) A new Discussion section is added immediately after R.C.M. 1001(g):

(g) *Argument.* After introduction of matters relating to sentence under this rule, counsel for the prosecution and defense may argue for an appropriate sentence. Trial counsel may not in argument purport to speak for the convening authority or any higher authority, or refer to the views of such authorities or any policy directive relative to punishment or to any punishment or quantum of punishment greater than that court-martial may adjudge. Trial counsel may, however, recommend a specific lawful sentence and may also refer to generally accepted sentencing philosophies, including rehabilitation of the accused, general deterrence, specific deterrence of misconduct by the accused, and social retribution. Failure to object to improper argument before the military judge begins to instruct the members on sentencing shall constitute waiver of the objection.

Discussion

''A victim, victims' counsel, or designee has no right to present argument under this rule.''

(q) Discussions are inserted throughout R.C.M. 1001A(e)(1) as follows:

Rule 1001A. Crime victims and Presentencing

(a) *In general.* A crime victim of an offense of which the accused has been found guilty has the right to be reasonably heard at a sentencing hearing relating to that offense. A victim under this rule is not considered a witness for purposes of Article 42(b). Trial counsel shall ensure the victim is aware of the opportunity to exercise that right. If the victim exercises the right to be reasonably heard, the victim shall be called by the court-martial. This right is independent of whether the victim testified during findings or is called to testify under R.C.M. 1001.

(b) *Definitions.*

(1) *Crime victim.* For purposes of this rule, a ''crime victim'' is an individual who has suffered direct physical, emotional, or pecuniary harm as a result of the commission of an offense of which the accused was found guilty.

(2) *Victim Impact.* For the purposes of this rule, ''victim impact'' includes any financial, social, psychological, or medical impact on the victim directly relating to or arising from the offense of which the accused has been found guilty.

(3) *Mitigation.* For the purposes of this rule, ''mitigation'' includes a matter to lessen the punishment to be adjudged by the court-martial or to furnish grounds for a recommendation of clemency.

(4) *Right to be reasonably heard.*

(A) *Capital cases.* In capital cases, for purposes of this rule, the ''right to be reasonably heard'' means the right to make a sworn statement.

(B) *Non-capital cases.* In non-capital cases, for purposes of this rule, the ''right to be reasonably heard'' means the right to make a sworn or unsworn statement.

(c) *Content of statement.* The content of statements made under subsections (d) and (e) of this rule may include victim impact or matters in mitigation.

(d) *Sworn statement.* The victim may give a sworn statement under this rule and shall be subject to cross-examination concerning the statement by the trial counsel or defense counsel or examination on the statement by the court-martial, or all or any of the three. When a victim is under 18 years of age, incompetent, incapacitated, or deceased, the sworn statement may be made by the victim's designee appointed under R.C.M. 801(a)(6). Additionally, a victim under 18 years of age may elect to make a sworn statement.

(e) *Unsworn statement.* The victim may make an unsworn statement and may not be cross-examined by the trial counsel or defense counsel upon it or examined upon it by the court-martial. The prosecution or defense may, however, rebut any statements of facts therein. The unsworn statement may be oral, written, or both. When a victim is under 18 years of age, incompetent, incapacitated, or deceased, the unsworn statement may be made by the victim's designee appointed under R.C.M. 801(a)(6). Additionally, a victim under 18 years of age may elect to make an unsworn statement.

(1) *Procedure for presenting unsworn statement.* After the announcement of findings, a victim who would like to present an unsworn statement shall provide a copy to the trial counsel, defense counsel, and military judge. The military judge may waive this requirement for good cause shown.

Discussion

''When the military judge waives the notice requirement under this rule, the military judge may conduct a session under Article 39(a) to ascertain the content of the victim's anticipated unsworn statement.''

(2) Upon good cause shown, the military judge may permit the victim's counsel to deliver all or part of the victim's unsworn statement.

Discussion

''If there are numerous victims, the military judge may reasonably limit the form of the statements provided.

A victim's unsworn statement should not exceed what is permitted under R.C.M. 1001A(c) and may not include a recommendation of a specific sentence. Upon objection by either party or *sua sponte,* a military judge may stop or interrupt a victim's unsworn statement that includes matters outside the scope of R.C.M. 1001A(c). A victim, victim's counsel, or designee has no separate right to present argument under R.C.M. 1001(g).''

(r) A new Discussion section is added immediately after R.C.M. 1103A(b)(3):

(3) *Authentication through action.* After authentication and prior to disposition of the record of trial pursuant to Rule for Courts-Martial 1111, sealed materials may not be examined in the absence of an order from the military judge upon a showing of good cause at a post-trial Article 39a session directed by the Convening Authority.

Discussion

''A convening authority who has granted clemency based upon review of sealed materials in the record of trial is not permitted to disclose the contents of

the sealed materials when providing a written explanation of the reason for such action, as directed under R.C.M. 1107.''

(s) The Discussion section following R.C.M. 1106(d)(3) is amended to read as follows:

(3) *Required contents.* Except as provided in subsection (e), the staff judge advocate or legal advisor shall provide the convening authority with a copy of the report of results of the trial, setting forth the findings, sentence, and confinement credit to be applied; a copy or summary of the pretrial agreement, if any; a copy of any statement submitted by a crime victim pursuant to R.C.M. 1l05A; any recommendation for clemency by the sentencing authority made in conjunction with the announced sentence; and the staff judge advocate's concise recommendation.

Discussion

''The recommendation required by this rule need not include information regarding other recommendations for clemency. It may include a summary of clemency actions authorized under R.C.M. 1107. *See* R.C.M. 1105(b)(2)(D) (pertaining to clemency recommendations that may be submitted by the accused to the convening authority).''

(t) The Discussion section immediately following R.C.M. 1107(c) is deleted.

(u) The Discussion section immediately following R.C.M. 1107(d)(1) is deleted.

(v) Discussions are inserted throughout R.C.M. 1107(d)(1) as follows:

(1) *In general.*

(A) The convening authority may not disapprove, commute, or suspend, in whole or in part, any portion of an adjudged sentence of confinement for more than six months.

(B) The convening authority may not disapprove, commute, or suspend that portion of an adjudged sentence that includes a dismissal, dishonorable discharge, or bad-conduct discharge.

(C) The convening authority may disapprove, commute, or suspend, in whole or in part, any portion of an adjudged sentence when doing so is not explicitly prohibited by this Rule. Actions affecting reduction in pay grade, forfeitures of pay and allowances, fines, reprimands, restrictions, and hard labor without confinement are not explicitly prohibited by this Rule.

(D) The convening authority shall not disapprove, commute, or suspend any mandatory minimum sentence of dismissal or dishonorable discharge except in accordance with subsection (E) of this rule.

(E) *Exceptions.*

(i) *Trial counsel recommendation.* Upon the recommendation of the trial counsel, in recognition of the substantial assistance by the accused in the investigation or prosecution of another person who has committed an offense, the convening authority or another person authorized to act under this section shall have the authority to disapprove, commute, or suspend the adjudged sentence, in whole or in part, even with respect to an offense for which a mandatory minimum sentence exists.

Discussion

''The phrase ''investigation or prosecution of another person who has committed an offense'' includes offenses under the UCMJ or other Federal, State, local, or foreign criminal statutes.''

(ii) *Pretrial agreement.* If a pretrial agreement has been entered into by the convening authority and the accused as authorized by R.C.M. 705, the convening authority shall have the authority to approve, disapprove, commute, or suspend a sentence, in whole or in part, pursuant to the terms of the pretrial agreement. The convening authority may commute a mandatory sentence of a dishonorable discharge to a bad-conduct discharge pursuant to the terms of the pretrial agreement.

(F) If the convening authority acts to disapprove, commute, or suspend, in whole or in part, the sentence of the court-martial for an offense, the convening authority shall provide, at the same time, a written explanation of the reasons for such action. The written explanation shall be made a part of the record of trial and action thereon.''

Discussion

''A sentence adjudged by a court-martial may be approved if it was within the jurisdiction of the court-martial to adjudge (*see* R.C.M. 201(f)) and did not exceed the maximum limits prescribed in Part IV and Chapter X of this Part for the offense(s) of which the accused legally has been found guilty.

When mitigating forfeitures, the duration and amounts of forfeiture may be changed as long as the total amount forfeited is not increased and neither the amount nor duration of the forfeitures exceeds the jurisdiction of the court-martial. When mitigating confinement or hard labor without confinement, the convening authority should use the equivalencies at R.C.M. 1003(b)(5)–(6), as appropriate.

Unless prohibited by this rule, the convening authority may disapprove, mitigate, or change to a less severe punishment any individual component of a sentence. For example, if an accused is found guilty of assault consummated by a battery and sentenced to a bad-conduct discharge, three months of confinement, and reduction to E–1, without a pre-trial agreement and without being able to apply the substantial assistance exception, the convening authority may disapprove or reduce any part of the sentence except the bad-conduct discharge.''

(w) The Discussion section following R.C.M. 1107(d)(2) is amended to read as follows:

(2) *Determining what sentence should be approved.* The convening authority shall, subject to the limitations in subsection (d)(1) above, approve that sentence that is warranted by the circumstances of the offense and appropriate for the accused.''

Discussion

''In determining what sentence should be approved, the convening authority should consider all relevant and permissible factors including the possibility of rehabilitation, the deterrent effect of the sentence, and all matters relating to clemency, such as pretrial confinement. *See also* R.C.M. 1001–1004.

When an accused is not serving confinement, the accused should not be deprived of more than two-thirds pay for any month as a result of one or more sentences by court-martial and other stoppages or involuntary deductions, unless requested by the accused. Since court-martial forfeitures constitute a loss of entitlement of the pay concerned, they take precedence over all debts.''

(x) The Discussion section immediately following R.C.M. 1107(e)(1)(C) is deleted.

(y) A new Discussion section is added immediately after R.C.M. 1301(c)(2):

(2) Notwithstanding subsection (c)(1) of this rule, summary courts-martial do not have jurisdiction over offenses under Articles 120(a), 120(b), 120b(a), 120b(b), forcible sodomy under Article 125, and attempts thereof under Article 80. Such offenses shall not be referred to a summary court-martial.

Discussion

''Pursuant to the National Defense Authorization Act for Fiscal Year 2014, only a general court-martial has jurisdiction to try penetrative sex offenses under subsections (a) and (b) of Article 120, subsections (a) and (b) of Article 120b, Article 125, and attempts to commit such penetrative sex offenses under Article 80.''

(z) The Discussion sections to R.C.M. 406(b)(4), R.C.M. 503(a)(1), and

707(c)(1) are amended by changing ''investigating officer'' to ''preliminary hearing officer'' for preliminary hearings occurring on or after 26 December 2014.

(aa) The Discussion section to R.C.M. 701(a)(6)(c) is amended by changing ''report of Article 32 investigation'' to ''report of Article 32 preliminary hearing'' for preliminary hearings occurring on or after 26 December 2014.

(bb) The Discussion sections to R.C.M. 705(d)(2) and R.C.M. 919(b) are amended by changing ''Article 32 investigation'' to ''Article 32 preliminary hearing'' for preliminary hearings occurring on or after 26 December 2014.

Section 2. Part IV, Punitive Articles, is Amended as Follows:

A new Discussion section is added immediately after Paragraph 16, Article 92—Failure to obey order or regulation, subsection subparagraph e(3)(d):

[Note: In cases where the dereliction of duty resulted in death or grievous bodily harm, add the following as applicable]

(d) That such dereliction of duty resulted in death or grievous bodily harm to a person other than the accused.

Discussion

''If the dereliction of duty resulted in death, the accused may also be charged under Article 119 or Article 134 (negligent homicide), as applicable.''

Section 3. Appendix 21, Analysis of the Rules for Courts-Martial, is Amended as Follows:

(a) The Analysis for Rule 201 is amended by inserting the following at the end:

''*2015 Amendment:* The discussion was amended in light of Solorio v. United States, 483 U.S. 435 (1987). *Solorio* overruled *O'Callahan* v. *Parker,* 395 U.S. 258 (1969), which had held that an offense under the Code could not be tried by court-martial unless the offense was ''service connected.'' *Solorio* overruled *O'Callahan.* The amendment strikes language that was inadvertently left in prior revisions of the Manual.''

(b) The Analysis for Rule 201(f) is amended by inserting the following at the end:

''(f) *2015 Amendment:* R.C.M. 201(f)(2)(D) was created to implement Section 1705(c) of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013, and applies to offenses occurring on or after 24 June 2014.''

(c) The Analysis for Rule 305 is amended by inserting the following at the end:

''(i) *2015 Amendment:* R.C.M. 305(i)(2) was revised to implement Articles 6b(a)(2)(E) and 6b(a)(4)(A), UCMJ, as created by Section 1701 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013.''

(d) The Analysis for Rule 305 is amended by inserting the following at the end:

''(n) *2015 Amendment:* R.C.M. 305(n) was created to implement Article 6b(a)(2)(E), UCMJ, as created by Section 1701 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013.''

(e) A new Analysis section is inserted for Rule 404A and reads as follows:

''*2015 Amendment:* This is a new rule created to implement Section 1702(a) of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013, and applies to preliminary hearings occurring on or after 26 December 2014.

(f) The Analysis to Rule 405 is amended to read as follows:

''*2015 Amendment:* This rule was created to implement Section 1702(a) of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013. This new rule took effect on 26 December 2014 pursuant to Section 531(g)(1) of the National Defense Authorization Act for Fiscal Year 2015, P.L. 113–291, 19 December 2014, and applies to preliminary hearings occurring on or after 26 December 2014.''

(g) The Analysis to Rule 601 is amended in paragraph (f) by removing the word ''new'' before ''provision.''

(h) The Analysis to Rule 601 is amended by inserting the following at the end:

''*2015 Amendment:* (g) Parallel convening authorities. The intent of this new provision is to allow a successor convening authority to exercise full authority over charges, without having to effectuate re-referral or potentially a new trial. The subsection incorporates a recommendation of the May 2013 report of the Defense Legal Policy Board (DLPB), Report of the Subcommittee on Military Justice in Combat Zones. The DLPB is a Federal Advisory Committee established to provide independent advice to the Secretary of Defense. The DLPB found that an inhibition to retaining cases in an area of operations is the inability of a convening authority to transmit a case to another convening authority after referral of charges without having to withdraw the charges.''

(i) The Analysis to Rule 702 is amended by inserting the following at the end:

''*2015 Amendment:* This rule was revised to implement Article 49, UCMJ, as amended by Section 532 of the Carl Levin and Howard P. ''Buck'' McKeon National Defense Authorization Act for Fiscal Year 2015, P.L. 113–291, 19 December 2014.''

(j) The Analysis to Rule 801(a) is amended by inserting the following at the end:

''*2015 Amendment:* R.C.M. 801(a)(6) was created to implement Section 1701 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013.''

(k) The Analysis to Rule 806(b) is amended by inserting the following at the end:

''*2015 Amendment:* R.C.M. 806(b)(2) was revised to implement Article 6b(a)(2), Article 6b(a)(3), and Article 6b(a)(5), UCMJ, as created by Section 1701 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013.''

(l) The Analysis to Rule 906(b) is amended by inserting the following at the end:

''*2015 Amendment:* R.C.M. 906(b)(8) was revised to implement Articles 6b(a)(2)(E) and 6b(a)(4)(A), UCMJ, as created by Section 1701 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013.''

(m) The Analysis to Rule 1001(a) is amended by inserting the following at the end:

''*2015 Amendment:* R.C.M. 1001(a)(1) was revised to implement Article 6b(a)(4)(B), UCMJ, as created by Section 1701 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013.''

(n) A new Analysis section is inserted for Rule 1001A and reads as follows:

''*2015 Amendment:* R.C.M. 1001A was added to implement Article 6b(a)(4)(B), UCMJ, as created by Section 1701 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013, concerning the right of a victim to be reasonably heard at a sentencing hearing relating to the offense. It is consistent with the principles of law and federal practice prescribed in 18 U.S.C. 3771(a)(4) and Federal Rule of Criminal Procedure 32(i)(4)(B), which requires the court to ''address any victim of the crime who is present at sentencing'' and ''permit the victim to be reasonably heard.'' *See* 10 U.S.C. 836(a). Additionally, the June 2014 report of the Response Systems to Adult Sexual Assault Crimes Panel (RSP) recommended that the President prescribe appropriate regulations to provide victims the right to make an unsworn victim impact statement, not subject to cross examination, during the

presentencing proceeding. The RSP was a congressionally mandated panel tasked to conduct an independent review and assessment of the systems used to investigate, prosecute, and adjudicate crimes involving adult sexual assault and related offenses.''

(o) The Analysis to Rule 1103A is amended by inserting the following at the end:

''*2015 Amendment:* This rule shall be implemented in a manner consistent with Executive Order 13526, as amended, concerning classified national security information.''

(p) The Analysis to Rule 1105(b) is amended by inserting the following at the end:

''*2015 Amendment:* R.C.M. 1105(b) was revised to implement Section 1706 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013, and applies to offenses occurring on or after 24 June 2014.''

(q) The Analysis to Rule 1107(b) is amended by inserting the following at the end:

''2015 Amendment: This subsection was revised to implement Article 60(c), UCMJ, as amended by Section 1702 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013, as well as Section 1706 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013, and applies to offenses occurring on or after 24 June 2014. For offenses occurring prior to 24 June 2014, refer to prior versions of R.C.M. 1107(b).''

(r) The Analysis to Rule 1107(c) is amended to read as follows:

''*2015 Amendment:* This subsection was substantially revised to implement Article 60(c), UCMJ, as amended by Section 1702 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013, and applies to offenses occurring on or after 24 June 2014. For offenses occurring prior to 24 June 2014, refer to prior versions of R.C.M. 1107(c).''

(s) The Analysis to Rule 1107(d) is removed and new analysis is amended to read as follows:

''*2015 Amendment:* This subsection was substantially revised to implement Article 60(c), UCMJ, as amended by Section 1702 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013, and applies to offenses occurring on or after 24 June 2014. For offenses occurring prior to 24 June 2014, refer to prior versions of R.C.M. 1107(d).''

(t) The Analysis to Rule 1107(f) is amended by inserting the following at the end:

''*2015 Amendment:* This subsection was revised to implement Article 60(c), UCMJ, as amended by Section 1702 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013, and applies to offenses occurring on or after 24 June 2014. For offenses occurring prior to 24 June 2014, refer to prior versions of R.C.M. 1107(f).''

(u) The Analysis to Rule 1108(b) is amended by inserting the following at the end:

''*2015 Amendment:* This subsection was revised to implement Article 60(c), UCMJ, as amended by Section 1702 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013, and applies to offenses occurring on or after 24 June 2014. For offenses occurring prior to 24 June 2014, refer to prior versions of R.C.M. 1108(b).''

(v) The Analysis to Rule 1301(c) is amended by inserting the following at the end:

''*2015 Amendment:* This subsection was revised to implement Section 1705 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013, and applies to offenses occurring on or after 24 June 2014.''

Section 4. Appendix 22, Analysis of the Military Rules of Evidence, is Amended as Follows:

(a) The Analysis to Rule 404 is amended by inserting the following at the end:

''*2015 Amendment:* This rule was revised to implement Section 536 of the Carl Levin and Howard P. ''Buck'' McKeon National Defense Authorization Act for Fiscal Year 2015, P.L. 113–291, 19 December 2014.''

(b) The Analysis to Rule 412 is amended by inserting the following at the end:

''*2015 Amendment:* Rule 412(c)(2) was revised in accordance with *LRM* v. *Kastenberg,* 72 M.J. 364 (C.A.A.F. 2013), and Section 534(c) of the Carl Levin and Howard P. ''Buck'' McKeon National Defense Authorization Act for Fiscal Year 2015, P.L. 113–291, 19 December 2014.''

(c) The Analysis to Rule 513 is amended by inserting the following at the end:

''*2015 Amendment:* Rule 513(e)(2) was revised in accordance with *LRM* v. *Kastenberg,* 72 M.J. 364 (C.A.A.F. 2013), and Sections 534(c) and 537 of the Carl Levin and Howard P. ''Buck'' McKeon National Defense Authorization Act for Fiscal Year 2015, P.L. 113–291, 19 December 2014.''

(d) The Analysis to Rule 514 is amended by inserting the following at the end:

''*2015 Amendment:* Rule 514(e)(2) was revised in accordance with *LRM* v. *Kastenberg,* 72 M.J. 364 (C.A.A.F. 2013), and Section 534(c) of the Carl Levin and Howard P. ''Buck'' McKeon National Defense Authorization Act for Fiscal Year 2015, P.L. 113–291, 19 December 2014. Rule 514 was also revised to protect communications made to the Department of Defense Safe Helpline, which is a crisis support service for victims of sexual assault in the Department of Defense. The Department of Defense Safe Helpline was established in 2011 under a contract with the Rape, Abuse & Incest National Network. Rule 514(e) was amended to adopt a legal threshold that must be satisfied before a military judge may order an in camera review of records or communications falling within the privilege. While not required by Section 537 of the Carl Levin and Howard P. ''Buck'' McKeon National Defense Authorization Act for Fiscal Year 2015, the Rule 514 threshold was modeled after the Rule 513 threshold required by that Section.''

(e) The Analysis to Rule 615 is amended by inserting the following at the end:

''*2015 Amendment:* Rule 615(e) was revised to implement Section 1701 of the National Defense Authorization Act for Fiscal Year 2014, P.L. 113–66, 26 December 2013.''

Section 5. Appendix 23, Analysis of Punitive Articles, is Amended as Follows:

Paragraph 16, Article 92—Failure to obey order or regulation, is amended by inserting the following at the end:

''*2015 Amendment:* Subparagraph b(3) was amended to increase the punishment for dereliction of duty when such dereliction results in grievous bodily harm or death. Subsection b(3)(d) incorporates a recommendation of the May 2013 report of the Defense Legal Policy Board (DLPB), Report of the Subcommittee on Military Justice in Combat Zones. The DLPB is a Federal Advisory Committee established to provide independent advice to the Secretary of Defense. The DLPB subcommittee primarily focused on civilian casualties in a deployed environment, and the DLPB found that the maximum punishment for dereliction of duty was not commensurate with the potential consequences of dereliction resulting in civilian casualties. The DLPB also found that the available punishment did not make alternative dispositions to court-martial a practical option because there was little incentive for an accused to accept these alternatives. This rule expands on the recommendation of the

DLPB and includes elevated maximum punishment for dereliction of duty that results in death or grievous bodily harm suffered by any person.''

Dated: July 2, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–16696 Filed 7–7–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Business Board; Notice of Federal Advisory Committee Meeting

AGENCY: DoD.

ACTION: Meeting notice.

SUMMARY: The Department of Defense is publishing this notice to announce the following Federal advisory committee meeting of the Defense Business Board. This meeting is open to the public.

DATES: The public meeting of the Defense Business Board (''the Board'') will be held on Thursday, July 23, 2015. The meeting will begin at 1:30 p.m. and end at 3:15 p.m. (Escort required; see guidance in the **SUPPLEMENTARY INFORMATION** section, ''Public's Accessibility to the Meeting.'')

ADDRESSES: Room 3E863 in the Pentagon, Washington, DC (Escort required; See guidance in the **SUPPLEMENTARY INFORMATION** section, ''Public's Accessibility to the Meeting.'')

FOR FURTHER INFORMATION CONTACT: The Board's Designated Federal Officer is Marcia Moore, Defense Business Board, 1155 Defense Pentagon, Room 5B1088A, Washington, DC 20301–1155, *marcia.L.moore12.civ@mail.mil,* 703–695–7563. For meeting information please contact Mr. Steven Cruddas, Defense Business Board, 1155 Defense Pentagon, Room 5B1088A, Washington, DC 20301–1155, *steven.m.cruddas.ctr@mail.mil,* (703) 697–2168. For submitting written comments or questions to the Board, send via email to mailbox address: *osd.pentagon.odam.mbx.defense-business-board@mail.mil.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The Board will hear an update from the Task Group on ''*Best Practices for Real Property Management.''* The Board will also deliberate the findings and recommendations from the Task Group on ''*Fostering an Innovative Culture through Corporate Engagement and Partnership.''*

The mission of the Board is to examine and advise the Secretary of Defense on overall DoD management and governance. The Board provides independent advice which reflects an outside private sector perspective on proven and effective best business practices that can be applied to DoD.

Availability of Materials for the Meeting: A copy of the agenda and the terms of reference for each Task Group study may be obtained from the Board's Web site at *http://dbb.defense.gov/meetings.* Copies will also be available at the meeting.

Meeting Agenda:

1:30 p.m.–1:40 p.m.—Opening remarks

1:40 p.m.–2:00 p.m.—Task Group Update on *''Best Practices for Real Property Management.''*

2:00 p.m.–3:15 p.m.—Task Group Out-brief and Board Deliberations on *''Fostering an Innovative Culture through Corporate Engagement and Partnership.''*

If time permits, the Board will hear oral comments. Written public comments are strongly encouraged.

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is limited and is on a first-come basis. All members of the public who wish to attend the public meeting must contact Mr. Steven Cruddas at the number listed in the **FOR FURTHER INFORMATION CONTACT** section no later than 12:00 p.m. on Thursday, July 16, 2015 to register and make arrangements for a Pentagon escort, if necessary. Public attendees requiring escort should arrive at the Pentagon Metro Entrance with sufficient time to complete security screening no later than 1:00 p.m. on July 23. To complete security screening, please come prepared to present two forms of identification and one must be a pictured identification card.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Mr. Cruddas at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Procedures for Providing Public Comments

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written comments to the Board about its mission and topics pertaining to this public meeting.

Written comments should be received by the DFO at least five (5) business days prior to the meeting date so that the comments may be made available to the Board for their consideration prior to the meeting. Written comments should be submitted via email to the email address for public comments given in the **FOR FURTHER INFORMATION CONTACT** section in either Adobe Acrobat or Microsoft Word format. Please note that since the Board operates under the provisions of the Federal Advisory Committee Act, as amended, all submitted comments and public presentations will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the Board's Web site.

Dated: July 1, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–16630 Filed 7–7–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Independent Review Panel on Military Medical Construction Standards; Notice of Federal Advisory Committee Meeting; Cancellation

AGENCY: Department of Defense (DoD).

ACTION: Notice of meeting; cancellation.

SUMMARY: On Tuesday, June 23, 2015 (80 FR 35943–35944), the Department of Defense published a notice announcing a meeting of the Independent Review Panel on Military Medical Construction Standards (''the Panel''), which was scheduled for Tuesday, July 14, 2015. This notice announces the cancellation of the July 14, 2015 meeting. Due to the Panel's desire to present a more inclusive report for public deliberation that further addresses the requirement, the scheduled Panel meeting on July 14, 2015 is cancelled.

FOR FURTHER INFORMATION CONTACT: Ms. Christine Bader, *christine.e.bader.civ@mail.mil,* (703) 681–6653 or Ms. Kendal Brown, *kendal.l.brown2.ctr@mail.mil,* (703) 681–6670.

SUPPLEMENTARY INFORMATION:

Meeting Announcement: Due to the Panel's desire to present a more inclusive report for public deliberation

that further addresses the requirement, the scheduled Panel meeting on July 14, 2015 is cancelled.

The Department of Defense, at the request of the members of the Independent Review Panel on Military Medical Construction Standards, has cancelled the previously announced meeting scheduled for July 14, 2015. The meeting will be rescheduled at a later date and announced according to 5 U.S.C., Appendix, section 10, and 41 CFR 102–3.150. Since the Designated Federal Officer for the Independent Review Panel on Military Medical Construction Standards was unable to provide public cancellation notification in sufficient time, as required by 41 CFR 102–3.150(a), the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day cancellation notification requirement.

Dated: July 2, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–16709 Filed 7–7–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0088]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Fast Response Survey System (FRSS) 107: Programs and Services for High School English Learners 2015

AGENCY: IES/National Center For Education Statistics, Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before August 7, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0088 via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* 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, Mailstop L–OM–2–2E319, Room 2E103, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kashka Kubzdela, 202–502–7411.

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: Fast Response Survey System (FRSS) 107: Programs and Services for High School English Learners 2015.

OMB Control Number: 1850–0733.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: School Districts (local government).

Total Estimated Number of Annual Responses: 1,700.

Total Estimated Number of Annual Burden Hours: 4,520.

Abstract: The Fast Response Survey System (FRSS) and the Postsecondary Education Quick Information System (PEQIS) collect issue-oriented data quickly and with minimum response burden outside of NCES' large recurring surveys. Both systems were designed to collect and report data on key education issues at the elementary and secondary levels, and to meet the data needs of Department of Education analysts, planners, and decision-makers when information cannot be collected quickly through NCES's large recurring surveys. The purpose of the FRSS 107 survey is to collect, beginning in September 2015, the first nationally representative data from school districts on programs and services designed to serve high school English Learners (ELs). Topics include instructional programs/approaches provided for high school ELs, the presence and characteristics of newcomer programs, use of online or computer-based programs to address the needs of English learners, participation of high school ELs in various district programs and services (*e.g.,* summer school, tutoring, career and technical training), presence of programs or services designed specifically for ELs in high school, materials and services that the district has available in native languages for high school ELs and their parents/guardians, use of native language for content instruction and for instructional support, information about types of educational programs or services that the district provides to ELs ages 18 to 21 seeking to newly enroll in the district, and the extent to which the district considers various factors (*e.g.,* English proficiency level, literacy in native language) when providing information about educational programs or services available to ELs ages 18 to 21 who are seeking to newly enroll in the district.

Dated: July 1, 2015.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–16660 Filed 7–7–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0089]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; 2016 Main National Assessment of Educational Progress (NAEP) Administration

AGENCY: IES/National Center for Education Statistics, Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a reinstatement of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before August 7, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0089 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov*. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will only accept comments during the comment period in this mailbox when the regulations.gov site is not available. 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, Mailstop L–OM–2–2E319, Room 2E103, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kashka Kubzdela, (202) 502–7411.

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: 2016 Main National Assessment of Educational Progress (NAEP) Administration

OMB Control Number: 1850–0790

Type of Review: A revision of an existing information collection

Respondents/Affected Public: Individuals

Total Estimated Number of Annual Responses: 74,193

Total Estimated Number of Annual Burden Hours: 40,156

Abstract: The National Assessment of Educational Progress (NAEP) is a federally authorized survey of student achievement at grades 4, 8, and 12 in various subject areas, such as mathematics, reading, writing, science, U.S. history, civics, geography, economics, and the arts. In the current legislation that reauthorized NAEP (20 U.S.C. 9622), Congress again mandated the collection of national education survey data through a national assessment program. This submission is for the 2016 Main NAEP and contains the following survey instruments: Grades 4, 8, and 12 core (demographic) student questions; grade 8 arts subject-specific student questions; grades 4 and 8 reading subject-specific student questions; grades 4 and 8 mathematics subject-specific student questions; grades 8 and 12 writing subject-specific student questions; grades 4 and 8 Puerto Rico Proof of Concept Study questions; grades 4 and 8 teacher questionnaires; and grades 4, 8, and 12 school questionnaires.

Dated: July 1, 2015.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2015–16661 Filed 7–7–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Savannah River Site

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River Site. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES:

Monday, July 27, 2015 1:00 p.m.–4:50 p.m.

Tuesday, July 28, 2015 8:30 a.m.–4:00 p.m.

ADDRESSES: New Ellenton Community Center, 212 Pine Hill Ave., New Ellenton, SC 29809.

FOR FURTHER INFORMATION CONTACT: de'Lisa Carrico, Office of External Affairs, Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, SC 29802; Phone: (803) 952–8607.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

Monday, July 27, 2015

1:00 p.m. Opening and Agenda Review
1:25 p.m. Work Plan Update
1:35 p.m. Combined Committees Session

Order of committees:

- Strategic & Legacy Management
- Administrative & Outreach
- Facilities Disposition & Site Remediation
- Waste Management
- Nuclear Materials

4:35 p.m. Public Comments Session
4:50 p.m. Adjourn

Tuesday, July 28, 2015

8:30 a.m. Opening, Pledge, Approval of Minutes, Chair Update, and Agenda Review

9:00 a.m. Agency Updates
10:15 a.m. Waste Management Committee Report
10:30 a.m. Break
10:45 a.m. Administrative & Outreach Committee Report
11:00 a.m. Public Comment
11:15 a.m. Lunch Break
1:15 p.m. Facilities Disposition & Site Remediation Committee Report
2:15 p.m. Break
2:30 p.m. Nuclear Materials Committee Report
3:15 p.m. Strategic & Legacy Management Committee Report
3:45 p.m. Public Comment
4:00 p.m. Adjourn

Public Participation: The EM SSAB, Savannah River Site, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact de'Lisa Carrico at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact de'Lisa Carrico's office at the address or telephone listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Gerri Flemming at the address or phone number listed above. Minutes will also be available at the following Web site: *http://cab.srs.gov/srs-cab.html.*

Issued at Washington, DC, on July 2, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–16688 Filed 7–7–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Advanced Scientific Computing Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of Renewal.

SUMMARY: Pursuant to section 14(a)(2)(A) of the Federal Advisory Committee Act (Pub. L. 92–463), and in accordance with Title 41 of the Code of Federal Regulations, section 102.3.65(a), and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the Advanced Scientific Computing Advisory Committee will be renewed for a two-year period beginning on July 1, 2015.

The Committee will provide advice to the Director, Office of Science (DOE), on the Advanced Scientific Computing Research Program managed by the Office of Advanced Scientific Computing Research.

Additionally, the renewal of the Advanced Scientific Computing Advisory Committee has been determined to be essential to the conduct of the Department of Energy business and to be in the public interest in connection with the performance of duties imposed upon the Department of Energy, by law and agreement. The Committee will operate in accordance with the provisions of the Federal Advisory Committee Act, adhering to the rules and regulations in implementation of that Act.

FOR FURTHER INFORMATION CONTACT: Mrs. Christine Chalk at (301) 903–7486.

Issued in Washington DC, on July 1, 2015.

LaTanya R. Butler,

Acting Committee Management Officer.

[FR Doc. 2015–16689 Filed 7–7–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13809–002]

Lock+TM Hydro Friends Fund XLVIII; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On March 27, 2015, Lock+TM Hydro Friends Fund XLVIII filed an application for a preliminary permit under section 4(f) of the Federal Power Act proposing to study the feasibility of the proposed Mississippi River Lock and Dam 14 Hydropower Project No. 13809–002, to be located at the existing U.S. Army Corps of Engineers' Mississippi River Lock and Dam No. 14 near the city of Hampton, Rock Island County, Illinois. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would be located completely within lands owned by the United States and consist of: (1) Three 105-foot-wide, 40-foot-hight Large Frame Modules (LFM) each containing seven 860 kilowatt (kW) hydropower turbines for a total installed capacity of 18,060 kW; (2) a debris screen and fish screen placed upstream of the LFM; (3) a 50-foot-long tailrace; (4) a switchyard adjacent to the LFM installation and containing a new transformer and control room; (5) a 3.5-mile-long, 69 kilovolt transmission line connecting the generating power to the local grid using an existing substation; and (6) appurtenant facilities. The LFM would be installed upstream of the dam in a single row across the Mississippi River on the side of the river farthest away from the navigational lock. The LFM would be anchored to new pilings or a concrete gravity structure in the river bed. The project is estimated to generate 102,000 megawatt hours annually.

Applicant Contact: Mr. Wayne F. Krouse, Chairman, Hydro Green Energy, LLC, Managing Partner, Lock+™ Hydro Friends Fund XLVIII, PO Box 43796, Birmingham, AL 35243; phone: 877–556–6566, extension 709.

FERC Contact: Sergiu Serban, (202) 502–6211.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications 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–13809–002.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13809) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: June 30, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–16684 Filed 7–7–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–495–000]

Columbia Gas Transmission, LLC; Notice of Intent To Prepare an Environmental Assessment for the Proposed Line 138 Abandonment and Lateral Construction Project, and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Line 138 Abandonment and Lateral Construction Project involving abandonment, construction, and operation of facilities by Columbia Gas Transmission, LLC (Columbia) in Fayette and Somerset Counties, Pennsylvania; Preston County, West Virginia; and Garret County, Maryland. The Commission will use this EA in its decision- making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EA. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before July 30, 2015.

If you sent comments on this project to the Commission before the opening of this docket on May 20, 2015, you will need to file those comments in Docket No. CP15–495–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

Columbia has provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site (*www.ferc.gov*).

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.''* If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number CP15–495–000 with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A Washington, DC 20426.

Summary of the Proposed Project

Columbia Gas proposes to abandon in place approximately 33 miles of 4-inch, 6-inch, 8-inch, 16-inch-diameter bare-steel pipeline and above ground appurtenances located on its existing Line 138 between in Fayette-Somerset Counties, Pennsylvania and Garrett County, Maryland. This section would be abandoned due to its age and condition. In addition, Columbia would construct approximately 150 feet of 2-inch-diameter pipe from its Line 1804/10240 right-of-way to the right-of-way of Line 138. Columbia would use the right-of-way of Line 138 to construct 3,350 feet of new 2-inch pipeline to connect with the Columbia of Pennsylvania Measuring Station in Somerset County, Pennsylvania to maintain service to the firm transportation customer.

Overall, the project would involve 115 separate areas of disturbance along Columbia's Line 138 in Pennsylvania, Maryland, and West Virginia. The general location of the project facilities is shown in appendix 1.[1]

Land Requirements for Construction

The proposed abandonment would disturb about 6.23 acres and the proposed lateral construction would disturb 4.83 acres of land during construction, including the temporary construction right-of-way, access roads, and contractor yards/staging areas.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [2] to discover and address concerns the public may have about proposals. This

[1] The appendices referenced in this notice will not appear in the **Federal Register.** Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- land use;
- water resources, fisheries, and wetlands;
- cultural resources;
- vegetation and wildlife; including migratory birds;
- air quality and noise;
- endangered and threatened species;
- public safety; and
- cumulative impacts.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. We may publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate with us in the preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Offices (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[4] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPOs as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the User's Guide under the ''e-filing'' link on the Commission's Web site.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site at *www.ferc.gov* using the ''eLibrary'' link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.,* C15–495). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502-8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: June 30, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–16682 Filed 7–7–15; 8:45 am]

BILLING CODE 6717–01–P

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[4] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14550–001]

New England Hydropower Company, LLC; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Exemption from Licensing.

b. *Project No.:* 14550–001.

c. *Date filed:* June 26, 2015.

d. *Applicant:* New England Hydropower Company, LLC.

e. *Name of Project:* Hanover Pond Dam Hydroelectric Project.

f. *Location:* On the Quinnipiac River, near the city of Meriden, in New Haven County, Connecticut. No federal lands would be occupied by project works or located within the project boundary.

g. *Filed Pursuant to:* Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 2705, 2708.

h. *Applicant Contact:* Mr. Michael C. Kerr, New England Hydropower Company, LLC, P.O. Box 5524, Beverly Farms, Massachusetts 01915; (978) 360–2547, *Michael@nehydropower.com*.

i. *FERC Contact:* John Ramer, (202) 502–8969, *john.ramer@ferc.gov*.

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: August 25, 2015.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. 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–14550–001.

m. The application is not ready for environmental analysis at this time.

n. The Hanover Pond Dam Hydroelectric Project would consist of: (1) An existing 25-foot-high, 150-foot-long earth embankment dam with four low-level sluice gates and a 250-foot-long concrete spillway; (2) the existing approximately 71.0-acre Hanover Pond with a storage capacity of 1,800 acre-feet at a normal operating elevation of about 87.3 feet NGVD29; (3) an existing 175-foot-long, 16.0-foot-wide fish ladder; (4) a new 8-foot-high, 12.5-foot-wide hydraulically-powered sluice gate equipped with a new 8-foot-high, 17-foot-wide trashrack with 9-inch bar spacing; (5) a new 78-foot-long, 12-foot-diameter buried precast concrete penstock; (6) a new 46.5-foot-long, 11.65-foot wide Archimedes screw generator unit, with an installed capacity of 192 kilowatts; (7) a new 12-foot-high, 18-foot-long, 16.0-foot-wide concrete powerhouse containing a new gearbox, generator, and electrical controls; (8) a new 15-foot-long, variable-width concrete tailrace; (9) a new 500-foot-long, 35-kilovolt above ground transmission line connecting the powerhouse to Connecticut Light and Power's distribution system; and (10) appurtenant facilities. The estimated annual generation of the proposed Hanover Pond Dam Project would be about 900 megawatt-hours.

o. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

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, contact FERC Online Support.

p. With this notice, we are initiating consultation with the New Hampshire State Historic Preservation Officer (SHPO), as required by section 106 of the National Historic Preservation Act and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

q. *Procedural schedule:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate (*e.g.,* study requests and/or application deficiencies may lengthen the schedule).

Issue Notice of Acceptance/Ready for Environmental Analysis—September 2015

Issue EA/Order—February 2016

Dated: June 30, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–16685 Filed 7–7–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF14–22–000]

Tennessee Gas Pipeline Company, L.L.C.; Notice of Intent To Prepare an Environmental Impact Statement for the Planned Northeast Energy Direct Project, Request for Comments on Environmental Issues, and Notice of Public Scoping Meetings

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental impact statement (EIS) that will discuss the environmental impacts of the Northeast Energy Direct Project (Project) involving construction and operation of facilities by Tennessee Gas Pipeline Company, L.L.C. (Tennessee Gas) in Pennsylvania, New York, Massachusetts, New Hampshire, and Connecticut. The Commission will use this EIS in its decision-making process to determine whether the Project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the Project. You can make a difference by providing us with your specific comments or concerns about the Project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EIS. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC, on or before August 31, 2015.

If you sent comments on this project to the Commission before the opening of this docket on September 15, 2014, you will need to file those comments in Docket No. PF14–22–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this Project. State and local government representatives should notify their constituents of this planned Project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a Tennessee Gas representative may contact you about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the Project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' is available for viewing on the FERC Web site for Citizen's Guides (*http://www.ferc.gov/for-citizens/citizen-guides.asp*). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Public Participation

For your convenience, there are four methods you can use to submit your comments to the Commission. The Commission will provide equal consideration to all comments received, whether filed in written form or provided verbally. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov*. Please carefully follow these instructions so that your comments are properly recorded.

You can file your comments electronically using the *eComment* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for interested persons to submit brief, text-only comments on a project;

You can file your comments electronically by using the *eFiling* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister*.'' If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type;

You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Be sure to reference the Project docket number PF14–22–000 with your submission; or

In lieu of sending written or electronic comments, the Commission invites you to attend one of the public scoping meetings its staff will conduct in the Project area, scheduled as follows.

FERC PUBLIC SCOPING MEETINGS

Date and time	Location	Location
Tuesday, July 14, 2015, 7:00 p.m.	Towanda Jr./Sr. High School, 1 High School Drive, Towanda, PA 18848, (570) 265–2101.	Birch Hill Catering, 1 Celebration Way, Castleton-on-Hudson, NY 12033, (518) 732–4444.
Wednesday, July 15, 2015, 6:30 p.m.	VFW, 386 Main St., Great Bend, PA 18848, (570) 879–4420.	Birch Hill Catering, 1 Celebration Way, Castleton-on-Hudson, NY 12033, (518) 732–4444.
Thursday, July 16, 2015, 7:00 p.m.	Foothills Performing Arts Center, 24 Market St., Oneonta, NY 13820, (607) 431–2080.	Days Inn, 160 Holiday Way, Schoharie, NY 12157, (518) 295–6088.
Tuesday, July 28, 2015, 7:00 p.m.	Taconic High School, 96 Valentine Rd., Pittsfield, MA 01201, (413) 448–9600.	
Wednesday, July 29, 2015, 6:30 p.m.	Nashua Radisson, 11 Tara Blvd., Nashua, NH 03062, (603) 888–9970.	Greenfield Middle School, 141 Davis St., Greenfield, MA 01301, (413) 772–1360.
Thursday, July 30, 2015, 6:30 p.m.	Milford Town Hall, Town Hall, One Union Square, Milford, NH 03055, (603) 249–0600.	Central Connecticut State University, 1615 Stanley St., New Britain, CT 06050, (860) 832–3200.
Tuesday, August 11, 2015, 7:00 p.m.	Dracut Senior High School, 1540 Lakeview Ave., Dracut, MA 01826, (978) 957–1500.	
Wednesday, August 12, 2015, 7:00 p.m.	Lunenburg High School, 1079 Massachusetts Ave., Lunenburg, MA 01462, (978) 582–4115.	

Please note that on five nights (July 14–16 and July 29–30), meetings will be held concurrently in two different locations. The same information will be presented at all of the meetings.

We [1] are planning on holding one additional scoping meeting near Winchester, New Hampshire, during the week of July 27–31, 2015. We will announce this meeting with a future notice once the location is finalized.

We will begin our sign up of speakers one hour prior to the start of each meeting. The scoping meetings will begin with a description of our environmental review process by Commission staff, after which speakers will be called. Each meeting will end once all speakers have provided their comments or when our contracted time for the facility closes. Please note that there may be a time limit to present comments (no less than 3 minutes), and speakers should structure their comments accordingly. If time limits are implemented, they will be strictly enforced to ensure that as many individuals as possible are given an opportunity to comment. The meetings will be recorded by a stenographer to ensure comments are accurately recorded. Transcripts will be entered into the formal record of the Commission proceeding.

Please note that this is not your only public input opportunity; please refer to the review process flow chart in appendix 1.[2]

[1] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[2] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202)

Summary of the Planned Project

Tennessee Gas plans to construct and operate approximately 412 miles of new natural gas transmission pipeline and associated facilities in Pennsylvania, New York, Massachusetts, New Hampshire, and Connecticut. This Project would also involve modifications at existing compressor and meter stations and construction of 9 new compressor stations, 14 new meter stations, and various appurtenant facilities. These facilities would be capable of providing 2.2 billion cubic feet per day of capacity to transport natural gas to markets in the northeastern United States and Canada.

The pipeline planned for construction includes supply path and market path components. The Supply Path component would deliver gas from the existing Tennessee Gas 300 Line to its existing 200 Line near Wright, New York. The Supply Path would include approximately 135 miles in Pennsylvania and New York, as well as 32 miles of pipeline loop along the 300 Line in Pennsylvania.

The Market Path would include approximately 188 miles of pipeline extending from Wright, New York, into Massachusetts and New Hampshire and then ending in Dracut, Massachusetts. The Market Path would generally be collocated with existing linear infrastructure.

In addition, the Project would include construction of nine pipeline laterals, loops,[3] or delivery lines in Massachusetts (38 miles), Connecticut (15 miles), and New Hampshire (7 miles) to provide natural gas to local markets.

The general location of the Project facilities is shown in appendix 2.

Land Requirements for Construction

Construction of the planned facilities would disturb about 6,761 acres of land for the pipeline and aboveground facilities, not including temporary access roads which are not yet determined. Following construction, Tennessee Gas would maintain about 2,602 acres for permanent operation of the Project's facilities, not including permanent access roads; the remaining acreage would be restored and revert to former uses. About 82 percent of the planned pipeline route parallels existing pipeline and utility rights-of-way.

502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[3] A pipeline loop is a segment of pipe constructed parallel to an existing pipeline to increase capacity.

The EIS Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us to discover and address concerns the public may have about proposals. This process is referred to as scoping. The main goal of the scoping process is to focus the analysis in the EIS on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EIS. We will consider all filed comments during the preparation of the EIS.

In the EIS we will discuss impacts that could occur as a result of the construction and operation of the planned Project under these general headings:

Geology and soils;
water resources and wetlands;
vegetation and wildlife;
cultural resources;
land use, recreation, and visual resources;
socioeconomics;
air quality and noise;
cumulative impacts; and
public safety.

As part of our analysis under NEPA, we will consider or recommend measures to avoid, minimize, or mitigate impacts on specific resources. We will also evaluate possible alternatives to the planned Project or portions of the Project. Tennessee Gas has proposed a number of alternatives, developed through the company's route selection process or identified by stakeholders, in draft Resource Report 10 filed with the FERC in Docket No. PF14–22–000 on March 13, 2015. During scoping, we are specifically soliciting comments on the range of alternatives for the Project.

Although no formal application has been filed, we have already initiated our environmental review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the FERC receives a formal application from Tennessee Gas. During the pre-filing process, we have contacted federal and state agencies to discuss their involvement in scoping and the preparation of the EIS.

The EIS will present our independent analysis of the issues. We will publish and distribute the draft EIS for public comment. After the comment period, we will consider all timely comments and revise the document, as necessary, before issuing a final EIS. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to this Project to formally cooperate with us in the preparation of the EIS.[4] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for Section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Offices (SHPOs), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[5] We will define the Project-specific Area of Potential Effects (APE) in consultation with the SHPOs as the Project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EIS for this Project will document our findings on the impacts on historic properties and summarize the status of consultations under Section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Indian tribes and Native American organizations; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in

[4] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[5] The Advisory Council on Historic Preservation regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for Project purposes, or who own homes within certain distances of aboveground facilities, and anyone who provides a mailing address when they submit comments on the Project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the planned Project.

Copies of the draft EIS will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 3).

Becoming an Intervenor

Once Tennessee Gas files its application with the Commission, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the User's Guide under the ''e-filing'' link on the Commission's Web site. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the Project.

Additional Information

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the *eLibrary* link. Click on the *eLibrary* link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.,* PF14–22–000). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called *eSubscription* which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: June 30, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–16686 Filed 7–7–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2804–033]

Goose River Hydro, Inc.; Notice of Intent To File License Application, Filing of Pre-Application Document, and Approving Use of the Traditional Licensing Process

a. *Type of Filing:* Notice of Intent to File License Application and Request to Use the Traditional Licensing Process.

b. *Project No.:* 2804–033.

c. *Date Filed:* May 29, 2015.

d. *Submitted By:* Goose River Hydro, Inc.

e. *Name of Project:* Goose River Hydroelectric Project.

f. *Location:* On the Goose River, in Waldo County, Maine. No federal lands are occupied by the project works or located within the project boundary.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. Potential *Applicant Contact:* Nicholas Cabral, Goose River Hydro, Inc., 41 Sedgewood Drive, Kennebunk, ME 04043; (207) 604–4394; email: *ncabral00@gmail.com.*

i. *FERC Contact:* Julia Kolberg at (202) 502–8261; or email at *julia.kolberg@ferc.gov.*

j. Goose River Hydro, Inc. filed its request to use the Traditional Licensing Process on May 29, 2015. Goose River Hydro, Inc. provided public notice of its request on May 29, 2015. In a letter dated June 30, 2015, the Director of the Division of Hydropower Licensing approved Goose River Hydro, Inc.'s request to use the Traditional Licensing Process.

k. With this notice, we are initiating informal consultation with the U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR part 402; and NOAA Fisheries under section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and implementing regulations at 50 CFR 600.920. We are also initiating consultation with the Maine State Historic Preservation Officer, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating Goose River Hydro, Inc. as the Commission's non-federal representative for carrying out informal consultation pursuant to section 7 of the Endangered Species Act and section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act; and consultation pursuant to section 106 of the National Historic Preservation Act.

m. Goose River Hydro, Inc. filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCONlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). A copy is also available for inspection and reproduction at the address in paragraph h.

o. The licensee states its unequivocal intent to submit an application for a new license for Project No. 2804. Pursuant to 18 CFR 16.8, 16.9, and 16.10 each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by March 20, 2018.

p. Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: June 30, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–16683 Filed 7–7–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866)208–3676, or for TTY, contact (202)502–8659.

Docket No.	File Date	Presenter or Requester
Prohibited:		
1. CP15–115–000	6/17/15	Paula Hargreaves.
2. CP15–137–000	6/18/15	Mark Hofflines.
Exempt:		
1. CP15–115–000	6/10/15	New York State Senator Robert G. Ortt.
2. CP15–138–000	6/15/15	FERC Staff.[1]
3. CP15–138–000	6/15/15	FERC Staff.[2]
4. CP13–483–000	6/15/15	FERC Staff.[3]
CP13–492–000		
5. CP14–96–000	6/15/15	U.S. Representative Stephen F. Lynch.
6. P–1494–000	6/15/15	U.S. Senator James M. Inhofe.
7. CP14–517–000	6/19/15	U.S. Senator John Cornyn.
CP14–518–000		
8. CP14–517–000	6/19/15	Texas Congressman Randy K. Weber.
CP14–518–000		
9. P–1494–000	6/19/15	U.S. Representative Markwayne Mullin.
10. CP14–96–000	6/19/15	U.S. Representative Stephen F. Lynch.
11. CP14–96–000	6/25/15	U.S. Representative Stephen L. Lynch, et al.[4]
12. CP13–483–000	6/25/15	FERC Staff.[5]
CP13–492–000		

[1] Record of June 12, 2015 telephone call with Transco Representative.

[2] Record of June 11, 2015 telephone call from landowner, Robyn Kochan.

[3] Notes from June 10, 2015 telephone conference call with federal cooperating agencies.

[4] Massachusetts State Senator Michael F. Rush, Massachusetts State Representative Edward F. Coppinger, and Boston City Councilor Matt O'Malley.

[5] Notes from June 24, 2015 telephone conference call with federal cooperating agencies.

Dated: June 29, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–16687 Filed 7–7–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0022; FRL–9929–36]

Pesticide Product Registration; Receipt of Applications for New Uses; Correction and Reopening of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; correction and reopening of comment period.

SUMMARY: EPA issued a notice in the **Federal Register** of May 6, 2015, concerning Pesticide Product Registration; Receipt of Applications for New Uses. The notice inadvertently identified the applications listed as being new active ingredients rather than new uses. This document corrects that error and also reopens the comment period for an additional 30 days. EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments, identified by the docket identification (ID) listed in the body of this document, must be received on or before August 7, 2015.

ADDRESSES: Follow the detailed instructions as provided under **ADDRESSES** in the **Federal Register** document of May 6, 2015.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

The Agency included in the **Federal Register** of May 6, 2015 (80 FR 26030) (FRL–9926–67) notice a list of those who may be potentially affected by this action.

B. How can I get copies of this document and other related information?

The dockets for these actions, identified by the following docket ID numbers: EPA–HQ–OPP–2015–0221 for Avermectin; EPA–HQ–OPP–2014–0878 for Fluazifop-p-butyl; EPA–HQ–OPP–2015–0168 for 1,2-Benzisothiazol-3(2H)-one, 2-butyl-; EPA–HQ–OPP–2015–0096 for Mandipropamid; EPA–HQ–OPP–2015–0263 for Cyazofamid; and EPA–HQ–OPP–2014–0590 for Pyrimethanil are 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.*

C. Why is the comment period being reopened?

This document reopens the public comment period for the Pesticide Product Registration; Receipt of Applications for New Uses notice, which was published in the **Federal Register** on May 6, 2015. EPA is hereby reopening the comment period 30 days because EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provision of FIFRA section 3(c)(4)(7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

II. What does this correction do?

FR Doc. 2015–10483 published in the **Federal Register** of May 6, 2015 (80 FR 26030) (FRL–9926–67) is corrected as follows:

1. On page 26030, third column, under the heading **Registration Applications**, the first paragraph, line three, correct ''active ingredients'' to read ''new uses.''

Authority: 7 U.S.C. 136 *et seq.*

Dated: June 22, 2015.

Daniel J. Rosenblatt,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2015–16519 Filed 7–7–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0296; FRL–9928–54]

Notice of Receipt of Requests To Voluntarily Cancel Certain Pesticide Registrations and Amend Registrations To Terminate Certain Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of requests by the registrants to voluntarily cancel their registrations of certain products containing the pesticides carfentrazone-ethyl, chlorsulfuron, dichlorprop-p, flufenpyr-ethyl, flutolanil, glyphosate, metsulfuron, MGK 264, paraquat dichloride, piperonyl butoxide, propoxur, pyrethrins, quizalofop, thifensulfuron-methyl, and tribenuron-methyl and to amend their malathion, propoxur, and sulfur dioxide product registrations to terminate one or more uses. The requests are to terminate the malathion use in or on cull fruits and vegetable dumps and terminate the sulfur dioxide use in or on grapes. The request would also terminate all indoor aerosol, spray, and liquid formulations of propoxur, terminate its use in food handling establishments, and terminate indoor crack and crevice use. The requests do not seek to cancel the last carfentrazone-ethyl, chlorsulfuron, dichlorprop-p, flutolanil, glyphosate, metsulfuron, MGK 264, paraquat dichloride, piperonyl butoxide, propoxur, pyrethrins, quizalofop, thifensulfuron-methyl, and tribenuron-methyl products registered for use in the United States. The requests, if granted, would terminate the last flufenpyr-ethyl products registered in the United States. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of these requests, or unless the registrants withdraw their requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the affected registrations have been

cancelled or uses terminated only if such sale, distribution, or use is consistent with the terms described in the final cancellation order.

DATES: Comments must be received on or before August 7, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2015–0296, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.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: Khue Nguyen, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0248; email address: *nguyen.khue@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

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. Background on the Receipt of Requests to Cancel and/or Amend Registrations to Terminate Uses

This notice announces receipt by EPA of requests from Syngenta Crop Protection, FMC Corporation, E. I. DuPont de Nemours and Company, Helena Chemical Company, Wellmark International, Ritter Chemical, Valent USA Corporation, Nufarm Americas, Nichino America, and Airgas USA to cancel certain product registrations and amend registrations to terminate certain uses of certain product registrations.

Carfentrazone-ethyl is a post-emergent herbicide registered for use to control broadleaf weeds in various agricultural crops, turf, aquatic areas, and industrial and utility sites. Paraquat dichloride is an herbicide registered to control weeds and grasses and as a desiccant/harvest aid in many agricultural and non-agricultural areas, including in/on vegetables, grains, cotton, grasses, fruit crops, trees, vines, and commercial buildings. In a letter to EPA dated January 6, 2015, Syngenta Crop Protection requested the cancellation of one product registration containing paraquat dichloride and one product registration containing both carfentrazone-ethyl and paraquat dichloride identified in Table 1 of Unit III. This request will not terminate the last carfentrazone-ethyl or paraquat dichloride products registered in the United States.

Chlorsulfuron is a pre- and post-emergent herbicide registered for use to control a variety of weeds on cereal grains, pasture and rangeland, industrial sites, and turf grass. In a letter to EPA dated April 20, 2015, E. I. DuPont de Nemours and Company requested that EPA cancel one product registration containing chlorsulfuron identified in Table 1 of Unit III. DuPont noted that it no longer sells or markets this registration and there were no existing stocks in the channels of trade, and therefore no existing stocks provision is requested. This request will not terminate the last chlorsulfuron pesticide products registered in the United States.

Dichlorprop-p is an herbicide registered for use to kill annual and perennial broadleaf weeds on ornamental lawns, recreational turf, sports fields, sod farms, roadsides, industrial sites, rights-of-ways, and forests. In a letter to EPA dated February 27, 2015, Nufarm Americas, Inc., requested that EPA cancel two product registrations containing dichlorprop-p identified in Table 1 of Unit III. This request will not terminate the last dichlorprop-p pesticide products registered in the United States.

Flufenpyr-ethyl is an herbicide registered for post-emergence control of broadleaf weeds in field corn, soybeans, and sugarcane. In a letter to EPA dated March 19, 2015, Valent USA Corporation requested that EPA cancel two product registrations containing flufenpyr-ethyl identified in Table 1 of Unit III because Valent no longer wished to support this active ingredient. Valent noted in an email to EPA dated April 24, 2015, that these product registrations were never manufactured and there were no existing stocks in the channels of trade, therefore no existing stocks provision is requested. This request will terminate the last flufenpyr-ethyl pesticide products in the United States.

Flutolanil is a systemic fungicide registered for use to control fungal diseases in certain food crops, including peanuts, potatoes, and rice and non-food sites such as turf, greenhouses, and ornamentals. In a letter to EPA dated March 31, 2015, Nichino America requested the cancellation of one Special Local Need (SLN) product registration identified in Table 1 of Unit III. Nichino requested cancellation of this registration because it was replaced by a more recently registered, identical SLN product under another registration number. This request will not terminate the last flutolanil pesticide products in the United States.

Glyphosate is a non-selective herbicide registered for use on many food and non-food crops as well as in non-crop areas. In a letter to EPA dated December 12, 2014, Ritter Chemical requested the cancellation of three products containing glyphosate identified in Table 1 of Unit III. This request will not terminate the last glyphosate products registered in the United States.

Malathion is a broad-spectrum organophosphate insecticide registered for use on various food and feed crops and in various non-agricultural settings including residential outdoor settings,

ornamental nursery stock, building perimeters, pastures and rangeland, and as part of regional pest eradication programs. In a letter to EPA dated April 14, 2015, Helena Chemical Company requested to amend its registration to terminate a use from a pesticide product registration identified in Table 2 of Unit III. Specifically, Helena requested amendment to terminate use on cull fruits and vegetable dumps because it no longer wished to support this use. This request will not terminate the last malathion products registered in the United States for these uses.

Metsulfuron is a sulfonylurea herbicide registered for use to control annual and perennial broadleaf weeds in certain agricultural, non-crop, and industrial areas, pasture and rangeland, turf, forestry, and marshes and wetland areas. Thifensulfuron-methyl and tribenuron-methyl are sulfonylurea herbicides registered for use on cereal grains, oilseed crops, soybeans, and cotton to control broadleaf weeds. In a letter to EPA dated April 20, 2015, E. I. DuPont de Nemours and Company requested the cancellation of one product containing metsulfuron, thifensulfuron-methyl, and tribenuron-methyl identified in Table 1 of Unit III. DuPont noted that it no longer sells or markets this registration and there were no existing stocks in the channels of trade, and therefore no existing stocks provision is requested. This request will not terminate the last metsulfuron, thifensulfuron-methyl, and tribenuron-methyl pesticide products registered in the United States.

Propoxur and pyrethrins are insecticides registered for use by pest control operators to kill a variety of insects including crickets, ants, cockroaches, silverfish and other pests. MGK 264 and piperonyl butoxide are insecticide synergists, which are designed to enhance the toxicity of other pesticides. These chemicals are registered for use in and around industrial, institutional, commercial (including food handling establishments and food processing plants), and residential facilities. In a letter to EPA dated February 6, 2015, Wellmark International requested that EPA cancel the propoxur, pyrethrins, MGK 264, and piperonyl butoxide pesticide product identified in Table 1 of Unit III. In a separate letter, dated February 6, 2015, Wellmark International requested to amend the propoxur, pyrethrins, MGK 264, and piperonyl butoxide pesticide product registrations identified in Table 2 of Unit III to terminate certain uses and certain formulation types. Specifically, Wellmark International requested that the following uses and formulations be terminated: All indoor aerosol, spray, and liquid formulations of propoxur; its use in food handling establishments; and indoor crack and crevice use. Wellmark International's requests will not terminate the last propoxur, pyrethrins, MGK 264, or piperonyl butoxide products registered in the United States, or the last propoxur, pyrethrins, MGK 264, or piperonyl butoxide pesticide products registered in the United States for these formulations or uses.

Quizalofop is a systemic herbicide registered for use to control annual and perennial weeds in various food/feed and non-food/non-feed crops. Food and feed uses include grains, legumes, cotton, garlic, soybean, and sugar beets. Non-food, non-feed uses include cottonwood and poplar plantations and uncultivated areas such as fencerows, roadsides, and paved areas. In a letter to EPA dated May 15, 2015, FMC Corporation requested the cancellation of one quizalofop product identified in Table 1 of Unit III. This request will not terminate the last quizalofop products registered in the United States.

Sulfur dioxide is a fungicide registered for use to control fungal disease on grapes. Sulfur dioxide products are formulated as a compressed liquid that converts to gas upon release and is registered for use in cold-storage warehouses, trucks, vans, and train cars for post-harvest grape fumigation. In a letter to EPA dated April 13, 2015, Airgas USA requested to amend its registration to terminate the use on grapes for the pesticide product registration identified in Table 2 of Unit III. Airgas no longer wished to support use on grapes. This request will not terminate the last sulfur dioxide products registered in the United States for this use.

III. What action is the agency taking?

This notice announces receipt by EPA of requests from registrants to cancel certain product registrations of carfentrazone-ethyl, chlorsulfuron, dichlorprop-p, flufenpyr-ethyl, flutolanil, glyphosate, metsulfuron, paraquat dichloride, propoxur, quizalofop, thifensulfuron-methyl, and tribenuron-methyl and terminate certain uses of malathion, propoxur, and sulfur dioxide product registrations. The affected products and the registrants making the requests are identified in Tables 1–3 of this unit.

Unless a request is withdrawn by the registrant or if the Agency determines that there are substantive comments that warrant further review of these requests, EPA intends to issue an order canceling the affected registrations and amending to terminate certain uses the affected registrations for which the Agency received use termination requests.

TABLE 1—CARFENTRAZONE-ETHYL, CHLORSULFURON, DICHLORPROP-P, FLUFENPYR-ETHYL, FLUTOLANIL, GLYPHOSATE, METSULFURON, MGK 264, PARAQUAT DICHLORIDE, PIPERONYL BUTOXIDE, PROPOXUR, PYRETHRINS, QUIZALOFOP, THIFENSULFURON-METHYL, AND TRIBENURON-METHYL PRODUCT REGISTRATIONS WITH REQUESTS FOR CANCELLATION

Registration number	Product name	Chemical name
100–1217	Gramoxone Inteon	Paraquat dichloride.
100–1316	Cyclone Star	Carfentrazone-ethyl, paraquat dichloride.
279–3183	Matador Herbicide	Quizalofop-p-ethyl.
352–522 [a]	DuPont Glean Fertilizer Compatible Herbicide	Chlorsulfuron.
352–586 [a]	DuPont Canvas Herbicide	Metsulfuron, thifensulfuron, tribenuron-methyl.
2724–819	Pyrocide Pressurized Ant & Roach Spray	Propoxur, pyrethrins, piperonyl butoxide, MGK 264.
9468–33	Kull 41 S	Glyphosate.
9468–34	Kull 62 MUP	Glyphosate.
9468–35	Kull TGAI Glyphosate	Glyphosate.
59639–109 [a]	Flufenpyr-ethyl Technical	Flufenpyr-ethyl.
59639–110 [a]	S–3153 WDG Herbicide	Flufenpyr-ethyl.
70596–6	Dichlorprop-p Technical	Dichlorprop-p.
70596–13	Dichlorprop-p (Technical Grade)	Dichlorprop-p.

TABLE 1—CARFENTRAZONE-ETHYL, CHLORSULFURON, DICHLORPROP-P, FLUFENPYR-ETHYL, FLUTOLANIL, GLYPHOSATE, METSULFURON, MGK 264, PARAQUAT DICHLORIDE, PIPERONYL BUTOXIDE, PROPOXUR, PYRETHRINS, QUIZALOFOP, THIFENSULFURON-METHYL, AND TRIBENURON-METHYL PRODUCT REGISTRATIONS WITH REQUESTS FOR CANCELLATION—Continued

Registration number	Product name	Chemical name
NV020006	Moncut 70–DF	Flutolanil.

[a] There are no existing stocks of these product registrations and no requests for existing stocks provisions. Therefore no existing stocks provision will be provided for these product registrations.

TABLE 2—MALATHION, PROPOXUR, AND SULFUR DIOXIDE PRODUCT REGISTRATIONS WITH REQUESTS FOR AMENDMENT TO TERMINATE ONE OR MORE USES

Registration number	Product name	Chemical name	Uses to be terminated
2724–818	Pyrocide Intermediate 7045.	Propoxur, MGK 264, piperonyl butoxide, pyrethrins.	Indoor aerosol, spray, and liquid formulations; use in food handling establishments and indoor crack and crevice use.
2724–820	Propoxur Technical Insecticide.	Propoxur	Indoor aerosol, spray, and liquid formulations; use in food handling establishments and indoor crack and crevice use.
2724–821	Propoxur 70% Concentrate	Propoxur	Indoor aerosol, spray, and liquid formulations; use in food handling establishments and indoor crack and crevice use.
5905–250	Fyfanon 8 lb. Emulsion	Malathion	Cull fruits and vegetable dumps.
89867–2	Airgas Sulfur Dioxide	Sulfur dioxide	Grapes.

Table 3 of this unit includes the names and addresses of record for the registrants of the products listed in Table 1 and Table 2 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Table 1 and Table 2 of this unit.

TABLE 3—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION AND/OR AMENDMENTS

EPA Company number	Company name and address
100	Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419.
279	FMC Corporation, 1735 Market Street, Philadelphia, PA 19103.
352	E.I. DuPont de Nemours and Company, 1007 Market St., Wilmington, DE 19898.
5905	Helena Chemical Company, 7664 Smythe Farm Road, Memphis, TN 38120.
2724	Wellmark International, 1501 E. Woodfield Road, Suite 200, West Schaumburg, IL 60173.
9468	Ritter Chemical, LLC, 9300 Baythorne Dr., Houston, TX 77041.
59639	Valent USA Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596.
70596	Nufarm Americas, Inc., 4020 Aerial Center Parkway, Suite 101, Morrisville, NC 27560.
71711	Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808.
89867	Airgas USA, LLC, 7217 Lancaster Pike, Suite A, P.O. Box 640, Hockessin, DE 19707.

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

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA (7 U.S.C. 136d(f)(1)(B)) requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) (7 U.S.C. 136d(f)(1)(C)) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrants request a waiver of the comment period, or

2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The carfentrazone-ethyl, chlorsulfuron, dichlorprop-p, flufenpyr-ethyl, flutolanil, glyphosate, malathion, metsulfuron, paraquat dichloride, quizalofop, sulfur dioxide, thifensulfuron-methyl, tribenuron-methyl registrants have requested that EPA waive the 180-day comment period. Accordingly, EPA will provide a 30-day comment period on the proposed product cancellations and use terminations. Because propoxur is not registered for any minor agricultural uses, this 180-day comment provision does not apply, and EPA is providing a 30-day comment period on the proposed propoxur product cancellations and use terminations.

V. Procedures for Withdrawal of Requests

Registrants who choose to withdraw a request for product cancellation or use termination should submit the withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the action. If the requests for voluntary cancellation and amendments to terminate uses are granted, the Agency intends to publish the cancellation order in the **Federal Register**.

In any order issued in response to these requests for cancellation of product registrations and for amendments to terminate uses, EPA proposes to include the following provisions for the treatment of any existing stocks of the products listed in Tables 1 and 2 of Unit III.

A. For Products 352–522, 352–586, and 59639–109 Identified in Table 1 of Unit III

The registrants reported to the Agency via written correspondence that there are no existing stocks of EPA registration numbers 352–522, 352–586, and 59639–109. Therefore, no existing stocks provision was requested by or is needed for these registrants. The registrants will be prohibited from selling or distributing these products upon cancellation of these products, except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks of the affected products until such stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled product.

B. For All Other Products Identified in Table 1 of Unit III

For the other voluntary product cancellations noted in Table 1 of Unit III, the registrants will be permitted to sell and distribute existing stocks of voluntarily canceled products for 1 year after the effective date of the cancellation, which will be the date of publication of the cancellation order in the **Federal Register**. Thereafter, registrants will be prohibited from selling or distributing the products identified in Table 1 of Unit III., except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

Persons other than the registrant may sell, distribute, or use existing stocks of the affected canceled products until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

C. For All Products Identified in Table 2 of Unit III

Once EPA has approved product labels reflecting the requested amendments to terminate uses for the products identified in Table 2 of Unit III, registrants will be permitted to sell or distribute products under the previously approved labeling for a period of 18 months after the date of **Federal Register** publication of the cancellation order, unless other restrictions have been imposed. Thereafter, registrants will be prohibited from selling or distributing the products whose labels include the terminated uses identified in Table 2 of Unit III., except for export consistent with FIFRA section 17 or for proper disposal.

Persons other than the registrant may sell, distribute, or use existing stocks of the products whose labels include the terminated uses until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the products with the terminated uses.

Authority: 7 U.S.C. 136 *et seq.*

Dated: June 29, 2015.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2015–16405 Filed 7–1–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9930–18–OA]

Notification of a Public Teleconference of the Science Advisory Board; Drinking Water Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public teleconference of the Drinking Water Committee (DWC) to review its draft report regarding the EPA's *Draft Fourth Contaminant Candidate List* (CCL4).

DATES: The public teleconference will be held on August 3, 2015, from 1:00 p.m. to 4:00 p.m. (Eastern Time).

ADDRESSES: The teleconference will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants further information concerning this public teleconference may contact Ms. Stephanie Sanzone, Designated Federal Officer (DFO) for the Drinking Water Committee, EPA Science Advisory Board Staff Office (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; by telephone at (202) 564–2067 or via email at *sanzone.stephanie@epa.gov*. General information concerning the EPA SAB can be found at *http://www.epa.gov/sab*.

SUPPLEMENTARY INFORMATION:

Background: The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a federal advisory committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to FACA and EPA policy, notice is hereby given that the SAB Drinking Water Committee will hold a public teleconference to discuss its draft report regarding the EPA *Draft Fourth Contaminant Candidate List (CCL 4) (February 4, 2015)*. The committee will provide advice to the Administrator through the chartered SAB.

EPA's Office of Water requested that the SAB Drinking Water Committee review the *Draft Fourth Contaminant List (CCL 4),* which was released for public review and comment on February 4, 2015 (80 FR 6076). The Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA, after consultation with the scientific community including the Science Advisory Board and opportunity for public comment, to publish a list every five years of currently unregulated contaminants that are known or anticipated to occur in public water systems and may require regulation under the SDWA (referred to as the Contaminant Candidate List, or CCL). The SAB Drinking Water Committee met on April 29–30, 2015, to receive agency briefings, hear public comments, and deliberate on responses to the EPA charge questions (80 FR 14130–14131). The purpose of the August 3, 2015, teleconference is to discuss the committee's draft report with responses to the charge questions. Additional information about this SAB advisory activity can be found at the following URL *http://yosemite.epa.gov/sab/*

sabproduct.nsf/fedrgstr_activites/CCL%204?OpenDocument.

Technical Contacts: Any technical questions concerning EPA's draft CCL 4 should be directed to Ms. Meredith Russell in the EPA Office of Water, by telephone at (202) 564–0814 or by email at *Russell.Meredith@epa.gov.*

Availability of Meeting Materials: Prior to the meeting, the review documents, agenda and other materials will be accessible through the calendar link on the blue navigation bar at *http://www.epa.gov/sab/.* Materials may also be accessed at the URL provided above.

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees and panels, including scientific advisory committees, provide independent advice to the EPA. Interested members of the public may submit relevant information on the topic of this advisory activity, and/or the group conducting the activity, for the SAB to consider during the advisory process. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for SAB committees and panels to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the DFO directly. *Oral Statements:* In general, individuals or groups requesting an oral presentation at the teleconference will be limited to three minutes. Interested parties wishing to provide comments should contact Ms. Sanzone, DFO, in writing (preferably via email) at the contact information noted above by July 27, 2015, to be placed on the list of public speakers for the meeting. *Written Statements:* Written statements will be accepted throughout the advisory process; however, for timely consideration by Committee members, statements should be supplied to the DFO (preferably via email) at the contact information noted above by July 27, 2015. It is the SAB Staff Office general policy to post written comments on the Web page for advisory meetings. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact Ms. Sanzone at the contact information provided above. To request accommodation of a disability, please contact Ms. Sanzone preferably at least ten days prior to the meeting to give EPA as much time as possible to process your request.

Dated: June 30, 2015.

Thomas H. Brennan,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2015–16721 Filed 7–7–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0393; FRL–9929–24]

Registration Review Interim Decisions; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's interim registration review decisions for the pesticides listed in the table in Unit II of this notice. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, that the pesticide can perform its intended function without causing unreasonable adverse effects on human health or the environment. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment. This document also announces the Agency's closure of the registration review docket diclofop-methyl. All pesticide products containing diclofop-methyl have been cancelled.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information, contact* the Chemical Review Manager identified in the table in Unit II. for the pesticide of interest.

For general information on the registration review program, contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8015; email address: *dumas.richard@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager identified in the table in Unit II. for the pesticide of interest.

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–2015–0393, 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.*

II. What action is the agency taking?

Pursuant to 40 CFR 155.58(c), this notice announces the availability of EPA's interim registration review decisions for the pesticides in the following table:

TABLE—REGISTRATION REVIEW INTERIM DECISIONS

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
Acetic acid and sodium diacetate, 4001	EPA–HQ–OPP–2008–0016	Cathryn Britton, *britton.cathryn@epa.gov*, (703) 308–0136.
Fosetyl-Al, 0646	EPA–HQ–OPP–2006–0379	Ricardo Jones, *jones.ricardo@epa.gov*, (703) 347–0493.
Picaridin, 7433	EPA–HQ–OPP–2014–0341	Ricardo Jones, *jones.ricardo@epa.gov*, (703) 347–0493.
Sodium fluoride, 3132	EPA–HQ–OPP–2014–0655	SanYvette Williams, *williams.Sanyvette@epa.gov*, (703) 305–7702.
Yellow mustard seed/sulfonic acid salts, 7619/7618.	EPA–HQ–OPP–2014–0762	Roy Johnson, *johnson.roy@epa.gov*, (703) 347–0492.

The registration review final decisions for these cases are dependent on the assessments of listed species under the Endangered Species Act (ESA), determinations on the potential for endocrine disruption, and/or pollinator risk assessments.

Acetic acid and sodium diacetate (Interim Decision). The registration review docket for acetic acid and sodium diacetate opened in March 2008. Acetic acid and sodium diacetate are two different active ingredients; sodium diacetate is a salt of acetic acid. Acetic acid is used as a preservative for post-harvest stored grains and hay intended for livestock feed. It is also applied as a non-selective herbicide for control of broadleaf weeds and grasses. Sodium diacetate is a fungicide and bactericide registered to control molds and bacteria. It is applied to hay to prevent spoilage and to silage as an aid in fermentation. The Agency has determined that previous human health assessments for acetic acid and sodium diacetate are sufficient for registration review and no human health risks of concern have been identified. The Agency completed a comprehensive ecological risk assessment for the nonselective herbicide use of acetic acid, including an endangered species assessment, and a qualitative ecological risk assessment for sodium diacetate. The Agency has made a No Effect determination for acetic acid used as a nonselective herbicide and all currently registered uses of sodium diacetate for all non-target organisms. EPA published the *Acetic Acid and Sodium Diacetate Proposed Interim Decision* in December 2014. One comment was received from the Center for Biological Diversity concurring with EPA's No Effect determination. No risk mitigation measures for human health or ecological effects are included in the interim decision.

Fosetyl-Al (Interim Decision). Fosetyl-Al is a phosphonate fungicide registered for use to control various oomycyete pathogens that cause fungal diseases on numerous crops. Fosetyl-Al is registered for use on agricultural crops including avocado, caneberries, citrus, grape, stone fruit, strawberry, certain tree nuts, tobacco, and certain vegetables. It is also registered for commercial use on ornamentals, turf, and conifer nurseries. EPA conducted quantitative risk assessments for both human health and ecological risk. The Agency also completed a partial screening level endangered species assessment, making a No Effects determination for listed species of fish, aquatic invertebrates, aquatic plans, and monocot plants. No human health risks of concern were identified. The ecological risk assessment indicated potential risks to birds, mammals, terrestrial and aquatic plants, and terrestrial invertebrates. In the **Federal Register** of December 24, 2014 (79 FR 77480) (FRL–9919–24), the Agency issued its *Proposed Interim Registration Review Decision* for fosetyl-Al for public comment. Fourteen comments were received, including comments on the Agency's proposal to increase the Restricted Entry Interval, require additional pollinator data and add pollinator advisory language to labels. The Agency's Interim Decision modifies the application directions for fosetyl-Al to mitigate ecological risks and updates labels to reflect current Agency policy for worker protection. It does not require additional pollinator data or pollinator advisory language on the product labels.

Picaridin (Interim Decision). Picaridin is a broad-spectrum insect repellent registered for use against biting flies, chiggers, fleas, mosquitoes, and ticks. Picaridin is labeled for use on human skin and footwear. The Agency completed qualitative ecological and human health risk assessments for picaridin, and found no risks of concern. The Agency has made a No Effects determination under the Endangered Species Assessment (ESA) for all listed species and No Modification of designated critical habitat for such species. In the **Federal Register** of December 24, 2014 (79 FR 77480) (FRL–9919–24), EPA issued the *Combined Work Plan and Proposed Interim Registration Review Decision,* indicating that no additional data would be needed for the picaridin registration review. Two comments were received, neither of which modified the proposed decision or work plan for picaridin. No risk mitigation measures for human health or ecological effects are included in the interim decision.

Sodium fluoride (Interim Decision). Sodium fluoride is registered for use as a wood preservative to protect the groundline portion of existing wooden utility poles. It is formulated as an impregnated pole wrap material. This use is not expected to result in direct or indirect food or drinking water exposure. Occupational and residential exposure is minimal by the dermal and inhalation routes, and the Agency has determined that a human health risk assessment was not needed. Based on the lack of potential exposure and toxic effects to fish, aquatic invertebrates, and birds, the Agency has made a No Effect determination for federally listed species and designated critical habitat.

Yellow mustard seed/sulfonic acid salts (Interim Decision). Yellow mustard seed and sulfonic acid salts are co-formulated as a rodenticide registered for the control of ground squirrels in rangelands, ornamental plantings, seed orchards and nurseries, golf courses, parks, and rights-of-way. The product is delivered into burrows occupied by these rodents through a modified hand-held spray wand with an aspirating muzzle to facilitate foaming action. The Agency relied on qualitative assessments conducted for yellow mustard seed/sulfonic acid salts at the time of the initial registration, and the Agency did not believe that updated or quantitative assessments were needed for registration review. No human health risks of concern or risks of

concern to non-listed species have been identified. No risk mitigation measures for human health or ecological effects are included in the interim decision.

Case Closure for Diclofop-methyl (PC Code: 110902, Case: 2160). Diclofop-methyl is an herbicide which was labeled for use on wheat, barley, and golf course turf. On October 23, 2014, the Agency received a request for voluntary cancellation of diclofop-methyl from the technical and end-use registrants; Bayer CropScience and Bayer Environmental Science, respectively. EPA subsequently issued a **Federal Register** notice announcing receipt of the request (FRL–9396–04), and allowed a 30-day period for public comment on the request. No substantive comments were received, and on June 10, 2015, EPA issued the cancellation order for all remaining registrations of products containing diclofop-methyl (FRL–9968–03), which sets out the existing stocks policy for such products. With the cancellation of all remaining diclofop-methyl products, the Agency is announcing the closure of the registration review case for the active ingredient.

Pursuant to 40 CFR 155.57, a registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA. EPA has considered the pesticides listed in the table in this unit in light of the FIFRA standard for registration. The Interim Decision documents for these pesticides in the docket describe the Agency's rationale for issuing a registration review interim decision for this pesticide.

In addition to an interim registration review decision document, the registration review docket for each of these pesticides may also include other relevant documents related to the registration review of the case. A proposed interim registration review decision was previously posted to each docket and the public was invited to submit any comments or new information relevant to the proposal.

EPA has addressed the substantive comments and information received during the 60-day comment period in the discussion for each pesticide listed in this document. During the 60-day comment period, no public comments were received for any of these cases that resulted in changes in the Agency's interim decisions.

Pursuant to 40 CFR 155.58(c), the registration review case docket for each pesticide discussed in this notice will remain open until all actions required in the interim decision have been completed.

Background on the registration review program is provided at: *http://www2.epa.gov/pesticide-reevaluation.* Links to earlier documents related to the registration review of the pesticide cases identified in this notice are provided in the Pesticide Chemical Search data base accessible at: *http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: June 26, 2015.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2015–16406 Filed 7–7–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0386; FRL–9929–23]

Registration Review; Draft Human Health and Ecological Risk Assessments; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's draft human health and ecological risk assessments for the registration reviews of flufenacet, flurprimidol, propoxur, and sodium acifluorfen, and opens a public comment period on these documents. In addition, this notice announces both the opening of the registration review docket for thidiazuron and the availability of the registration review draft human health and ecological risk assessments for thidiazuron. The Agency is opening a public comment period on both the Preliminary Work Plan and the draft risk assessments for thidiazuron. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

DATES: Comments must be received on or before September 8, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number for the specific pesticide of interest provided in Table 1 of Unit III, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.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 pesticide specific information contact* the Chemical Review Manager listed as the contact in Table 1 of Unit III.

For general questions on the registration review program, contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8015; email address: *dumas.richard@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager for the case in question, listed in Table 1 of Unit III of this notice.

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.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Authority

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed comprehensive draft human health and ecological risk assessments, including, in some cases, a screening level endangered species assessment, for all uses of these pesticides. After reviewing comments received during the public comment period, EPA may issue revised risk assessments, explain any changes to the draft risk assessments, respond to comments, and request public input on risk mitigation before completing proposed registration review decisions for flufenacet, flurprimidol, propoxur, sodium acifluorfen, and thidiazuron.

EPA is conducting its registration review of the pesticide cases listed in Table 1 of Unit III. of this notice pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or human dietary risks of concern from residues that result from the use of a pesticide in or on food.

III. Registration Reviews

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registrations for the pesticides listed in Table 1 of this Unit to ensure that each pesticide on the list continues to satisfy the FIFRA standard for registration—that is, that these pesticides can still be used without unreasonable adverse effects on human health or the environment.

TABLE 1—DRAFT RISK ASSESSMENTS BEING MADE AVAILABLE FOR PUBLIC COMMENT

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
Flufenacet, 7245	EPA–HQ–OPP–2010–0863	Margaret Hathaway, *hathaway.margaret@epa.gov,* 703–305–5076.
Flurprimidol, 7000	EPA–HQ–OPP–2009–0630	Kelly Ballard, *ballard.kelly@epa.gov,* 703–305–8126.
Propoxur, 2555	EPA–HQ–OPP–2009–0806	Brittany Pruitt, *pruitt.brittany@epa.gov,* 703–347–0289.
Sodium acifluorfen, 2605	EPA–HQ–OPP–2010–0135	Christina Scheltema, *scheltema.christina@epa.gov,* 703–308–2201.
Thidiazuron, 4092	EPA–HQ–OPP–2015–0381	Khue Nguyen, *nguyen.khue@epa.gov,* 703–347–0248.

Flufenacet. Draft Human Health and Ecological Risk Assessments (EPA–HQ–OPP–2010–0863). Flufenacet is a pre-emergent, anilide herbicide registered for use on wheat, perennial grasses grown for seed, corn for silage, field and sweet corn, soybeans, and triticale. There are no registered residential uses of flufenacet. EPA has completed draft human health and ecological risk assessments, including a screening-level listed species assessment, for all flufenacet uses. EPA acknowledges that further refinements to the listed species assessment will be completed in future revisions and requests public comment on specific areas that will reduce the uncertainties associated with the characterization of risk to listed species identified in the current assessment.

Flurprimidol. Draft Human Health and Ecological Risk Assessments (EPA–HQ–OPP–2009–0630). Flurprimidol is a plant growth regulator belonging to the pyrimidine class. It is registered for use on golf courses and ornamental turf; for landscape/woody ornamental plants and ornamental trees; and for ornamental plants grown in containers in nurseries, greenhouses, and shadehouses. EPA conducted a comprehensive human health risk assessment and did not identify any risks of concern for dietary, residential, or occupational exposures. EPA also conducted a screening level ecological risk assessment that addressed only the tree injection use of flurprimidol. Potential risks to birds, mammals, and plants were identified. All other uses of flurprimidol were addressed in a 2010 ecological risk assessment, which is posted to the registration review docket. An endangered species assessment has not been completed for flurprimidol at this time.

Propoxur. Draft Human Health and Ecological Risk Assessments (EPA–HQ–OPP–2009–0806). Propoxur is a carbamate insecticide registered for use by pest control operators to kill a variety of insects including crickets, ants, cockroaches, and silverfish. It is registered for use in and around residential, industrial, institutional, and commercial facilities (including food handling establishments and food processing plants). EPA has completed draft human health and ecological risk assessments, including a screening-level listed species assessment for all propoxur uses. EPA acknowledges that

further refinements to the listed species assessment will be completed in future revisions and requests public comment on specific areas that will reduce the uncertainties associated with the characterization of risk to listed species identified in the current assessment.

Sodium acifluorfen. Draft Human Health and Ecological Risk Assessments (EPA–HQ–OPP–2010–0135). Sodium acifluorfen is a post-emergent herbicide registered for use on peanuts, soybeans, strawberries, and rice. EPA has completed draft human health and ecological risk assessments for all sodium acifluorfen uses. There are no anticipated human health risks of concern. The draft ecological risk assessment indicates that there is direct risk of adverse effects to non-target organisms, including fish, birds, and mammals, and species for which these taxa serve as surrogates, and non-target terrestrial plants. The assessment did not find risks of concern for aquatic plants.

Thidiazuron. Combined Docket Opening and Release of Draft Human Health and Ecological Risk Assessments (EPA–HQ–OPP–2015–0381). Thidiazuron is a plant growth regulator registered for use as a defoliant on cotton. There are no non-agricultural uses of thidiazuron. EPA has completed a combined problem formulation/preliminary ecological risk assessment and combined scoping document/preliminary human health risk assessment for thidiazuron. No human health risks of concern were identified. The ecological risk assessment indicated potential risks of concern to birds, terrestrial-phase amphibians, reptiles, and terrestrial plants. The Agency did not complete an endangered species risk assessment.

Pursuant to 40 CFR 155.53(c), EPA is providing an opportunity, through this notice of availability, for interested parties to provide comments and input concerning the Agency's draft human health and ecological risk assessments for these pesticides. Such comments could address, among other things, the Agency's risk assessment methodologies and assumptions, as applied to these draft risk assessments. The Agency will consider all comments received during the public comment period and make changes, as appropriate, to the draft human health and ecological risk assessments. EPA may then issue revised risk assessments, explain any changes to the draft risk assessments, and respond to comments. In the **Federal Register** notice announcing the availability of any such revised risk assessments for these pesticides, if the revised risk assessments indicate risks of concern, the Agency may provide a comment period for the public to submit suggestions for mitigating the risks identified in the revised risk assessments before developing a proposed registration review decision on the affected pesticide.

1. Other related information. Additional information on the individual pesticides discussed in this notice is available through the Pesticide Registration Review Status Web page, at *http://www2.epa.gov/pesticide-reevaluation/individual-pesticides-registration-review.* Information on the Agency's registration review program and its implementing regulation is available at *http://www2.epa.gov/pesticide-reevaluation.*

2. *Information submission requirements.* Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.
- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.
- Submitters must clearly identify the source of any submitted data or information.
- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

Authority: 7 U.S.C. 136 *et seq.*

Dated: June 22, 2015.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2015–16422 Filed 7–7–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 15–679]

Media Bureau Announces Incentive Auction Eligible Facilities and Deadline for Filing Pre-Auction Technical Certification Form

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document announces each full power and Class A station facility eligible for protection in the repacking process and for relinquishment in the reverse auction (*i.e.,* ''eligible facility''), as well as the date by which a licensee with a eligible facility must file a Pre-Auction Technical Certification Form (FCC Form 2100, Schedule 381) (approved under OMB control under 3060–1206). An Appendix is attached to the Public Notice listing each eligible facility. The Public Notice also establishes a process for licensees to file a Petition for Eligible Entity Status in order to request that a facility not listed in the Appendix attached to the Public Notice be treated as an eligible facility.

DATES: The deadline for filing a Pre-Auction Technical Certification Form (FCC Form 2100, Schedule 381) is July 9, 2015. The deadline for filing a Petition for Eligible Entity Status is July 9, 2015. If granted, the Bureau will notify the petitioner of the date by which it must file its Pre-Auction Technical Certification Form as part of its decision. Furthermore, if the Commission grants a petition for reconsideration of the Incentive Auction R&O and in doing so extends discretionary protection to a different facility, or a facility that is not currently listed in the Appendix attached to the Public Notice, the licensee must file a Pre-Auction Technical Certification Form for each eligible facility no later than seven (7) days after release of the Commission's decision or by July 9, 2015, whichever is later.

FOR FURTHER INFORMATION CONTACT: Kevin Harding, Hossein Hashemzadeh, or Evan Morris, Video Division, Media Bureau, Federal Communications Commission, (202) 418–1600.

SUPPLEMENTARY INFORMATION: The Media Bureau (Bureau) announces each station facility eligible for protection in the repacking process and for relinquishment in the reverse auction (*i.e.,* eligible facility). Each eligible facility is listed in an Appendix attached to the Public Notice, which includes each eligible facility's call sign, facility identification number, community of license (city and state), license file number, channel number, type of service, and name of the licensee. The Appendix is available at *http://transition.fcc.gov/Daily_Releases/Daily_Business/2015/db0609/DA-15-679A2.pdf.* Additionally, the Bureau announces that any licensee with a station listed in the Appendix must file an FCC Form 2100, Schedule 381 (Pre-Auction Technical Certification Form or Form), through which it will verify and certify to the accuracy of the authorization and underlying Database Technical Information for each eligible facility by July 9, 2015. ''Database Technical Information'' means all underlying technical data that sets forth the operational parameters of the facility, including but not limited to the technical information that may be found in the Commission's Consolidated Database System (as well as the successor Licensing Management System) and Antenna Registration System. Accordingly, when a licensee certifies on the Pre-Auction Technical Certification Form to the accuracy of underlying Database Technical Information for an eligible facility, it must review all technical information on file with the Commission related to that eligible facility. When making its certification a licensee should not limit its review solely to the information provided for each eligible facility in the Appendix.

In the Incentive Auction R&O, the Federal Communications Commission (Commission) adopted rules and procedures for conducting the broadcast television incentive auction, including rules for determining which full power and Class A television station facilities would be eligible for protection in the repacking process and participation in the reverse auction. *See* Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions, GN Docket No. 12–268, *Report and Order,* 29 FCC Rcd 6567 (2014) (*Incentive Auction R&O*). The Commission also instructed the Bureau to issue a Public Notice specifying the deadline by which all full power and Class A licensees subject to either discretionary or mandatory protection, with limited exception, must either be licensed or have an application for a license to cover the construction permit on file (FCC Form 2100, Schedules B or F/FCC Forms 302 or 302–CA) in order to qualify as an eligible facility. *Incentive Auction R&O,* 29 FCC Rcd 6651, n.615 Pursuant to that authority, the Bureau designated May 29, 2015 as the Pre-Auction Licensing Deadline. Media Bureau Designates May 29, 2015 as Pre-Auction Licensing Deadline, *Public Notice,* 30 FCC Rcd 393 (2015).

While the Appendix attached to the Public Notice is intended to represent a complete list of all Class A and full power station facilities eligible for protection in the repacking process and relinquishment in the reverse auction, if a licensee believes that the Appendix omits an eligible facility, it should file with the Commission a ''Petition for Eligible Entity Status'' by July 9, 2015. The petition must request that the facility be designated an eligible facility, and the caption should include the name of the licensee, station's call sign, station's community of license (city and state), facility identification number, channel number, and file number for the authorization the licensee believes should be eligible. The petitioner must explain the reason it believes the facility is eligible consistent with the Incentive Auction R&O (*e.g.,* the facility was subject to mandatory or discretionary protection). The Bureau will process petitions in an expeditious manner and inform the petitioner of its decision well in advance of the reverse auction. All petitions must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission, and to the attention of Barbara A. Kreisman, Chief, Video Division, Media Bureau, Room 2–A666. An electronic copy should also be sent to Barbara Kreisman at *Barbara.Kreisman@fcc.gov* and to Evan Morris at *Evan.Morris@fcc.gov.*

To ensure a stable and accurate database, and to facilitate the repacking process, the Incentive Auction R&O specified that the Commission would require all full power and Class A television stations to verify and certify to the accuracy of the information contained in the Commission's databases with respect to their protected facilities. The R&O also directed the Bureau to develop a form and announce by Public Notice the deadline and procedures for filing the form. *Incentive Auction R&O,* 29 FCC Rcd at 6651, n.615; *Incentive Auction R&O,* 29 FCC Rcd at 6656, para. 195, n.646. Accordingly, the Bureau announces that licensees listed in the Appendix have until July 9, 2015, to file, through the Commission's Licensing Management System (LMS), a Pre-Auction Technical Certification Form (FCC Form 2100, Schedule 381). Licensees must file a separate Form for each eligible facility listed in the Appendix. If a Pre-Auction Technical Certification Form for an eligible facility is not filed by July 9, 2015, we will consider the authorization in the Appendix and the underlying Database Technical Information for that facility as of May 29, 2015 to be accurate for purposes of determining protection in the repacking process and the spectrum usage rights eligible for relinquishment in the reverse auction.

If a licensee certifies in the Form that there is a discrepancy between the authorization and the underlying Database Technical Information on file with the Commission (*e.g.,* the Commission has made an error and the facility authorization listed in the Appendix or underlying Database Technical Information is incorrect), the licensee must attach an exhibit to the Form providing the correct information. The Bureau will review and correct such errors as appropriate. The Bureau will take such corrections into account for purposes of determining protection in the repacking process and the spectrum usage rights eligible for relinquishment in the reverse auction.

In the alternative, if a licensee certifies in the Form that its eligible facility has been operating with parameters at variance from those specified in the authorization listed in the Appendix and the underlying Database Technical Information, the licensee must either revise its operations to reflect the licensed parameters or file an application for modification of its facility (FCC Form 2100, Schedules A or E) and seek a Special Temporary Authorization to allow it to continue to operate with parameters at variance pending grant of its modified license. If an application for modification is filed prior to submitting the Pre-Auction Technical Certification Form, the file number of that application must be provided on the Form. However, consistent with our objective of a stable and accurate database to facilitate the repacking process, we will rely on the operating parameters as specified in the authorization listed in the Appendix and the underlying Database Technical Information. Modifications occasioned by a licensee's operating at variance from those parameters, even if granted and ultimately licensed, will not be taken into account for purposes of determining protection in the repacking process and the spectrum usage rights eligible for relinquishment in the reverse auction.

In the Incentive Auction R&O, the Commission directed the Office of Engineering and Technology (OET) to release a detailed summary of baseline coverage area and population served by each television station to be protected in the repacking process. *Incentive Auction R&O,* 29 FCC Rcd at 6635, para. 145. The final baseline released by OET will contain the final list of eligible stations based on corrections to eligible facilities resulting from their certification in the Pre-Auction Technical Certification Form and any granted Petitions for Eligible Entity Status or Petitions for Reconsideration of the Incentive Auction R&O. Several parties have filed petitions for reconsideration of the Incentive Auction R&O requesting that discretionary protection be extended to facilities not currently protected under the R&O. The Commission is currently considering those petitions and the attached Appendix is not intended to pre-judge their outcome. If the Commission grants a petition for reconsideration and extends discretionary protection to a different facility, or a facility that is not currently listed in the Appendix, the licensee must file a Pre-Auction Technical Certification Form for each eligible facility no later than seven (7) days after release of the Commission's decision or by July 9, 2015, whichever is later.

This action is taken by the Media Bureau pursuant to authority delegated by 47 CFR 0.283 of the Commission's rules.

Barbara A. Kreisman,

Chief, Video Division, Media Bureau, Federal Communications Commission.

[FR Doc. 2015–16754 Filed 7–7–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0550 and OMB 3060–0560]

Information Collections Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal 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 Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before August 7, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov;* and to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the Web page *http://www.reginfo.gov/public/do/PRAMain*, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: *OMB Control Number:* 3060–0550.

Title: Local Franchising Authority Certification, FCC Form 328; Section 76.910, Franchising Authority Certification.

Form No.: FCC Form 328.

Type of Review: Revision of a currently approved collection.

Respondents: State, local or tribal governments; Businesses or other for-profit entities.

Number of Respondents and Responses: 7 respondents; 13 responses.

Estimated Time per Response: 2 hours.

Frequency of Response: One-time reporting requirement; Third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in section 3 of the Cable Television Consumer Protection and Competition Act of 1992 (47 U.S.C. 543), as well as sections 4(i), 4(j), and 623 of the Communications Act of 1934, as amended, and section 111 of the STELA Reauthorization Act of 2014.

Total Annual Burden: 26 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: On June 3, 2015, the Commission released a Report and Order, MB Docket No. 15–53; FCC 15–62. The Report and Order adopted a rebuttable presumption that cable operators are subject to competing provider effective competition.

The information collection requirements consist of:

FCC Form 328. Pursuant to section 76.910, a franchising authority must be certified by the Commission to regulate the basic service tier and associated equipment of a cable system within its jurisdiction. To obtain this certification, the franchising authority must prepare and submit FCC Form 328. The Report and Order revises section 76.910 to require a franchising authority filing Form 328 to submit specific evidence demonstrating its rebuttal of the presumption in section 76.906 that the cable system is subject to competing provider effective competition pursuant to section 76.905(b)(2). The franchising authority bears the burden of submitting evidence rebutting the presumption that competing provider effective competition, as defined in section 76.905(b)(2), exists in the franchise area.

Unless a franchising authority has actual knowledge to the contrary, it may rely on the presumption in section 76.906 that the cable system is not subject to one of the other three types of effective competition.

Evidence establishing lack of effective competition. If the evidence establishing the lack of effective competition is not otherwise available, section 76.910(b)(4) provides that franchising authorities may request from a multichannel video programming distributor (''MVPD'') information regarding the MVPD's reach and number of subscribers. An MVPD must respond to such request within 15 days. Such responses may be limited to numerical totals.

Franchising authority's obligations if certified. Section 76.910(e) of the Commission's rules currently provides that, unless the Commission notifies the franchising authority otherwise, the certification will become effective 30 days after the date filed, provided, however, that the franchising authority may not regulate the rates of a cable system unless it: (1) Adopts regulations (i) consistent with the Commission's regulations governing the basic tier and (ii) providing a reasonable opportunity for consideration of the views of interested parties, within 120 days of the effective date of the certification; and (2) notifies the cable operator that the franchising authority has been certified and has adopted the required regulations.

OMB Control Number: 3060–0560.

Title: Section 76.911, Petition for Reconsideration of Certification.

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: State, local or tribal governments; Businesses or other for-profit entities.

Number of Respondents and Responses: 15 respondents; 25 responses.

Estimated Time per Response: 2–10 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 collection of information is contained in sections 4(i) and 623 of the Communications Act of 1934, as amended.

Total Annual Burden: 130 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: On June 3, 2015, the Commission released a Report and Order, MB Docket No. 15–53; FCC 15–62. The Report and Order adopted a rebuttable presumption that cable operators are subject to competing provider effective competition. Reversing the previous rebuttable presumption of no effective competition and adopting the procedures discussed in the Report and Order will result in changes to the information collection burdens.

The information collection requirements consist of: Petitions for reconsideration of certification, oppositions and replies thereto, cable operator requests to competitors for information regarding the competitor's reach and number of subscribers if evidence establishing effective competition is not otherwise available, and the competitors supplying this information.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2015–16662 Filed 7–7–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0214, 3060–0519, 3060–1162 and 3060–1180]

Information Collections Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal 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 comments should be submitted on or before August 7, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov;* and to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain*, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0214.

Title: Sections 73.3526 and 73.3527, Local Public Inspection Files; Sections 76.1701 and 73.1943, Political Files.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not for-profit institutions; Individuals or households.

Number of Respondents and Responses: 24,558 respondents; 63,234 responses.

Estimated Time per Response: 1 hour to 104 hours.

Frequency of Response: On occasion reporting requirement; Recordkeeping requirement; Third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in 47 U.S.C. 151, 152, 154(i), 303, 307 and 308.

Total Annual Burden: 2,375,336 hours.

Total Annual Costs: $882,236.

Privacy Act Impact Assessment: The FCC is preparing a PIA.

Nature and Extent of Confidentiality: The personally identifiable information (PII) in this information collection is in part covered by the system of records notice (SORN), FCC/MB–1, ''Ownership of Commercial Broadcast Stations,'' 74 FR 59978 (2009). The Commission is currently drafting a Privacy Impact Assessment (PIA) for the records covered by this SORN.

The FCC also prepared a system of records, FCC/MB–2, ''Broadcast Station Public Inspection Files,'' to cover the personally identifiable information (PII) that may be included in the broadcast station public inspection files. Respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The public and FCC use the information in the public file to evaluate information about the broadcast licensee's performance, to ensure that broadcast stations are addressing issues concerning the community which it is licensed to serve and to ensure that stations entering into time brokerage agreements comply with Commission policies pertaining to licensee control and to the Communications Act and the antitrust laws. Placing joint sales agreements in the public inspection file facilitates monitoring by the public, competitors and regulatory agencies. Television broadcasters are required to send each cable operator in the station's market a copy of the election statement applicable to that particular cable operator. Placing these retransmission consent/must-carry elections in the public file provide public access to documentation of station's elections which are used by cable operators in negotiations with television stations and by the public to ascertain why some stations are/are not carried by the cable systems.

Maintenance of political files by broadcast stations and by cable television systems enables the public to assess money expended and time allotted to a political candidate and to ensure that equal access was afforded to other legally qualified candidates for public office.

OMB Control Number: 3060–0519.

Title: Rules and Regulations Implementing the Telephone Consumer Protection Act (TCPA) of 1991, CG Docket No. 02–278.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Individuals or households; Not-for-profit institutions.

Number of Respondents and Responses: 34,948 respondents; 147,368,997 responses.

Estimated Time per Response: .004 hours (15 seconds) to 1 hour.

Frequency of Response: Recordkeeping requirement; Annual, on occasion and one-time reporting requirements; Third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for the information collection requirements is found in the Telephone Consumer Protection Act of 1991 (TCPA), Public Law 102–243, December 20, 1991, 105 Stat. 2394, which added section 227 of the Communications Act of 1934, [47 U.S.C. 227] Restrictions on the Use of Telephone Equipment.

Total Annual Burden: 666,138 hours. Total Annual Cost: $2,745,000.

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's system of records notice (SORN), FCC/CGB–1, ''Informal Complaints and Inquiries.'' As required by the Privacy Act, 5 U.S.C. 552a, the Commission also published a SORN, FCC/CGB–1 ''Informal Complaints, Inquiries, and Requests for Dispute Assistance'', in the **Federal Register** on August 15, 2014 (79 FR 48152) which became effective on September 24, 2014. A system of records for the do-not-call registry was created by the Federal Trade Commission (FTC) under the Privacy Act. The FTC originally published a notice in the **Federal Register** describing the system. See 68 FR 37494, June 24, 2003. The FTC updated its system of records for the do-not-call registry in 2009. See 74 FR 17863, April 17, 2009.

Privacy Impact Assessment: Yes.

Needs and Uses: The reporting requirements included under this OMB Control Number 3060–0519 enable the Commission to gather information regarding violations of section 227 of the Communications Act, the Do-Not-Call Implementation Act (Do-Not-Call Act), and the Commission's implementing rules. If the information collection was not conducted, the Commission would be unable to track and enforce violations of section 227 of the Communications Act, the Do-Not-Call Act, or the Commission's implementing rules. The Commission's implementing rules provide consumers with several options for avoiding most unwanted telephone solicitations.

The national do-not-call registry supplements the company-specific do-not-call rules for those consumers who wish to continue requesting that particular companies not call them. Any company that is asked by a consumer, including an existing customer, not to call again must honor that request for five (5) years.

A provision of the Commission's rules, however, allows consumers to give specific companies permission to call them through an express written agreement. Nonprofit organizations, companies with whom consumers have an established business relationship, and calls to persons with whom the telemarketer has a personal relationship are exempt from the ''do-not-call'' registry requirements.

On September 21, 2004, the Commission released the Safe Harbor Order establishing a limited safe harbor in which persons will not be liable for placing autodialed and prerecorded message calls to numbers ported from a wireline service within the previous 15 days. The Commission also amended its existing National Do-Not-Call Registry safe harbor to require telemarketers to scrub their lists against the Registry every 31 days.

On December 4, 2007, the Commission released the DNC NPRM seeking comment on its tentative conclusion that registrations with the Registry should be honored indefinitely, unless a number is disconnected or reassigned or the consumer cancels his registration.

On June 17, 2008, in accordance with the Do-Not-Call Improvement Act of 2007, the Commission revised its rules to minimize the inconvenience to consumers of having to re-register their preferences not to receive telemarketing calls and to further the underlying goal of the National Do-Not-Call Registry to protect consumer privacy rights. The Commission released a Report and Order in CG Docket No. 02–278, FCC 08–147, amending the Commission's rules under the Telephone Consumer Protection Act (TCPA) to require sellers and/or telemarketers to honor registrations with the National Do-Not-Call Registry so that registrations will not automatically expire based on the current five year registration period.

Specifically, the Commission modified section 64.1200(c)(2) of its rules to require sellers and/or telemarketers to honor numbers registered on the Registry indefinitely or until the number is removed by the database administrator or the registration is cancelled by the consumer.

On February 15, 2012, the Commission released a Report and Order in CG Docket No. 02–278, FCC 12–21, revising its rules to: (1) Require prior express written consent for all autodialed or prerecorded telemarketing calls to wireless numbers and for all prerecorded telemarketing calls to residential lines; (2) eliminate the established business relationship exception to the consent requirement for prerecorded telemarketing calls to residential lines; (3) require telemarketers to include an automated, interactive opt-out mechanism in all prerecorded telemarketing calls, to allow consumers more easily to opt out of future robocalls during a robocall itself; and (4) require telemarketers to comply with the 3% limit on abandoned calls during each calling campaign, in order to discourage intrusive calling campaigns.

Finally, the Commission also exempted from the Telephone Consumer Protection Act requirements prerecorded calls to residential lines made by health care-related entities governed by the Health Insurance Portability and Accountability Act of 1996.

OMB Control Number: 3060–1162.

Title: Closed Captioning of Video Programming Delivered Using Internet Protocol, and Apparatus Closed Caption Requirements.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households; Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents and Responses: 1,322 respondents; 3,666 responses.

Estimated Time per Response: 0.084 to 10 hours.

Frequency of Response: One time and on occasion reporting requirements; Recordkeeping requirement; Third-party disclosure requirement.

Obligation to Respond: Mandatory and required to obtain or retain benefits. The statutory authority for this information collection is contained in the Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260, 124 Stat. 2751, and Sections 4(i), 4(j), 303, 330(b), 713, and 716 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 303, 330(b), 613, and 617.

Total Annual Burden: 10,062 hours.

Total Annual Cost: $95,700.

Privacy Act Impact Assessment: Yes. As required by OMB Memorandum M–03–22 (September 26, 2003), the FCC completed a Privacy Impact Assessment (PIA) on June 28, 2007, that gives a full and complete explanation of how the FCC collects, stores, maintains, safeguards, and destroys the PII covered by these information collection requirements. The PIA may be reviewed at: *http://www.fcc.gov/omd/privacyact/Privacy5FImpact5FAssessment.html.*

Nature and Extent of Confidentiality: Some assurances of confidentiality are being provided to the respondents. Parties filing petitions for exemption based on economic burden, requests for Commission determinations of technical feasibility and achievability, requests for purpose-based waivers, or responses to complaints alleging violations of the Commission's rules may seek confidential treatment of information they provide pursuant to the Commission's existing confidentiality rules.

The Commission is not requesting that individuals who file complaints alleging violations of our rules (complainants) submit confidential information (*e.g.,* credit card numbers, social security numbers, or personal financial information) to us. We request that complainants submit their names, addresses, and other contact information, which enables us to process complaints. Any use of this information is covered under the routine uses listed in the Commission's SORN, FCC/CGB–1, ''Informal Complaints, Inquiries, and Requests for Dispute Assistance.''

The PIA that the FCC completed on June 28, 2007 gives a full and complete explanation of how the FCC collects, stores, maintains, safeguards, and destroys PII, as required by OMB regulations and the Privacy Act, 5 U.S.C. 552a. The PIA may be viewed at: *http://www.fcc.gov/omd/privacyact/Privacy5FImpact5FAssessment.html.*

The Commission will update the PIA to cover the PII collected related to this information collection to incorporate various revisions to it as a result of revisions to the SORN and as required by OMB's Memorandum M–03–22 (September 26, 2003) and by the Privacy Act, 5 U.S.C. 552a.

Needs and Uses: The Twenty-First Century Communications and Video Accessibility Act of 2010 (CVAA) directed the Commission to revise its regulations to mandate closed captioning on IP-delivered video programming that was published or exhibited on television with captions after the effective date of the regulations. Accordingly, the Commission requires video programming owners (VPOs) to send program files to video programming distributors and providers (hereinafter VPDs) with required captions, and it requires VPDs to enable the rendering or pass through of all required captions to the end user. The CVAA also directed the Commission to revise its regulations to mandate that all apparatus designed to receive, play back, or record video programming be equipped with built-in closed caption decoder circuitry or capability designed to display closed-captioned video programming, except that apparatus that use a picture screen that is 13 inches or smaller and recording devices must comply only if doing so is achievable. These rules are codified at 47 CFR 79.4 and 79.100–79.104.

The information collection requirements consist of:

(a) Mechanism for information about video programming subject to the IP closed captioning requirements.

Pursuant to 47 CFR 79.4(c)(1)(ii) and (c)(2)(ii) of the Commission's rules, VPOs and VPDs must agree upon a mechanism to make information available to VPDs about video programming that becomes subject to the requirements of 47 CFR 79.4 on an ongoing basis. VPDs must make a good faith effort to identify video programming that must be captioned when delivered using IP using the agreed upon mechanism.

For example, VPOs and VPDs may agree on a mechanism whereby the VPOs provide captions or certifications that captions are not required, and update those certifications and provide captions when captions later become required. A VPD may rely in good faith on a certification by a VPO that the programming need not be captioned: (1) If the certification includes a clear and concise explanation of why captions are not required; and (2) if the VPD is able to produce the certification to the Commission in the event of a complaint. VPOs may provide certifications for specific programming or a more general certification, for example, for all programming covered by a particular contract.

VPDs may seek Commission determinations that other proposed mechanisms provide adequate information for them to rely on in good faith by filing an informal request and providing sufficient information for the Commission to make such determinations.

(b) Contact information for the receipt and handling of written closed captioning complaints.

Pursuant to 47 CFR 79.4(c)(2)(iii), VPDs must make their contact information available to end users for the receipt and handling of written IP closed captioning complaints. The required contact information includes the name of a person with primary responsibility for IP captioning issues and who can ensure compliance with these rules, as well as the person's title or office, telephone number, fax number, postal mailing address, and email address. VPDs must keep this information current and update it within 10 business days of any change. The Commission expects that such contact information will be prominently displayed in a way that it is accessible to all end users. A general notice on the VPD's Web site with such contact information, if provided, must be provided in a location that is conspicuous to viewers.

(c) Petitions for exemption based on ''economic burden.''

Pursuant to 47 CFR 79.4(d), a VPO or VPD may petition the Commission for a full or partial exemption from the closed captioning requirements for IP-delivered video programming based upon a showing that they would be economically burdensome. Petitions for exemption must be supported with sufficient evidence to demonstrate economic burden (significant difficulty or expense). The Commission will consider four specific factors when determining economic burden and any other factors the petitioner deems relevant, along with any available alternatives that might constitute a reasonable substitute for the closed captioning requirements. Petitions and subsequent pleadings must be filed electronically.

The Commission will place such petitions on public notice. Comments or oppositions to the petition may be filed electronically within 30 days after release of the public notice of the petition, and must include a certification that the petitioner was served with a copy. The petitioner may reply to any comments or oppositions filed within 20 days after the close of the period for filing comments or oppositions, and replies must include a certification that the commenting or opposing party was served with a copy. Upon a finding of good cause, the Commission may lengthen or shorten any comment period and waive or establish other procedural requirements. Petitions and responsive pleadings must include a detailed, full showing, supported by affidavit, of any facts or considerations relied on.

(d) Complaints alleging violations of the closed captioning rules for IP-delivered video programming.

Pursuant to 47 CFR 79.4(e), a written complaint alleging a violation of the closed captioning rules for IP-delivered video programming may be filed with the Commission or with the VPD responsible for enabling the rendering or pass through of the closed captions for the video programming. Complaints must be filed within 60 days after the date the complainant experienced a problem with captioning. Such complaints should (but are not required to) include certain information.

If a complaint is filed first with the VPD, the VPD must respond in writing to the complainant within 30 days after receipt of a closed captioning compliant. If a VPD fails to respond timely, or the response does not satisfy the consumer, the complainant may re-file the complaint with the Commission within 30 days after the time allotted for the VPD to respond. If a consumer re-files the complaint with the Commission (after filing with the VPD) and the complaint satisfies the requirements, the Commission will forward the complaint to the named VPD, and to any other VPD and/or VPO that Commission staff determines may be involved, who then must respond in writing to the Commission and the complainant within 30 days after receipt of the complaint from the Commission.

If a complaint is filed first with the Commission and the complaint satisfies the requirements, the Commission will forward the complaint to the named VPD and/or VPO, and to any other VPD and/or VPO that Commission staff determine may be involved, who must respond in writing to the Commission and the complainant within 30 days after receipt of the complaint from the Commission. In response to a complaint, a VPD and/or VPO must provide the Commission with sufficient records and documentation. The Commission will review all relevant information provided by the complainant and the subject VPDs and/or VPOs, as well as any additional information the Commission deems relevant from its files or public sources. The Commission may request additional information from any relevant entities when, in the estimation of Commission staff, such information is needed to investigate the complaint or adjudicate potential violation(s) of Commission rules. When the Commission requests additional information, parties to which such requests are addressed must provide the requested information in the manner and within the time period the Commission specifies.

(e) Requests for Commission determination of technical feasibility of apparatus closed caption requirements.

Pursuant to 47 CFR 79.103(a), as of January 1, 2014, all digital apparatus designed to receive or play back video programming that uses a picture screen of any size must be equipped with built-in closed caption decoder circuitry or capability designed to display closed-captioned video programming, if technically feasible. If new apparatus or classes of apparatus for viewing video programming emerge on which it would not be technically feasible to include closed captioning, parties may raise that argument as a defense to a complaint or, alternatively, file a request under 47 CFR 1.41 for a Commission determination of technical feasibility before manufacturing or importing the product.

(f) Requests for Commission determination of achievability of apparatus closed caption requirements.

Pursuant to 47 CFR 79.103(a), as of January 1, 2014, all digital apparatus designed to receive or play back video programming that use a picture screen less than 13 inches in size must be equipped with built-in closed caption decoder circuitry or capability designed to display closed-captioned video programming, only if doing so is achievable. In addition, pursuant to 47 CFR 79.104(a), as of January 1, 2014, all apparatus designed to record video programming must enable the rendering or the pass through of closed captions such that viewers are able to activate and de-activate the closed captions as the video programming is played back, only if doing so is achievable.

Manufacturers of such apparatus may petition the Commission, pursuant to 47 CFR 1.41, for a full or partial exemption from the closed captioning requirements before manufacturing or importing the apparatus or may assert as a response to a complaint that these requirements, in full or in part, are not achievable. Pursuant to 47 CFR 79.103(b)(3), such a petition or response must be supported with sufficient evidence to demonstrate that compliance is not achievable (meaning with reasonable effort or expense) and the Commission will consider four specific factors when making such determinations. In evaluating evidence offered to prove that compliance was not achievable, the Commission will be informed by the analysis in the ACS Order.

(g) Petitions for purpose-based waivers of apparatus closed caption requirements.

Manufacturers seeking certainty prior to the sale of a device may petition the Commission, pursuant to 47 CFR 79.104(b)(4), for a full or partial waiver of the closed captioning requirements based on one of the following provisions:

(i) The apparatus is primarily designed for activities other than receiving or playing back video programming transmitted simultaneously with sound; or

(ii) The apparatus is designed for multiple purposes, capable of receiving or playing back video programming transmitted simultaneously with sound but whose essential utility is derived from other purposes.

(h) Complaints alleging violations of the apparatus closed caption requirements.

Consumers may file written complaints alleging violations of the Commission's rules, 47 CFR 79.101–79.104, requiring apparatus designed to receive, play back, or record video programming to be equipped with built-in closed caption decoder circuitry or capability designed to display closed-captions. A written complaint filed with the Commission must be transmitted to the Consumer and Governmental Affairs Bureau through the Commission's online informal complaint filing system, U.S. Mail, overnight delivery, or facsimile. Such complaints should include certain information about the complainant and the alleged violation. The Commission may forward such complaints to the named manufacturer or provider, as well as to any other entity that Commission staff determines may be involved, and may request additional information from any relevant parties when, in the estimation of Commission staff, such information is needed to investigate the complaint or adjudicate potential violations of Commission rules.

OMB Control Number: 3060–1180.

Title: Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities, state, local, or tribal government and not for profit institutions.

Number of Respondents: 378 respondents; 378 responses.

Estimated Time per Response: 0.5 to 2 hours.

Frequency of Response: One-time and on occasion reporting requirements, twice within 12 years reporting requirement, 6, 10 and 12-years reporting requirements and third party disclosure 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 of the Communications Act of 1934.

Total Annual Burden: 581 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The FCC adopted the Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions Report and Order, FCC 14–50, on May 15, 2014, published at 79 FR 48442 (Aug. 15, 2014). The Commission seeks approval from the Office of Management and Budget (OMB) for some of the information collection requirements contained in FCC 14–50. The Commission will use the information to ensure compliance with required filings of notifications, certifications, license renewals, license cancelations, and license modifications. Also, such information will be used to minimize interference and to determine compliance with Commission's rules.

The following is a description of the information collection requirements for which the Commission seeks OMB approval:

Section 27.14(k) requires 600 MHz licensees to demonstrate compliance with performance requirements by filing a construction notification with the Commission, within 15 days of the applicable benchmark.

Section 27.14(t)(6) requires 600 MHz licensees to make a renewal showing as a condition of each renewal. The showing must include a detailed description of the applicant's provision of service during the entire license period and address: (i) The level and quality of service provided by the applicant (including the population served, the area served, the number of subscribers, the services offered); (ii) the date service commenced, whether service was ever interrupted, and the duration of any interruption or outage; (iii) the extent to which service is provided to rural areas; (iv) the extent to which service is provided to qualifying tribal land as defined in 47 CFR 1.2110(f)(3)(i); and (v) any other factors associated with the level of service to the public.

Section 27.17(c) requires 600 MHz licensees to notify the Commission within 10 days of discontinuance if they permanently discontinue service by filing FCC Form 601 or 605 and requesting license cancellation.

Section 27.19(b) requires 600 MHz licensees with base and fixed stations in the 600 MHz downlink band within 25 kilometers of Very Long Baseline Array (VLBA) observatories to coordinate with the National Science Foundation (NSF) prior to commencing operations.

Section 27.19(c) requires 600 MHz licensees that intend to operate base and fixed stations in the 600 MHz downlink band in locations near the Radio Astronomy Observatory site located in Green Bank, Pocahontas County, West Virginia, or near the Arecibo Observatory in Puerto Rico, to comply with the provisions in 47 CFR 1.924.

Section 74.602(h)(5)(ii) requires 600 MHz licensees to notify the licensee of a studio-transmitter link (TV STL), TV relay station, or TV translator relay station of their intent to commence wireless operations and the likelihood of harmful interference from the TV STL, TV relay station, or TV translator relay station to those operations within the wireless licensee's licensed geographic service area. The notification is to be in the form of a letter, via certified mail, return receipt requested and must be sent not less than 30 days in advance of approximate date of commencement of operations.

Section 74.602(h)(5)(iii) requires all TV STL, TV relay station and TV translator relay station licensees to modify or cancel their authorizations and vacate the 600 MHz band no later than the end of the post-auction transition period as defined in 47 CFR 27.4.

These rules which contain information collection requirements are designed to provide for flexible use of this spectrum by allowing licensees to choose their type of service offerings, to encourage innovation and investment in mobile broadband use in this spectrum, and to provide a stable regulatory environment in which broadband deployment would be able to develop through the application of standard terrestrial wireless rules. Without this information, the Commission would not be able to carry out its statutory responsibilities.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2015–16663 Filed 7–7–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 011961–019.

Title: The Maritime Credit Agreement.

Parties: Maersk Line A/S; China Shipping Container Lines Co. Ltd.; Cosco Container Lines Company Limited; Hanjin Shipping Co., Ltd.; Independent Container Line Ltd.; Kawasaki Kisen Kaisha Ltd.; United Arab Shipping Company; Wallenius Wilhelmsen Logistics AS; and Zim Integrated Shipping Services, Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100, Washington, DC 20036.

Synopsis: The amendment deletes Companhia Libra De Navegacao; Compania Sud American De Vapores, S.A.; Compania Libra de Navegacion Uruguay S.A.; Norasia Container Lines Limited and Dole Ocean Cargo Express as parties to the agreement. It also corrects the address of party United Arab Shipping Company.

Agreement No.: 012279–002.

Title: Hyundai Glovis/Grimaldi Space Charter Agreement.

Parties: Hyundai Glovis Co. Ltd. and Grimaldi Deep Sea S.p.A. and Grimaldi Euromed S.p.A. (acting as a single party).

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Conner; 1627 I Street NW., Suite 1100, Washington, DC 20006–4007.

Synopsis: The amendment adds Grimaldi Euromed S.p.A. as a party to the agreement.

Agreement No.: 012349.

Title: CMA CGM/HLAG U.S.-West Med Slot Charter Agreement.

Parties: CMA CGM S.A. and Hapag-Lloyd Aktiengesellschaft.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Conner; 1627 I Street NW., Suite 1100, Washington, DC 20006–4007.

Synopsis: The Agreement would authorize CMA CGM to charter space to Hapag-Lloyd in the trade between the U.S. Atlantic Coast on the one hand, and France, Italy and Spain on the other hand.

By Order of the Federal Maritime Commission.

Dated: July 2, 2015.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2015–16714 Filed 7–7–15; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act (PRA), to approve of and assign OMB numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the PRA Submission, supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB number.

DATES: Comments must be submitted on or before September 8, 2015.

ADDRESSES: You may submit comments, identified by *FR Y–16,* by any of the following methods:

- Agency Web site: *http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Email: *regs.comments@federalreserve.gov.* Include OMB 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/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons. Accordingly, your 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 (between 18th and 19th Streets NW) Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays.

Additionally, commenters may send a copy of their comments to the OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235 725 17th Street NW., Washington, DC 20503 or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files, once approved. These documents will also be made available on the Federal Reserve Board's public Web site at: *http://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears below.

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

Request for Comment on Information Collection Proposal

The following information collection, which is being handled under this delegated authority, has received initial Board approval and is hereby published for comment. At the end of the comment period, the proposed information collection, along with an analysis of comments and recommendations received, will be submitted to the Board for final approval under OMB delegated authority. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;

b. The accuracy of the Federal Reserve's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection 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.

Proposal to approve under OMB delegated authority the extension for three years, with revision, of the following report:

Report title: Annual Company-Run Stress Test Report for $10–50 Billion Companies.

Agency form number: FR Y–16.

OMB control number: 7100–0356.

Frequency: Annual.

Reporters: Bank holding companies (BHCs) and savings and loan holding companies (SLHCs) with average total consolidated assets of greater than $10 billion but less than $50 billion, and any affiliated or unaffiliated state member bank (SMB) with average total consolidated assets of more than $10 billion but less than $50 billion excluding SMB subsidiaries of covered companies.

Estimated annual reporting hours: BHCs: 24,388 hours; SLHCs: 3,283 hours; SMBs: 4,690 hours; One-time implementation: 7,200 hours.

Estimated average hours per response: BHCs: 469 hours; SLHCs: 469 hours; SMBs: 469 hours; One-time implementation: 3,600 hours.

Number of respondents: BHCs: 52; SLHCs: 7; SMBs: 10; One-time implementation: 2.

General description of report: This information collection is authorized pursuant section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), which specifically authorizes the Board to issue regulations implementing the annual stress testing requirements for its supervised institutions (12 U.S.C. 5365(i)(2)(C)). More generally, with respect to BHCs, section 5(c) of the Bank Holding Company Act (12 U.S.C. 1844(c)), authorizes the Board to require a BHC and any subsidiary ''to keep the Board informed as to—(i) its financial condition, [and] systems for monitoring and controlling financial and operating risks . . . .'' Section 9(6) of the Federal Reserve Act (12 U.S.C. 324), requires SMBs to make reports of condition to their supervising Reserve Bank in such form and containing such information as the Board may require. Finally, with respect to SLHCs, under section 312 of the Dodd-Frank Act (12 U.S.C. 5412), the Board succeeded to all powers and authorities of the Office of Thrift Supervision, U.S. Department of the Treasury, and its Director, including the authority to require SLHCs to ''file . . . such reports as may be required . . . in such form and for such periods as the [agency] may prescribe'' (12 U.S.C. 1467a(b)(2)).

The obligation to respond is mandatory. Section 165(i)(2)(A) provides that ''financial companies that have total consolidated assets [meeting the asset thresholds] . . . and are regulated by a primary Federal financial regulatory agency shall conduct annual stress tests.'' Section 165(i)(2)(B) provides that a company required to conduct annual stress tests ''shall submit a report to the Board and to its primary financial regulatory agency at such time, in such form, and containing such information as the primary financial regulatory agency shall require'' (12 U.S.C. 5365(i)(2)(B)).

As noted under section 165(i)(2)(C)(iv), companies conducting annual stress tests under these provisions are ''require[d] . . . to publish a summary of the results of the required stress tests.'' (12 U.S.C. 5365(i)(2)(C)(iv)). Regarding the information collected by the Board, however, as such information will be collected as part of the Board's supervisory process, it may be accorded confidential treatment under Exemption 8 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(8)). This information also is the type of confidential commercial and financial information that may be withheld under Exemption 4 of FOIA (5 U.S.C. 552(b)(4)).

Abstract: The annual FR Y–16 report collects quantitative projections of revenues, losses, assets, liabilities, and capital across three scenarios provided by the Board (baseline, adverse, and severely adverse) and qualitative supporting information on the methodologies and processes used to develop these internal projections. The FR Y–16 collects data through two primary schedules: (1) The Results Schedule (which includes the quantitative results of the stress tests under the baseline, adverse, and severely adverse scenarios for each quarter of the planning horizon) and (2) the Scenario Variables Schedule. In addition, respondents are required to submit a summary of the qualitative information supporting its quantitative projections. The qualitative supporting information must include:

- A description of the types of risks included in the stress test;
- a summary description of the methodologies used in the stress test;
- an explanation of the most significant causes for the changes in regulatory capital ratios, and
- the use of the stress test results.

Current Actions: Board staff proposes the following revisions and clarifications to the FR Y–16 report, effective for the 2016 stress test cycle: (1) Change the report as-of date from September 30 to December 31, (2) change the reporting submission or due date from March to July, and (3) modify the reporting instructions to clarify a number of items.

Board of Governors of the Federal Reserve System, July 1, 2015.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2015–16631 Filed 7–7–15; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–CECANF–2015–05; Docket No. 2015–0005; Sequence No. 5]

Commission To Eliminate Child Abuse and Neglect Fatalities; Announcement of Meeting; Correction

AGENCY: Commission To Eliminate Child Abuse and Neglect Fatalities, General Services Administration.

ACTION: Meeting notice; correction.

SUMMARY: The Commission to Eliminate Child Abuse and Neglect Fatalities (CECANF) published a document in the **Federal Register** of June 22, 2015 concerning the request for comments on a meeting open to the public on Wednesday, July 15, 2015 and Thursday, July 16, 2015 in Madison, Wisconsin. The document contains an incorrect address.

DATES: The meeting will be held on Wednesday, July 15, 2015, from 8:00 a.m. to 5:15 p.m. and Thursday, July 16, 2015, from 8:00 a.m. to 12:30 p.m. Central Daylight Time (CDT). Comments regarding this meeting should be received by Monday, July 13, 2015, for consideration prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Visit the CECANF Web site at *https://eliminatechildabusefatalities.sites.usa.gov/.* or contact Patricia Brincefield, Communications Director, at 202–818–9596, U.S. General Services Administration, 1800 F Street NW., Room 7003D, Washington DC 20405, Attention: Tom Hodnett (CD) for CECANF.

Correction

In the **Federal Register** of June 22, 2015, in FR Vol. 80, No. 119, on page 35649, in the third column, on lines 13–14, correct the **ADDRESSES** caption to read:

ADDRESSES: CECANF will convene its meeting at the Madison Marriott West, 1313 John Q. Hammons Drive, Middleton, Wisconsin. This site is accessible to individuals with disabilities. The meeting also will be made available via teleconference and/or webinar.

Dated: June 30, 2015.

Amy Templeman,

Acting Executive Director.

[FR Doc. 2015–16698 Filed 7–7–15; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''*Assessing the Impact of the National Implementation of TeamSTEPPS Master Training Program.*'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on April 10th, 2015 and allowed 60 days for public comment. No substantive comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by August 7, 2015.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer). Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Assessing the Impact of the National Implementation of TeamSTEPPS Master Training Program

AHRQ, in collaboration with the Department of Defense's (DoD) Tricare Management Activity (TMA), developed TeamSTEPPS® (''Team Strategies and Tools to Enhance Performance and Patient Safety'') to provide an evidence-based suite of tools and strategies for teaching teamwork-based patient safety to health care professionals. In 2007, AHRQ and DoD coordinated the national implementation of the TeamSTEPPS Program. The main objective of this program is to improve patient safety by training a select group of stakeholders such as Quality Improvement Organization (QIO) personnel, High Reliability Organization (HRO) staff, and health care system staff in various teamwork, communication, and patient safety concepts, tools, and techniques. Ultimately, TeamSTEPPS will help to build a national and state-level infrastructure for supporting teamwork-based patient safety efforts in health care organizations.

The National Implementation of TeamSTEPPS Master Training Program includes the training of ''Master Trainers'' in various health care systems capable of stimulating the utilization and adoption of TeamSTEPPS in their health care delivery systems, providing technical assistance and consultation on implementing TeamSTEPPS, and developing various channels of learning (*e.g.,* user networks, various educational venues) for continuing support and improvement of teamwork in health care. AHRQ has already trained a corps of over 5,000 participants to serve as the Master Trainer infrastructure supporting national adoption of TeamSTEPPS. An anticipated 2,400 participants, who are undergoing training now, will be studied in this assessment. After training, these participants will become Master Trainers in TeamSTEPPS and will have the opportunity to observe the program's tools and strategies in action. In addition to developing a corps of Master Trainers, AHRQ has also developed a series of support mechanisms for this effort including a data collection Web tool, a TeamSTEPPS call support center, and a monthly consortium to address any challenges encountered implementing TeamSTEPPS.

Participants applied to the program as teams representing their organizations and were accepted as training participants after having completed an organizational readiness assessment. Due to the differences among the types of organizations participating in the program, participants will apply the tools and concepts differently within and/or beyond their home organizations. For example:

- Health care system staff (or implementers) from hospitals, home health agencies, nursing homes, large physician practices, and other direct care organizations are more likely than other participants to implement the TeamSTEPPS materials on a daily basis and will be more likely to affect specific work processes being conducted within an organization. As a result, health care system participants are likely to have a focused and specific impact that is limited to their organization.
- QIO\HRO\Hospital Association\State Health Department participants (or facilitators) will be more likely to have both an in-depth and broad impact if they use the TeamSTEPPS materials to assist a particular organization in its patient safety activities, as well as to provide general patient safety guidance to a large number of organizations.

To clarify the differences among the participants, a logic model has been developed that highlights the roles of the different types of participants, the types of activities in which they are likely to engage after training, and the potential outcomes that may stem from these activities. The logic model served as a guide for developing questions for a web-based questionnaire and qualitative interviews to ensure that participant and leadership feedback is captured as thoroughly and accurately as possible.

AHRQ is conducting an ongoing evaluation of the National Implementation of TeamSTEPPS Master Training Program. The goals of this evaluation are to examine the extent to which training participants have been able to:

(1) Implement the TeamSTEPPS products, concepts, tools, and techniques in their home organizations and,

(2) spread that training, knowledge, and skills to their organizations, local areas, regions, and states.

The National Implementation of TeamSTEPPS program is led by AHRQ through its contractor, the Health Research and Educational Trust (HRET). This study is being conducted by HRET's subcontractor, IMPAQ International. The work is being

conducted pursuant to AHRQ's statutory authority to conduct and support research, evaluations, and training on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the goals of this assessment the following two data collections will be implemented:

(1) Training participant questionnaires to examine post-training activities and teamwork outcomes as a result of training from multiple perspectives. The questionnaire is directed to all Master Training participants, and will cover post-training activities, implementation experiences, facilitators and barriers to implementation encountered, and perceived outcomes as a result of these activities. Advance notice, invitations to participate, reminder emails, and thank you letters to respondents are included in the participant questionnaire.

(2) Semi-structured interviews will be conducted with members from organizations who participated in the TeamSTEPPS Master Training Program. Information gathered from these interviews will be analyzed and used to draft a ''lessons learned'' document that will capture additional detail on the issues related to participants' and organizations' abilities to implement and disseminate TeamSTEPPS post-training. The organizations will vary in terms of type of organization (*e.g.,* QIO or hospital associations versus health care systems) and region (*i.e.,* Northeast, Midwest, Southwest, Southeast, Mid-Atlantic, West Coast). In addition, we will strive to ensure that the distribution of organizations mirrors the distribution of organizations in the Master Training population. For example, if the distribution of organizations is such that only one out of every five organizations is a QIO, we will ensure that a maximum of two organizations in the site visit sample are QIOs. The interviews will more accurately reveal the degree of training spread for the organizations included. Interviewees will be drawn from qualified individuals serving in one of two roles (*i.e.,* implementers or facilitators). The interview protocol will be adapted for each role based on the respondent group and to some degree, for each individual, based on their training and patient safety experience. There is also an informed consent form that each participant will be required to sign prior to beginning the interview.

The final product for this evaluation will be a report that documents the background, methodology, results (including any patterns or themes emerging from the data), limitations of the study, and recommendations for future training programs and tool development. The results of this evaluation will help AHRQ understand the extent to which participants and participating organizations have been able to employ various TeamSTEPPS tools and concepts and the barriers and facilitators they encountered. This information will help guide AHRQ in developing and refining other patient safety tools and future training programs for patient safety.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in the study. Semi-structured interviews will be conducted with a maximum of nine individuals from each of nine participating organizations and will last about one hour each. The training participant questionnaire will be completed by approximately 10 individuals from each of about 240 organizations and is estimated to require 20 minutes to complete. The total annualized burden is estimated to be 881 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to participate in the study. The total cost burden is estimated to be $39,240.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Semi-structured interview	9	9	60/60	81
Training participant questionnaire	240	10	20/60	800
Total	249	NA	NA	881

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Semi-structured interview	9	81	$45.31	$3,670
Training participant questionnaire	240	800	45.31	36,248
Total	249	881	NA	39,918

* Based upon the mean of the average wages for all health professionals (29–0000) for the training participant questionnaire and for executives, administrators, and managers for the organizational leader questionnaire presented in the National Compensation Survey: Occupational Wages in the United States, May 2014, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm.*

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the

collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2015–16646 Filed 7–7–15; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2103]

Talib Khan: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Talib Khan from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Khan was convicted of two felonies under Federal law for conduct relating to the regulation of a drug product. Mr. Khan was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Khan failed to respond. Mr. Khan's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective July 8, 2015.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade (ELEM–4144), Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act.

On March 11, 2014, the U.S. District Court for the Eastern District of Virginia entered judgment against Mr. Khan for one count of conspiracy in violation of 18 U.S.C. 371, and one count of introducing misbranded drugs into interstate commerce, in violation of 21 U.S.C. 331(a) and 333(a)(2) and 18 U.S.C. 2.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for this conviction is as follows: Mr. Khan was a cofounder and co-owner of Gallant Pharma International Inc. (Gallant Pharma), between August 2009 and August 2013. Gallant was a company dedicated to the illegal importation and sale of misbranded and non-FDA approved chemotherapy drugs and injectable cosmetic drugs and devices in the United States.

As cofounder and co-owner of Gallant Pharma, Mr. Khan was primarily responsible for the international aspect of the conspiracy, including: (1) Determining which drugs and devices to sell in the United States; (2) establishing relationships with international suppliers; (3) directing those suppliers to send drugs and devices to transshippers in Canada and the United Kingdom; (4) arranging for transshipment from Canada and the United Kingdom to the United States; (5) interviewing, hiring, and training sales representatives in the United States; (6) and paying suppliers, sales representatives, and office employees out of foreign bank accounts. Gallant Pharma was not licensed as a prescription drug wholesaler by the Commonwealth of Virginia. Some of the drugs and devices that Mr. Khan acquired were not approved by the FDA for use on patients in the United States. Mr. Khan admitted that the drugs sold by Gallant Pharma were prescription only and were misbranded in that, among other things, they did not bear adequate directions for use and were not subject to an exemption from that requirement, and they were accompanied by non-FDA approved packaging and inserts. The drugs Mr. Kahn's company sold also lacked the FDA-required pedigree, which protects patient health by tracking each sale, purchase, or trade of a drug from the time of manufacturing to delivery to the patient, and some drug packaging and inserts were written solely in languages other than English.

Immediately after establishing Gallant Pharma's presence in the Eastern District of Virginia, on or about September 25, 2009, Mr. Khan received a cease and desist letter from a law firm on behalf of Medicis, the exclusive authorized marketer of Restylane and Perlane in the United States and Canada. The letter informed Mr. Khan's company that its marketing of these drugs violated the FD&C Act and could subject Gallant Pharma to substantial criminal and civil penalties. The letter included Gallant Pharma's marketing materials, which falsely claimed that Gallant Pharma had been ''strictly working with the current FDA rules and regulations for almost 10 years.''

Mr. Khan purchased drugs and devices from suppliers in, among other places, Turkey, Switzerland, the United Kingdom, and the United Arab Emirates. In or around March 2011, after a coconspirator's medical license had expired, Mr. Khan altered the expiration date on the medical license to make it appear that the license was still valid.

On at least 18 occasions, Mr. Khan personally completed false customs declarations and thereby illegally imported misbranded drugs and devices from Canada to the Eastern District of Virginia. Mr. Khan also personally accepted and processed orders for Gallant Pharma customers.

Between August 2009 and August 2013, Gallant Pharma received illegal proceeds of at least $12,400,000 from the sale of misbranded and non-FDA approved drugs and devices in the United States. Mr. Khan admitted that he was an organizer or leader of this criminal activity and he additionally admitted that his actions were in all respects knowing, voluntary, and intentional, and did not occur by accident, mistake, or for another innocent reason.

As a result of his conviction, on March 19, 2015, FDA sent Mr. Khan a notice by certified mail proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on the finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Khan was convicted of felonies under Federal law for conduct related to the regulation of a drug product. The proposal also offered Mr. Khan an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to

request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on March 23, 2015. Mr. Khan failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Talib Khan has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Talib Khan is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see DATES)(see section 201(dd), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act, (21 U.S.C. 321(dd), 335a(c)(1)(B), and 335a(c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Talib Khan, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Khan provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications from Talib Khan during his period of debarment (section 306(c)(1)(B) of the FD&C Act (21 U.S.C. 335a(c)(1)(B))).

Any application by Mr. Khan for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA–2014–N–2103 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 25, 2015.

Douglas Stearn,

Director, Division of Compliance Policy, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2015–16664 Filed 7–7–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than August 7, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 594–4306.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal, Infant, and Childhood Home Visiting (Home Visiting) Program Fiscal Year (FY) 2015, FY2016, FY2017 Non-Competing Continuation Annual Progress Report for Formula Grant.

OMB No.: 0915–0355—Extension.

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (Home Visiting) Program, administered by the Health Resources and Services Administration (HRSA) in close partnership with the Administration for Children and Families (ACF), supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. The purpose of this formula grant program is to: support the delivery of coordinated and comprehensive voluntary early childhood home visiting program services and effective implementation of high-quality evidence-based practices. The fifty states, District of Columbia, and 5 territories and nonprofit organizations that would provide services in jurisdictions that have not directly applied for or been approved for a grant are eligible for formula grants and submit non-competing continuation progress reports annually. There are 56 jurisdictions eligible for formula awards and 56 formula awards are issued annually.

Need and Proposed Use of the Information: This information collection is needed for eligible entities to report progress under the Home Visiting Program annually. On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (ACA). Section 2951 of the ACA amended Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Home Visiting Program (*http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf,* pages 216–225). A portion of funding under this program is awarded to participating states and eligible jurisdictions by formula. The purpose of formula funding is to support the delivery of coordinated and comprehensive voluntary early childhood home visiting program services and effective implementation of high-quality evidence-based practices.

The information collected will be used to review grantee progress on proposed project plans sufficient to permit project officers to assess whether the project is performing adequately to achieve the goals and objectives that were previously approved. This report will also provide implementation plans for the upcoming year, which project officers can use to assess to whether the plan is consistent with the grant as approved, and will result in implementation of a high-quality project that will complement the home visiting program as a whole. Progress Reports are submitted to project officers through the Electronic HandBooks (EHB). Failure to collect this information would result in the inability of the project officers to exercise due diligence in monitoring and overseeing the use of grant funds in keeping with legislative, policy, and programmatic requirements. Grantees are required to provide a performance narrative with the following sections: project identifier

information, accomplishments and barriers, home visiting program goals and objectives, update on the home visiting program promising approach, implementation of the home visiting program in targeted at-risk communities, progress toward meeting legislatively-mandated reporting on benchmark areas, home visiting quality improvement efforts, and updates on the administration of the home visiting program.

In the event a new Funding Opportunity Announcement is issued annually for the formula grant program, the application for new grant funds may take the place of completion of a non-competing continuation progress report.

Likely Respondents: Grantees with Home Visiting Formula Awards Awarded in Federal FYs 2013—2017.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden—Hours: The burden estimates presented in the table below are based on consultations with a few states on the guidance. Grantees receive a new formula grant annually and are expected to report on progress annually, so the expectation is that grantees would submit non-competing continuation progress reports four times between federal fiscal years 2015 and 2018. Only seven grantees are currently implementing a promising approach and require an annual update on the promising approach.

Form name	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total burden hours
Formula Grant Award	56	4	224	42	9408
Total	56	4	224	42	9408

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–16697 Filed 7–7–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Clinical and Preventive Services; Division of Behavioral Health; Domestic Violence Prevention Initiative

Announcement Type: New —Limited Competition

Funding Announcement Number: HHS–2015–IHS–DVPI–0001

Catalog of Federal Domestic Assistance Number (CFDA): 93.933

Key Dates

Application Deadline Date: September 8, 2015

Review Date: September 14–18, 2015

Earliest Anticipated Start Date: September 30, 2015

Signed Tribal Resolutions Due Date: September 11, 2015

Proof of Non-Profit Status Due Date: September 8, 2015

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS), an agency which is part of the Department of Health and Human Services (HHS), is accepting applications for a five-year funding cycle, to continue the planning, development, and implementation of the Domestic Violence Prevention Initiative (Short Title: DVPI). This program was first established by the Omnibus Appropriations Act of 2009, Public Law 111–8, 123 Stat. 524, 735, and continued in the annual appropriations acts since that time. This program is authorized under the authority of 25 U.S.C. 13, the Snyder Act, and the Indian Health Care Improvement Act, 25 U.S.C. 1601–1683. The amounts made available for the DVPI shall be allocated at the discretion of the Director, IHS and shall remain available until expended. IHS utilizes a national funding formula developed in consultation with Tribes and the National Tribal Advisory Committee (NTAC) on behavioral health, as well as conferring with urban Indian health programs (UIHPs). The funding formula provides the allocation methodology for each IHS Service Area. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

From August 2010–August 2015, IHS funded 65 IHS, Tribal, Tribal organizations, and UIHPs that participated in a nationally coordinated five-year demonstration pilot project to expand outreach and increase awareness of domestic and sexual violence and provide victim advocacy, intervention, case coordination, policy development, community response teams, and community and school education programs. The DVPI promotes the development of evidence-based and practice-based models that represent culturally appropriate prevention and treatment approaches to domestic and sexual violence from a community-driven context. For a complete listing of demonstration pilot projects, please visit *www.ihs.gov/dvpi/pilotprojects.*

Purpose

The primary purpose of this grant program is to accomplish the DVPI goals listed below:

1. Build Tribal, UIHP, and Federal capacity to provide coordinated community responses to American Indian/Alaska Native (AI/AN) victims of domestic and sexual violence.

2. Increase access to domestic and sexual violence prevention, advocacy, crisis intervention, and behavioral health services for AI/AN victims and their families.

3. Promote trauma-informed services for AI/AN victims of domestic and sexual violence and their families.

4. Offer healthcare provider and community education on domestic and sexual violence.

5. Respond to the healthcare needs of AI/AN victims of domestic and sexual violence.

6. Incorporate culturally appropriate practices and/or faith-based services for AI/AN victims of domestic and sexual violence.

To accomplish the DVPI goals, IHS invites applicants to address one of the Purpose Areas below:

- Purpose Area 1: Domestic and Sexual Violence Prevention, Advocacy, and Coordinated Community Responses
- Purpose Area 2: Provide Forensic Healthcare Services

In certain circumstances, applicants may choose to apply for more than one Purpose Area. If this is the case, applicants must submit a *separate application for each Purpose Area.* IHS encourages applicants to develop and submit applications that emphasize cross-system collaboration among the Purpose Areas, the inclusion of family, youth and community resources, and the application of cultural approaches.

Evidence-Based Practices, Practice-Based Evidence, Promising Practices, and Local Efforts

IHS strongly emphasizes the use of data and evidence in policymaking and program development and implementation. Applicants under each Purpose Area must identify one or more evidence-based practice, practice-based evidence, best or promising practice, and/or local effort they plan to implement in the Project Narrative section of their application. The DVPI Web site (*http://www.ihs.gov/dvpi/bestpractices/*) is one resource that applicants may use to find information to build on the foundation of prior domestic and sexual violence prevention and treatment efforts, in order to support the IHS, Tribes, Tribal organizations, and UIHPs in developing and implementing Tribal and/or culturally appropriate domestic and sexual violence prevention and early intervention strategies.

Purpose Areas

Purpose Area 1: Domestic and Sexual Violence Prevention, Advocacy, and Coordinated Community Responses: IHS is seeking applicants to address the following broad objectives:

- Expand crisis intervention, counseling, advocacy, behavioral health, and case management services to victims of domestic and sexual violence;
- Foster coalitions and networks to improve coordination and collaboration among victim service providers, healthcare providers, and other responders;
- Educate and train service providers on trauma, domestic violence, and sexual assault and its impact on victims;
- Promote community education for adults and youth on domestic and sexual violence;
- Improve organizational practices to improve services for individuals seeking services for domestic and sexual violence;
- Establish coordinated community response policies, protocols, and procedures to enhance domestic and sexual violence intervention and prevention;
- Integrate culturally appropriate practices and/or faith-based services to facilitate the social and emotional well-being of victims and their children; and
- Implement trauma informed care interventions to support victims and their children.

Purpose Area 2: Forensic Healthcare: IHS is seeking applicants to address the following broad objectives:

- Expand available medical forensic services to victims of domestic and sexual violence;
- Foster coalitions and networks to improve coordination and collaboration among forensic healthcare programs to ensure adequate services exist either on-site or by referral for victims of domestic and sexual violence 24/7 year round;
- Educate and train providers to conduct medical forensic examinations;
- Promote community education on available medical forensic services;
- Improve health system organizational practices to improve medical forensic services and care coordination among victim services;
- Establish local health system policies for sexual assault, domestic violence, and child maltreatment;
- Integrate culturally appropriate treatment services throughout the medical forensic examination process; and
- Implement trauma informed care interventions to support victims and their children.

Limited Competition Justification

There is limited competition under this announcement because the authorizing legislation restricts eligibility to Tribes that meet specific criteria. See the Consolidated Appropriations Act of 2008, Public Law 110–161, 121 Stat. 1844, 2135.

II. Award Information

Type of Award

Grant.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2015 is approximately $7,600,000. Individual award amounts are anticipated to be from $50,000 to $200,000. IHS expects to allocate funding for the 12 IHS service areas as described below. Applicants will be awarded according to their location within their respective IHS service area and will not compete with applicants from other IHS service areas. UIHP applicants will be selected from a category set aside for UIHP applicants only. UIHP awards will be $100,000 each. The amount of funding available for competing and continuation awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the Agency. IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

The number of anticipated awards is dependent on the number of applications received in response to the announcement and available funds. The funding breakdown by area is as follows:

Alaska IHS Service Area

IHS expects to provide $1,100,500 in total awards for a 12-month project period.

Albuquerque IHS Service Area

IHS expects to provide $332,000 in total awards for a 12-month project period.

Bemidji IHS Service Area

IHS expects to provide $326,500 in total awards for a 12-month project period.

Billings IHS Service Area

IHS expects to provide $303,500 in total awards for a 12-month project period.

California IHS Service Area

IHS expects to provide $235,000 in total awards for a 12-month project period.

Great Plains IHS Service Area

IHS expects to provide $1,008,100 in total awards for a 12-month project period.

Nashville IHS Service Area

IHS expects to provide $144,000 in total awards for a 12-month project period.

Navajo IHS Service Area

IHS expects to provide $1,155,700 in total awards for a 12-month project period.

Oklahoma City IHS Service Area

IHS expects to provide $1,365,500 in total awards for a 12-month project period.

Phoenix IHS Service Area

IHS expects to provide $578,000 in total awards for a 12-month project period.

Portland IHS Service Area

IHS expects to provide $351,700 in total awards for a 12-month project period.

Tucson IHS Service Area

IHS expects to provide $99,500 in total awards for a 12-month project period.

Urban Indian Health Programs

IHS expects to provide $600,000 in total awards for a 12-month project period.

Project Period

The project period is for five years and will run consecutively from September 30, 2015, to September 29, 2020.

Continuation Applications

The current funding announcement is a request for the submission of proposals for a five-year project proposal; however due to the limited amount of funding available for competing and continuation awards issued under this announcement, the funds are subject to the availability of appropriations and budgetary priorities of the Agency (also reference ''Estimated Funds Available'' in this section, ''Award Information''). Therefore, awardees will be required to submit a Continuation Application at the end of each project year (dates to be determined) after the initial funding award for Project Year 1, which will assist in determining continued funding from Project Year to Project Year for the five-year project funding cycle. Awardees will be required to submit an entire application package including all components listed under ''Content and Form Application Submission'' in the GrantSolutions System to assist in determination of continued funding.

The continuation applications will assist IHS in ensuring that all awardees are meeting their goals and objectives, carrying out project activities, and submitting required documentation in a timely manner according to the terms and conditions of their Notice of Award (NoA) and the behavioral health program requirements.

III. Eligibility Information

1. Eligibility

To be eligible for this ''Limited Competition'' in an effort to address behavioral health disparities within AI/AN communities, IHS is limiting eligibility to Federally recognized Tribes, Tribal organizations, and Urban Indian organizations. Eligible applicants are as follows:

- Federally recognized Indian Tribe, as defined by 25 U.S.C. 1603(14);
- Tribal organization, as defined by 25 U.S.C. 1603(26);
- Urban Indian organization as defined by 25 U.S.C. 1603(29). Applicants must provide proof of non-profit status with the application, *e.g.,* 501(c)(3).

Note: Please refer to ''Tribal Resolution'' subsection and Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

a. If application budgets exceed the highest dollar amount outlined under the ''Estimated Funds Available'' section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

b. Awardee Meetings

Awardees are required to send the Project Director and/or Project Coordinator (the individual who runs the day-to-day project operations) to an annual DVPI meeting. Participation will be in-person or virtual meetings. The awardee is required to include travel for this purpose in the budget and narrative of the project proposal. At these meetings, awardees will present updates and results of their projects including note of significant or ongoing concerns related to project implementation or management. Federal staff will provide updates and technical assistance to awardees in attendance.

The in-person meeting location(s) will be determined at a later date but for purposes of project budget development, awardees should estimate costs for Denver, CO as a potential site that is accessible to most of ''Indian Country.'' Attendance at these meetings is mandatory for the Project Director/Project Coordinator.

Tribal Resolution

Signed Tribal Resolution—A signed Tribal resolution *from each of* the Indian Tribes served by the project *must accompany the electronic application submission.* An Indian Tribe that is proposing a project affecting another Indian Tribe must include *resolutions from all affected Tribes to be served.* Applications by Tribal organizations will not require a specific Tribal resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities.

Draft Tribal resolutions are acceptable in lieu of an official signed resolution and *must* be submitted along with the electronic application submission prior to the official application deadline date or prior to the start of the Objective Review Committee (ORC) date. *However, an official signed Tribal resolution must be received by DGM prior to the beginning of the objective review. If an official signed resolution is not received by the review date listed under the Key Dates section on page one of this announcement, the application will be considered incomplete and ineligible.*

Official signed Tribal resolutions can be mailed to DGM, Attn: Patience Musikikongo, 801 Thompson Avenue, TMP Suite 360, Rockville, Maryland 20852. Applicants submitting Tribal resolutions after or aside from the required online electronic application submission must ensure that the information is received by IHS/DGM. It is highly recommended that the documentation be sent by a delivery method that includes delivery confirmation and tracking. Please contact Ms. Patience Musikikongo by telephone at (301) 443–2059 prior to the review date regarding submission questions.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the application deadline date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by IHS by obtaining documentation confirming delivery (*i.e.* FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at *http://www.Grants.gov* or *https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_funding.*

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Cover letter.
- Table of contents.
- Abstract (must be single-spaced and should not exceed one page).
- Application forms:
  - SF–424, Application for Federal Assistance.
  - SF–424A, Budget Information—Non-Construction Programs.
  - SF–424B, Assurances—Non-Construction Programs.
- Statement of Need (must be single-spaced and not exceed two pages).
  - Includes the Tribe, Tribal organization or UIHP background information.
- Project Narrative (must be included as an attachment to the application package and must be single-spaced and not exceed 20 pages).
  - Proposed scope of work, goals and objectives, and activities that provide a description of what will be accomplished, including a one-page timeline chart, and a plan for local data collection.
- Budget and Budget Narrative (must be single-spaced and not exceed four pages).
- Tribal Resolution or Tribal Letter of Support (only required for Tribes and Tribal organizations).
  - See Key Dates for separate due date submission requirement
- Letter(s) of Support from organization's Board of Directors (or relevant equivalent), Local Organizational Partners and Tribal or Urban Indian Organizational and Community Partners (All Applicants).
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all key personnel.
- Position descriptions for all key personnel.
- Contractor/consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required) in order to receive IDC.
- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) A–133 required Financial Audit or other required audit (if applicable).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
- Face sheets from audit reports. These can be found on the FAC Web site: *http://harvester.census.gov/sac/dissem/accessoptions.html?submit=Go+To+Database.*

Public Policy Requirements

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the discrimination policy.

Requirements for Project and Proposals

The project narrative should be a separate Word document that is no longer than 20 pages and must: be single-spaced, type written, consecutively numbered pages, using black type not smaller than 12 characters per one inch, and be printed on one side only of standard size 8½″ x 11″ paper.

Succinctly address and answer all questions listed under required application components and place all responses and required information in the correct section (noted below), or they shall not be considered or scored. These narratives will assist the ORC in becoming familiar with the applicant's activities and accomplishments prior to this grant award. If the narrative exceeds the page limit, only the first twenty (20) pages will be reviewed. The 20-page limit for the narrative does not include the cover letter, table of contents, abstract, statement of need, standard forms, Tribal resolutions, budget and budget narrative, and/or other appendix items.

Applications must include the following *REQUIRED* application components:

- Cover Letter—Includes the title of the program and all contact information for the Tribe/Tribal organization or UIHP.
- Table of Contents
- Abstract—Provides a summary of all the key information for the project. Must not exceed one single-spaced page.
- Statement of Need—Provides the facts and evidence that support the need for the project and establishes that the Tribe/Tribal organization or UIHP understands the problems and can reasonably address them. Provides background information on the Tribe/Tribal organization or UIHP. May not exceed two single-spaced pages.
- Project Narrative—The project narrative (description) describes the project. May not exceed 20 single-spaced pages.

Required components in the project narrative are as follows:

A. Goals and Objectives
B. Project Activities
C. Timeline Chart
D. Organization Capacity and Staffing/Administration
E. Plan for Local Data Collection

- Budget and Budget Narrative—Applicants are to submit a budget and budget narrative for *Project Year 1 only.* The budget and budget narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative for the *first project year expenses only.* The budget and budget narrative may not exceed four single-spaced pages for both documents combined.

The DVPI Proposal Template and associated templates for the Timeline Chart, Biographical Sketch, Budget and Budget Narrative, can be located and downloaded at the DVPI Web site: *www.ihs.gov/dvpi/funding announcement.*

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 11:59 p.m. Eastern Daylight Time (EDT) on the application deadline date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. Grants.gov will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact Grants.gov Customer Support via email to *support@grants.gov* or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Paul Gettys (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten (10) days prior to the application deadline. Please do not contact DGM until you have received a

Grants.gov tracking number. In the event you are not able to obtain a tracking number, call DGM as soon as possible.

If the applicant needs to submit a paper application instead of submitting electronically through Grants.gov, a waiver must be requested. Prior approval must be requested and obtained from Ms. Tammy Bagley, Acting Director, DGM, (see Section IV.6 below for additional information). The waiver must: 1) be documented in writing (emails are acceptable) *before* submitting a paper application, and 2) include clear justification for the need to deviate from the required electronic grants submission process. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Tammy.Bagley@ihs.gov.* Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval *must* be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Acting Director, DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer, DGM. Paper applications must be received by DGM no later than 5:00 p.m., EST, on the application deadline date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the *http://www.Grants.gov* Web site to submit an application electronically and select the ''Find Grant Opportunities'' link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the completed application via the *http://www.Grants.gov* Web site. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If the applicant receives a waiver to submit paper application documents, they must follow the rules and timelines that are noted below. The applicant must seek assistance at least ten (10) days prior to the application deadline date listed in the Key Dates section on page one of this announcement.

Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or *http://www.Grants.gov* registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in *http://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting the application electronically, please contact Grants.gov Support directly at: *support@grants.gov* or (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the Agency must be obtained.
- If it is determined that a waiver is needed, the applicant must submit a request in writing (emails are acceptable) to *GrantsPolicy@ihs.gov* with a copy to *Tammy.Bagley@ihs.gov.* Please include a clear justification for the need to deviate from the standard electronic submission process.
- If the waiver is approved, the application should be sent directly to DGM by the application deadline date listed in the Key Dates section on page one of this announcement.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through Grants.gov as the registration process for SAM and Grants.gov could take up to fifteen working days.
- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by DGM.
- All applicants must comply with any page limitation requirements described in this funding announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from Grants.gov containing a Grants.gov tracking number. DGM will download the application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither DGM nor the behavioral health program will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.
- IHS will not acknowledge receipt of applications.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access it through *http://fedgov.dnb.com/webform,* or to expedite the process, call (866) 705–5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended (Transparency Act), to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that are not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with SAM is free of charge. Applicants may register online at *https://www.sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for

DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: *https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics.*

V. Application Review Information

The instructions for preparing the application statement of need, project narrative, budget and budget narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The 20 page narrative should include activities for the proposed one-year project. The statement of need, project narrative, budget and budget narrative sections should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 65 points is required for funding. Points are assigned as follows:

1. Criteria

Applications will be reviewed and scored according to the *quality* of responses to the required application components in Sections A–E.

- In developing the Statement of Need, Project Narrative, Budget and Budget Narrative sections of the application, use the instructions provided for each section, which have been tailored to this program.
- The Statement of Need should not exceed two single-spaced pages.
- The Project Narrative (required components, Sections A–E, in ''Requirements for Project Proposals'') together should not exceed 20 single-spaced pages.
- The Budget and Budget Narrative the applicant provides will be considered by reviewers in assessing the applicant's response, along with the material in the Project Narrative. The budget and budget narrative must not exceed four single-spaced pages.
- The applicant *must* use the five sections (Sections A–E) listed below in developing the: 1) Statement of Need (Section A); 2) Project Narrative (Sections B, C and D); and 3) Budget and Budget Narrative (Section E). The applicant *must* place the required information in the correct section, *or it will not be considered.* The application will be scored according to how well the applicant addresses the requirements for each section of the Statement of Need, Project Narrative, Budget and Budget Narrative.
- The number of points after each heading is the maximum number of points a review committee may assign to that section. Although scoring weights are not assigned to individual bullets, each bullet is assessed in deriving the overall section score.

Section A: Statement of Need (35 Points)

1. Identify the proposed catchment area and provide demographic information on the population(s) to receive services through the targeted systems or agencies, *e.g.,* race, ethnicity, Federally recognized Tribe, language, age, socioeconomic status, sexual identity (sexual orientation, gender identity) and other relevant factors, such as literacy. Describe the stakeholders and resources in the catchment area that can help implement the needed infrastructure development.

2. Based on the information and/or data currently available, document the prevalence of domestic and sexual violence.

3. Based on the information and/or data currently available, document the need for an enhanced infrastructure to increase the capacity to implement, sustain, and improve effective domestic and sexual violence services in the proposed catchment area that is consistent with the purpose of the program and the intent of the funding opportunity announcement. Based on current available data, describe the service gaps and other problems related to the need for infrastructure development. Identify the source of the data. Documentation of need may come from a variety of qualitative and quantitative sources. Examples of data sources for the quantitative data that could be used are local epidemiologic data (Tribal Epidemiology Centers, IHS area offices), state data (*e.g.,* from state needs assessments, Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health), and/or national data (*e.g.,* from Centers for Disease Control and Department of Justice or Census data). This list is not exhaustive; applicants may submit other valid data, as appropriate for the applicant's program.

4. Describe the existing behavioral health service gaps, barriers, and other systemic challenges related to the need for planning and infrastructure development and coordination of domestic and sexual violence services.

5. Describe potential project partners and community resources in the catchment area that can participate in the planning process and infrastructure development.

6. Affirm the goals of the project are consistent with priorities of the Tribal government or board of directors and that the governing body is in support of this application.

Section B: Project Narrative/Proposed Approach/Project Plan (20 Points)

1. Describe the purpose of the proposed project, including a clear statement of goals and objectives. Describe how achievement of goals will increase system capacity to support effective domestic and sexual violence.

2. Describe how project activities will increase the capacity of the identified community to plan and improve the coordination of a collaborative service system for victims of domestic and sexual violence. Describe anticipated barriers to progress of the project and how these barriers will be addressed.

3. Discuss how the proposed approach addresses the local language, concepts, attitudes, norms and values about domestic and sexual violence.

4. Describe how the proposed project will address issues of diversity within the population of focus including age, race, gender, ethnicity, culture/cultural identity, language, sexual orientation, disability, and literacy.

5. Describe how members of the community (including youth and families that may receive services) will be involved in the planning, implementation, and performance assessment of the project.

6. Describe how the efforts of the proposed project will be coordinated with any other related Federal grants, including IHS, SAMHSA, or Bureau of Indian Affairs (BIA) services provided in the community (if applicable).

7. Provide a timeline chart depicting a realistic timeline for the entire project period showing key activities, milestones, and responsible staff. These key activities should include the requirements outlined in the chosen Purpose Area. [Note: The timeline chart should be part of the Project Narrative as specified in the ''Requirements for Project Proposals'' section. It should not be placed in as an attachment.]

8. If the applicant plans to include an advisory body in the project, describe its membership, roles and functions, and frequency of meetings.

9. Identify any other organization(s) that will participate in the proposed project. Describe their roles and responsibilities and demonstrate their commitment to the project. Include a list of these organizations as an *attachment* to the project proposal/application. In the attached list, indicate the organizations that the Tribe/Tribal organization or UIHP has worked with

or currently works with. [Note: The attachment will not count as part of the 20-page maximum.]

Section C: Organizational Capacity (15 Points)

1. Describe the management capability and experience of the applicant Tribe, Tribal organization, or UIHP and other participating organizations in administering similar grants and projects.

2. Discuss the applicant Tribe, Tribal organization, or UIHP experience and capacity to provide culturally appropriate/competent services to the community and specific populations of focus.

3. Describe the resources available for the proposed project (*e.g.,* facilities, equipment, information technology systems, and financial management systems).

4. Describe how program continuity will be maintained if/when there is a change in the operational environment (*e.g.,* staff turnover, change in project leadership, change in elected officials) to ensure stability over the life of the grant.

5. Provide a complete list of staff positions for the project, including the Project Director, Project Coordinator, and other key personnel, showing the role of each and their level of effort and qualifications.

6. Include position descriptions as *attachments* to the project proposal/application for the Project Director, Project Coordinator, and all key personnel. Position descriptions should be no longer than one page each. [Note: Attachments will not count against the 20 page maximum].

7. For staff that are identified and currently on staff, include a biographical sketch (not to include personally identifiable information) for the Project Director, Project Coordinator, and other key positions as *attachments* to the project proposal/application. Each biographical sketch should not exceed one page. Reviewers will not consider information past page one.

Note: [Attachments will not count against the 20 page maximum]

Do not include any of the following:

i. Personally Identifiable Information;

ii. Resumes; or

iii. Curriculum Vitae

Section D: Local Data Collection and Program Evaluation (20 Points)

Describe the applicant's plan for gathering local data, submitting data requirements, and document the applicant's ability to ensure accurate data tracking and reporting.

Funded projects are required to coordinate data collection efforts with a regional (IHS Area) evaluator. The regional evaluators will be identified and funded by IHS and coordinated with each local project and will feed the regional and national evaluation for DVPI. Awardees will work with the regional evaluator(s) to evaluate the core processes, outcomes, impacts, and benefits associated with the DVPI. Awardees shall collect local data related to the project and submit it in semi-annual progress reports. The data collected and submitted through the progress reports will be made available to the regional and national evaluator(s) for DVPI. The purpose of the regional and national evaluation is to assess the extent to which the projects are successful in achieving project goals and objectives and to determine the impact of DVPI-related activities on individuals and the larger community.

Progress reporting will be required on national and regionally selected data elements related to program outcomes and financial reporting for all awardees. Progress reports will be collected semi-annually throughout the project on a web-based portal. Progress reports include the compilation of quantitative (numerical) data (*e.g.,* number served; screenings completed, etc.) and of qualitative or narrative (text) data. The regional and national evaluators will also coordinate the narrative data collection and provide an analysis of funded projects' responses to open-ended questions about ''program accomplishments,'' ''barriers to implementation,'' and description of partnership and coalition work.

The reporting portal will be open to project staff on a 24 hour/7 day week basis for the duration of each reporting period. Reporting form formats allow awardees to report outcomes and include open-ended questions about current accomplishments and barriers during the reporting period. In addition, financial report forms (SF–425), which document funds received and expended during the semi-annual reporting period, will be available. All materials will be provided on the portal and are to be submitted online. Technical assistance for web-based data entry and for the completion of required fiscal documents will be timely and readily available to awardees by assigned IHS Project Officers.

Section E: Budget and Justification (10 Points)

The applicant is required to include a line item budget for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative for *Project Year 1 only.* The budget should match the scope of work described in the project narrative for the *first project year expenses only.* The page limitation should not exceed four single-spaced pages.

The applicant must provide a narrative justification of the items included in the proposed budget supporting the mission and goals of DVPI, as well as a description of existing resources and other support the applicant expects to receive for the proposed project. Other support is defined as funds or resources, whether Federal, non-Federal or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions or non-Federal means. (This should correspond to Item #18 on the applicant's SF–424, Estimated Funding.) Provide a narrative justification supporting the development or continued collaboration with other partners regarding the proposed activities to be implemented.

Additional Documents Can Be Uploaded as Appendix Items in Grants.gov

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal, urban and Federal reviewers appointed by the IHS Program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer, DGM. Applicants will be notified by DGM, via email, to outline minor missing

components (*i.e.,* budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by DGM in our grant system, GrantSolutions (*https://www.grantsolutions.gov*). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 65 points, and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application submitted. The IHS program office will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum score of 65 points and were deemed by the ORC to be ''Approved'', but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2015, the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS Grants Management Official announcing to the Project Director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

Grants are administered in accordance with the following regulations, policies, and OMB cost principles:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements HHS Awards, located at 45 CFR part 75.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' located at 45 CFR part 75, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of IDC in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of Interior (Interior Business Center) *http://www.doi.gov/ibc/services/Indirect_Cost_Services/index.cfm.* For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under ''Agency Contacts'' or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: 1) the imposition of special award provisions; and 2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Reports must be submitted electronically via GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Progress reports are required annually through the national DVPI online progress report data portal, within thirty (30) days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the reporting period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within ninety (90) days of expiration of the budget/project period.

B. Financial Reports

Federal Financial Report FFR (SF–425), Cash Transaction Reports are due thirty (30) days after the close of every calendar quarter to the Payment Management Services, HHS at: *http://www.dpm.psc.gov.* It is recommended that the applicant also send a copy of the FFR (SF–425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: the Progress Reports and Federal Financial Report (SF–425).

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires OMB to establish a single searchable database,

accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: 1) the project period start date was October 1, 2010 or after and 2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit DGM Grants Policy Web site at: *https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics.*

Telecommunication for the hearing impaired is available at: TTY (301) 443–6394.

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Beverly Cotton, Director, IHS Division of Behavioral Health, 801 Thompson Avenue, Rockville, MD 20874, Phone: (301) 443–2038, Fax: (301) 443–7623, Email: *dbh@ihs.gov.*

2. Questions on grants management and fiscal matters may be directed to: Patience Musikikongo, GMS, IHS Division of Grants Management, 801 Thompson Ave, TMP Suite 379, Rockville, MD 20874, Phone: (301) 443–2059, Fax: (301) 443–9602, *Patience.Musikikongo@ihs.gov.*

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, Phone: (301) 443–2114; or the DGM main line (301) 443–5204, Fax: (301) 443–9602, E-Mail: *Paul.Gettys@ihs.gov.*

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Pub. L. 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: June 30, 2015.

Robert G. McSwain,

Acting Director, Indian Health Service.

[FR Doc. 2015–16750 Filed 7–7–15; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Announcement Number: HHS–2015–IHS–MSPI–0001; Catalog of Federal Domestic Assistance Number (CFDA): 93.933]

Division of Behavioral Health; Office of Clinical and Preventive Services; Methamphetamine and Suicide Prevention Initiative; Announcement Type: New—Limited Competition

Key Dates

Application Deadline Date: September 8, 2015.

Review Date: September 14–18, 2015.

Earliest Anticipated Start Date: September 30, 2015.

Signed Tribal Resolutions Due Date: September 11, 2015.

Proof of Non-Profit Status Due Date: September 8, 2015.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS), an agency which is part of the Department of Health and Human Services (HHS), is accepting applications for a five-year funding cycle to continue the planning, development, and implementation of the Methamphetamine and Suicide Prevention Initiative (Short Title: MSPI). This program was first established by the Consolidated Appropriations Act of 2008, Public Law 110–161, 121 Stat. 1844, 2135, and has been continued in the annual appropriations acts since that time. This program is authorized under the authority of 25 U.S.C. 13, the Snyder Act, and the Indian Health Care Improvement Act, 25 U.S.C. 1601–1683. The amounts made available for the MSPI shall be allocated at the discretion of the Director of IHS and shall remain available until expended. IHS utilizes a national funding formula developed in consultation with Tribes and the National Tribal Advisory Committee (NTAC) on behavioral health, as well as conferring with urban Indian health programs (UIHPs). The funding formula provides the allocation methodology for each IHS Service Area. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

From September 2009–August 2015, IHS funded 130 IHS, Tribal, and UIHPs that participated in a nationally coordinated six-year demonstration pilot project, focusing on providing methamphetamine and suicide prevention and intervention resources for Indian Country. The MSPI promotes the use and development of evidence-based and practice-based models that represent culturally-appropriate prevention and treatment approaches to methamphetamine use and suicide prevention from a community-driven context. For a complete listing of demonstration pilot projects, please visit *www.ihs.gov/mspi/pilotprojects.*

Purpose

The primary purpose of this grant program is to accomplish the MSPI goals listed below:

1. Increase Tribal, UIHP, and Federal capacity to operate successful methamphetamine prevention, treatment, and aftercare and suicide prevention, intervention, and postvention services through implementing community and organizational needs assessment and strategic plans.

2. Develop and foster data sharing systems among Tribal, UIHP, and Federal behavioral health service providers to demonstrate efficacy and impact.

3. Identify and address suicide ideations, attempts, and contagions among American Indian and Alaska Native (AI/AN) populations through the development and implementation of culturally appropriate and community relevant prevention, intervention, and postvention strategies.

4. Identify and address methamphetamine use among AI/AN populations through the development and implementation of culturally appropriate and community relevant prevention, treatment, and aftercare strategies.

5. Increase provider and community education on suicide and methamphetamine use by offering appropriate trainings.

6. Promote positive AI/AN youth development and family engagement

through the implementation of early intervention strategies to reduce risk factors for suicidal behavior and substance abuse.

Funded projects are not expected to address all of the MSPI goals, only those relevant to the Purpose Area for which they are applying.

To accomplish the MSPI goals, IHS invites applicants to address one of the Purpose Areas below:

- Purpose Area 1: Community and Organizational Needs Assessment and Strategic Planning
- Purpose Area 2: Suicide Prevention, Intervention, and Postvention
- Purpose Area 3: Methamphetamine Prevention, Treatment, and Aftercare
- Purpose Area 4: Generation Indigenous Initiative Support.

In certain circumstances, applicants may choose to apply for more than one Purpose Area. If this is the case, applicants must submit a *separate application for each Purpose Area.* IHS encourages applicants to develop and submit applications that emphasize cross-system collaboration among the Purpose Areas, the inclusion of family, youth and community resources, and the application of cultural approaches.

Evidence-Based Practices, Practice-Based Evidence, Promising Practices, and Local Efforts

IHS strongly emphasizes the use of data and evidence in policymaking and program development and implementation. Applicants under Purpose Area 2, Purpose Area 3, and Purpose Area 4 must identify one or more evidence-based practice, practice-based evidence, best or promising practice, and/or local effort that they plan to implement in the Project Narrative section of their application. The MSPI Web site (*http://www.ihs.gov/mspi/bestpractices/*) is one resource that applicants may use to find information to build on the foundation of prior methamphetamine and suicide prevention and treatment efforts, in order to support the IHS, Tribes, and UIHPs in developing and implementing Tribal and/or culturally appropriate methamphetamine and suicide prevention and early intervention strategies.

Purpose Areas

Purpose Area 1: Community and Organizational Needs Assessment and Strategic Planning: Lessons learned from the demonstration pilot project phase of the MSPI revealed the need for AI/AN communities to have access to resources, funding, and technical assistance to assess the needs of their community for suicide and/or methamphetamine use to develop strategic approaches and leverage community and organizational resources before implementing specific programs. Strategic planning is especially critical to maximize available resources and eliminate duplicative efforts. Strategic planning should address gaps in policies and resources, as well as program barriers. Planning should focus on utilizing data from the community and organizational needs assessment to ensure coordinated community responses as well as system linkages for suicide prevention and methamphetamine use services. Based on the community and organizational needs assessment and analysis, projects will develop a strategic plan to address suicide and/or methamphetamine use (or other addicting substances). IHS is seeking applicants to address MSPI goals #1 and #2 by addressing the following two items:

- Assess and develop strategic approaches of leveraging community and organizational resources to address suicide and methamphetamine use; and
- Develop data sharing systems for continuous assessment and strategic planning.

Purpose Area 2: Suicide Prevention, Intervention, and Postvention: The focus of Purpose Area 2 is on the prevention, intervention, and postvention of suicide, suicide contagion, and suicide attempts or ideations among AI/AN populations.

IHS is seeking applicants to address MSPI goals #3 and #5 by focusing on the following broad objectives:

- Expand available behavioral health care treatment services;
- Foster coalitions and networks to improve care coordination;
- Educate and train providers in the care of methamphetamine and other substance use disorders;
- Promote community education to prevent the use and spread of methamphetamine;
- Improve health system organizational practices to improve treatment services for individuals seeking treatment for methamphetamine and other substance use disorders that contribute to suicide;
- Establish local health system policies to address methamphetamine use and other substance use disorders that contribute to suicide;
- Integrate culturally appropriate treatment services; and
- Implement trauma informed care services and programs.

Purpose Area 3: Methamphetamine Prevention, Treatment, and Aftercare: The focus of Purpose Area 3 is on the prevention, treatment, and aftercare for methamphetamine use (and other addicting substances) among AI/AN populations. In addition to prevention programming, MSPI funds can be used to provide behavioral health treatment services (*i.e.,* direct services including in-patient and out-patient treatment, intervention, and aftercare).

IHS is seeking applicants to address MSPI goals #4 and #5 by focusing on the following broad objectives:

- Expand available behavioral health care treatment services;
- Foster coalitions and networks to improve care coordination;
- Educate and train providers in the care of methamphetamine and other substance use disorders;
- Promote community education to prevent the use and spread of methamphetamine;
- Improve health system organizational practices to improve treatment services for individuals seeking treatment for methamphetamine and other substance use disorders that contribute to suicide;
- Establish local health system policies to address methamphetamine use and other substance use disorders that contribute to suicide;
- Integrate culturally appropriate treatment services; and
- Implement trauma informed care services and programs.

Purpose Area 4: Generation Indigenous Initiative Support: The focus of Purpose Area 4 is to promote early intervention strategies and implement positive youth development programming to reduce risk factors for suicidal behavior and substance abuse. IHS is seeking applicants to address MSPI goal #6 by working with Native youth ages 8 to 24 years old on the following broad objectives:

- Implement evidence-based and practice-based approaches to build resiliency, promote positive development, and increase self-sufficiency behaviors among Native youth;
- Promote family engagement; and
- Increase access to prevention activities for youth to prevent methamphetamine use and other substance use disorders that contribute to suicidal behaviors, in culturally appropriate ways.

Limited Competition Justification

There is limited competition under this announcement because the authorizing legislation restricts eligibility to Tribes that meet specific criteria. See the Consolidated Appropriations Act of 2008, Public Law 110–161, 121 Stat. 1844, 2135.

II. Award Information

Type of Award

Grant.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2015 is approximately $12,500,000. IHS expects to allocate funding for the 12 IHS service areas as described below. Applicants will be awarded according to their location within their respective IHS service area and will not compete with applicants from other IHS service areas. UIHP applicants will be selected from a category set aside for UIHP applicants only. UIHP awards will be $100,000 each. The amount of funding available for competing and continuation awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the Agency. IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

The number of anticipated awards is dependent on the number of applications received in response to the announcement and available funds. The funding breakdown by area is as follows:

Alaska IHS Service Area

IHS expects to provide $1,684,000 in total awards ranging from $50,000 to $300,000 for a 12-month project period.

Albuquerque IHS Service Area

IHS expects to provide $703,000 in total awards ranging from $50,000 to $150,000 for a 12-month project period.

Bemidji IHS Service Area

IHS expects to provide $706,000 in total awards ranging from $50,000 to $150,000 for a 12-month project period.

Billings IHS Service Area

IHS expects to provide $703,000 in total awards ranging from $50,000 to $150,000 for a 12-month project period.

California IHS Service Area

IHS expects to provide $815,000 in total awards ranging from $50,000 to $150,000 for a 12-month project period.

Great Plains IHS Service Area

IHS expects to provide $1,201,000 in total awards ranging from $50,000 to $200,000 for a 12-month project period.

Nashville IHS Service Area

IHS expects to provide $333,000 in total awards ranging from $50,000 to $150,000 for a 12-month project period.

Navajo IHS Service Area

IHS expects to provide $1,988,000 in total awards ranging from $50,000 to $300,000 for a 12-month project period.

Oklahoma City IHS Service Area

IHS expects to provide $1,908,000 in total awards ranging from $50,000 to $300,000 for a 12-month project period.

Phoenix IHS Service Area

IHS expects to provide $1,335,000 in total awards ranging from $50,000 to $200,000 for a 12-month project period.

Portland IHS Service Area

IHS expects to provide $917,000 in total awards ranging from $50,000 to $100,000 for a 12-month project period.

Tucson IHS Service Area

IHS expects to provide $206,000 in total awards ranging from $50,000 to $112,500 for a 12-month project period.

Urban Indian Health Programs

IHS expects to provide $1,000,000 in total awards for a 12-month project period.

Project Period

The project period is for five years and will run consecutively from September 30, 2015, to September 29, 2020.

Continuation Applications

The current funding announcement is a request for the submission of proposals for a five-year project proposal; however due to the limited amount of funding available for competing and continuation awards issued under this announcement, the funds are subject to the availability of appropriations and budgetary priorities of the Agency (also reference ''Estimated Funds Available'' in this section, ''Award Information''). Therefore, awardees will be required to submit a Continuation Application at the end of each project year (dates to be determined) after the initial funding award for Project Year 1, which will assist in determining continued funding from Project Year to Project Year for the five-year project funding cycle. Awardees will be required to submit an entire application package including all components listed under ''Content and Form Application Submission'' in the GrantsSolutions System to assist in determination of continued funding.

The continuation applications will assist IHS in ensuring that all awardees are meeting their goals and objectives, carrying out project activities, and submitting required documentation in a timely manner and according to the terms and conditions of their Notice of Award (NoA) and the behavioral health program requirements.

III. Eligibility Information

1. Eligibility

To be eligible for this ''Limited Competition'' in an effort to address behavioral health disparities within AI/AN communities, IHS is limiting eligibility to Federally recognized Tribes, Tribal organizations, and urban Indian organizations. Eligible applicants are as follows:

- Federally recognized Indian Tribe, as defined by 25 U.S.C. 1603(14);
- Tribal organization, as defined by 25 U.S.C. 1603(26);
- Urban Indian organization, as defined by 25 U.S.C. 1603(29).

Applicants must provide proof of non-profit status with the application, *e.g.,* 501(c)(3).

Note: Please refer to section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

a. If application budgets exceed the highest dollar amount outlined under the ''Estimated Funds Available'' section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

b. Awardee Meetings

Awardees are required to send the Project Director and/or Project Coordinator (the individual who runs the day-to-day project operations) to an annual MSPI meeting. Participation will be in-person or virtual meetings. The awardee is required to include travel for this purpose in the budget and narrative of the project proposal. At these meetings, awardees will present updates and results of their projects including note of significant or ongoing concerns related to project implementation or management. Federal staff will provide updates and technical assistance to awardees in attendance.

Tribal Resolution

Signed Tribal Resolution—A signed Tribal resolution *from each of* the Indian Tribes served by the project *must accompany the electronic application submission.* An Indian Tribe that is proposing a project affecting another Indian Tribe must include *resolutions from all affected Tribes to be served.* Applications by Tribal organizations will not require a specific Tribal resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities.

Draft Tribal resolutions are acceptable in lieu of an official signed resolution and *must* be submitted along with the electronic application submission prior to the official application deadline date or prior to the start of the Objective Review Committee (ORC) date. However, an official signed Tribal resolution must be received by DGM prior to the beginning of the objective review. If an official signed resolution is not received by the review date listed under the Key Dates section on page one of this announcement, the application will be considered incomplete and ineligible.

Official signed Tribal resolutions can be mailed to DGM, Attn: Cherron Smith, 801 Thompson Avenue, TMP Suite 360, Rockville, Maryland 20852. Applicants submitting Tribal resolutions after or aside from the required online electronic application submission must ensure that the information is received by IHS/DGM. It is highly recommended that the documentation be sent by a delivery method that includes delivery confirmation and tracking. Please contact Ms. Cherron Smith by telephone at (301) 443–2192 prior to the review date regarding submission questions.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the application deadline date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by IHS by obtaining documentation confirming delivery (*i.e.* FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at *http://www.Grants.gov* or *https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_funding.*

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Cover letter.
- Table of contents.
- Abstract (must be single-spaced and should not exceed one page).
- Application forms:
  - SF–424, Application for Federal Assistance.
  - SF–424A, Budget Information—Non-Construction Programs.
  - SF–424B, Assurances—Non-Construction Programs.
- Statement of Need (must be single-spaced and not exceed two pages).
  - Includes the Tribe, Tribal organization, or UIHP background information.
- Project Narrative (must be included as an attachment to the application package and must be single-spaced and not exceed 20 pages).
  - Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page timeframe chart, and a plan for local data collection.
- Budget and Budget Narrative (must be single-spaced and not exceed four pages).
- Tribal Resolution or Tribal Letter of Support (only required for Tribes and Tribal organizations).
  - See Key Dates for separate due date submission requirement.
- Letter(s) of Support from organization's Board of Directors (or relevant equivalent), Local Organizational Partners and Tribal or Urban Indian Organizational and Community Partners (All Applicants).
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all key personnel.
- Position descriptions for all key personnel.
- Contractor/consultant qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required) in order to receive IDC.
- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) A–133 required Financial Audit or other required audit (if applicable).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
- Face sheets from audit reports. These can be found on the FAC Web site: *http://harvester.census.gov/sac/dissem/accessoptions.html?submit=Go+To+Database*

Public Policy Requirements

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the discrimination policy.

Requirements for Project Proposals

The project narrative should be a separate Word document that is no longer than 20 pages and must: be single-spaced, type written, consecutively numbered pages, using black type not smaller than 12 characters per one inch, and be printed on one side only of standard size 8½'' x 11'' paper.

Succinctly address and answer all questions listed under required application components and place all responses and required information in the correct section (noted below), or they shall not be considered or scored. These narratives will assist the ORC in becoming familiar with the applicant's activities and accomplishments prior to this grant award. If the narrative exceeds the page limit, only the first twenty (20) pages will be reviewed. The 20-page limit for the narrative does not include the cover letter, table of contents, abstract, statement of need, standard forms, Tribal resolutions, budget and budget narrative, and/or other appendix items.

Applications must include the following required application components:

- Cover Letter—Includes the title of the program and all contact information for the Tribe/Tribal organization or UIHP.
- Table of Contents.
- Abstract—Provides a summary of all the key information for the project. Must not exceed one single-spaced page.
- Statement of Need—Provides the facts and evidence that support the need for the project and establishes that the Tribe/Tribal organization or UIHP understands the problems and can

reasonably address them. Provides background information on the Tribe/Tribal organization or UIHP. May not exceed two single-spaced pages.

• Project Narrative—The project narrative (description) describes the project. May not exceed 20 single-spaced pages.

Required components in the project narrative are as follows:

A. Goals and Objectives.

B. Project Activities.

C. Timeline Chart.

D. Organization Capacity and Staffing/Administration.

E. Plan for Local Data Collection.

• Budget and Budget Narrative—Applicants are to submit a budget and budget narrative for *Project Year 1 only.* The budget and budget narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative for the first project year only. The budget and budget narrative may not exceed four single-spaced pages for both documents combined.

The MSPI Proposal Template and associated templates for the Timeline Chart, Biographical Sketch, Budget and Budget Narrative, can be located and downloaded at the MSPI Web site: *http://www.ihs.gov/mspi/fundingannouncement.*

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 11:59 p.m. Eastern Daylight Time (EDT) on the application deadline date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. Grants.gov will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact Grants.gov Customer Support via email to *support@grants.gov* or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Paul Gettys (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten (10) days prior to the application deadline. Please do not contact DGM until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call DGM as soon as possible.

If the applicant needs to submit a paper application instead of submitting electronically through Grants.gov, a waiver must be requested. Prior approval must be requested and obtained from Ms. Tammy Bagley, Acting Director of DGM, (see section IV.6, Electronic Submission Requirements, below for additional information). The waiver must: (1) Be documented in writing (emails are acceptable) before submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Tammy.Bagley@ihs.gov.* Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval must be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Acting Director of DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of DGM. Paper applications must be received by DGM no later than 5:00 p.m., EDT, on the application deadline date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

4. Intergovernmental Review

E.O. 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

• Pre-award costs are not allowable.

• The available funds are inclusive of direct and appropriate indirect costs.

• Only one grant/cooperative agreement will be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the *http://www.Grants.gov* Web site to submit an application electronically and select the ''Find Grant Opportunities'' link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the completed application via the *http://www.Grants.gov* Web site. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If the applicant receives a waiver to submit paper application documents, they must follow the rules and timelines that are noted below. The applicant must seek assistance at least ten (10) days prior to the application deadline date listed in the Key Dates section on page one of this announcement.

Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or *http://www.Grants.gov* registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

• Please search for the application package in *http://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.

• If you experience technical challenges while submitting the application electronically, please contact Grants.gov Support directly at: *support@grants.gov* or (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).

• Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the Agency must be obtained.

• If it is determined that a waiver is needed, the applicant must submit a request in writing (emails are acceptable) to *GrantsPolicy@ihs.gov* with a copy to *Tammy.Bagley@ihs.gov.* Please include a clear justification for the need to deviate from the standard electronic submission process.

• If the waiver is approved, the application should be sent directly to DGM by the application deadline date listed in the Key Dates section on page one of this announcement.

• Applicants are strongly encouraged not to wait until the deadline date to begin the application process through Grants.gov as the registration process for SAM and Grants.gov could take up to fifteen working days.

• Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by DGM.

• All applicants must comply with any page limitation requirements described in this funding announcement.

• After electronically submitting the application, the applicant will receive an automatic acknowledgment from

Grants.gov containing a Grants.gov tracking number. DGM will download the application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither DGM nor the behavioral health program will notify the applicant that the application has been received.

- Email applications will not be accepted under this announcement.
- IHS will not acknowledge receipt of applications.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access it through *http://fedgov.dnb.com/webform,* or to expedite the process, call (866) 705–5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended (Transparency Act), to report information on subawards. Accordingly, all IHS grantees must notify potential first-tier subrecipients that no entity may receive a first-tier subaward unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that are not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with SAM is free of charge. Applicants may register online at *https://www.sam.gov*.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: *https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics*.

V. Application Review Information

The instructions for preparing the application statement of need, project narrative, budget and budget narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The 20 page narrative should include activities for the proposed one-year project. The statement of need, project narrative, budget and budget narrative sections should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 65 points is required for funding. Points are assigned as follows:

1. Criteria

Applications will be reviewed and scored according to the *quality* of responses to the required application components in sections A–E.

- In developing the Statement of Need, Project Narrative, Budget and Budget Narrative sections of the application, use the instructions provided for each section, which have been tailored to this program.
- The Statement of Need should not exceed two single-spaced pages.
- The Project Narrative (required components, sections A–E, in ''Requirements for Project Proposals'') together should not exceed 20 single-spaced pages.
- The Budget and Budget Narrative the applicant provides will be considered by reviewers in assessing the applicant's response, along with the material in the Project Narrative. The budget and budget narrative must not exceed four single-spaced pages.
- The applicant must use the five sections (sections A–E) listed below in developing the: (1) Statement of Need (section A); (2) Project Narrative (sections B, C and D); and (3) Budget and Budget Narrative (section E). The applicant must place the required information in the correct section, or it will not be considered. The application will be scored according to how well the applicant addresses the requirements for each section of the Statement of Need, Project Narrative, Budget and Budget Narrative.
- The number of points after each heading is the maximum number of points a review committee may assign to that section. Although scoring weights are not assigned to individual bullets, each bullet is assessed in deriving the overall section score.

Section A: Statement of Need (35 Points)

1. For all Purpose Areas: Identify the proposed catchment area and provide demographic information on the population(s) to receive services through the targeted systems or agencies, *e.g.,* race, ethnicity, Federally recognized Tribe, language, age, socioeconomic status, sexual identity (sexual orientation, gender identity), and other relevant factors, such as literacy. Describe the stakeholders and resources in the catchment area that can help implement the needed infrastructure development.

2. For Purpose Area #1 only: Document the need and lack of data currently available. Document the need for an enhanced infrastructure and strategic planning processes to inform the work in the community.

3. For Purpose Areas #2, #3, and #4: Based on the information and/or data currently available, document the prevalence of suicide ideations, attempts and completions, methamphetamine use rates, and alcohol and substance abuse rates. For Purpose Area #4, the data should be geared toward AI/AN children and youth.

4. For Purpose Areas #2, #3, and #4: Based on the information and/or data currently available, document the need for an enhanced infrastructure to increase the capacity to implement, sustain, and improve effective substance abuse prevention and/or behavioral health services in the proposed catchment area that is consistent with the purpose of the program and the funding opportunity announcement. Based on available data, describe the service gaps and other problems related to the need for infrastructure development. Identify the source of the data. Documentation of need may come from a variety of qualitative and quantitative sources. Examples of data sources for the quantitative data that could be used are local epidemiologic data (Tribal Epidemiology Centers, IHS area offices), state data (*e.g.,* from state needs assessments, Substance Abuse and Mental Health Administration's (SAMHSA) National Survey on Drug Use and Health), and/or national data (*e.g.,* from SAMHSA's National Survey

on Drug Use and Health or from National Center for Health Statistics/ Centers for Disease Control reports, and Census data). This list is not exhaustive; applicants may submit other valid data, as appropriate for the applicant's program.

5. For all Purpose Areas: Describe the existing behavioral health service gaps, barriers, and other systemic challenges related to the need for planning and infrastructure development and coordination of behavioral health and wellness services.

6. For all Purpose Areas: Describe potential project partners and community resources in the catchment area that can participate in the planning process and infrastructure development.

7. For all Purpose Areas: Affirm the goals of the project are consistent with priorities of the Tribal government or board of directors and that the governing body is in support of this application.

Section B: Project Narrative/Proposed Approach/Project Plan (20 Points)

1. For all Purpose Areas: Describe the purpose of the proposed project, including a clear statement of goals and objectives. Describe how achievement of goals will increase system capacity to support the goals and objectives or activities in the Purpose Area for which the applicant is applying.

2. For all Purpose Areas: Describe how project activities will increase the capacity of the identified community to plan and improve the coordination of a collaborative behavioral health and wellness service systems. Describe anticipated barriers to progress of the project and how these barriers will be addressed.

3. For all Purpose Areas: Discuss how the proposed approach addresses the local language, concepts, attitudes, norms and values about suicide, and/or methamphetamine use.

4. For all Purpose Areas: Describe how the proposed project will address issues of diversity within the population of focus including age, race, gender, ethnicity, culture/cultural identity, language, sexual orientation, disability, and literacy.

5. For all Purpose Areas: Describe how members of the community (including youth and families that may receive services) will be involved in the planning, implementation, and data collection and regional evaluation of the project.

6. For all Purpose Areas: Describe how the efforts of the proposed project will be coordinated with any other related Federal grants, including IHS, SAMHSA, or Bureau of Indian Affairs (BIA) services provided in the community (if applicable).

7. For all Purpose Areas: Provide a timeline chart depicting a realistic timeline for the entire project period showing key activities, milestones, and responsible staff. These key activities should include the requirements outlined in the chosen Purpose Area. [Note: The timeline chart should be part of the Project Narrative as specified in the ''Requirements for Project Proposals'' section. It should not be placed as an attachment.]

8. For all Purpose Areas: If the applicant plans to include an advisory body in the project, describe its membership, roles and functions, and frequency of meetings.

9. For all Purpose Areas: Identify any other organization(s) that will participate in the proposed project. Describe their roles and responsibilities and demonstrate their commitment to the project. Include a list of these organizations as an *attachment* to the project proposal/application. In the attached list, indicate the organizations that the Tribe/Tribal organization or UIHP has worked with or currently works with. [Note: The attachment will not count as part of the 20-page maximum.]

Section C: Organizational Capacity and Staffing/Administration (15 Points)

All Purpose Areas should address all of the components listed below:

1. Describe the management capability and experience of the applicant Tribe, Tribal organization, or UIHP and other participating organizations in administering similar grants and projects.

2. Discuss the applicant Tribe, Tribal organization, or UIHP experience and capacity to provide culturally appropriate/competent services to the community and specific populations of focus.

3. Describe the resources available for the proposed project (*e.g.,* facilities, equipment, information technology systems, and financial management systems).

4. Describe how project continuity will be maintained if/when there is a change in the operational environment (*e.g.,* staff turnover, change in project leadership, change in elected officials) to ensure project stability over the life of the grant.

5. Provide a complete list of staff positions for the project, including the Project Director, Project Coordinator, and other key personnel, showing the role of each and their level of effort and qualifications.

6. Include position descriptions as *attachments* to the project proposal/ application for the Project Director, Project Coordinator, and all key personnel. Position descriptions should not exceed one page each. [Note: Attachments will not count against the 20 page maximum].

7. For staff that are identified and currently on staff, include a biographical sketch (not to include personally identifiable information) for the Project Director, Project Coordinator, and other key positions as *attachments* to the project proposal/application. Each biographical sketch should not exceed one page. Reviewers will not consider information past page one. [**Note:** Attachments will not count against the 20 page maximum]. Do not include any of the following:

i. Personally Identifiable Information;
ii. Resumes; or
iii. Curriculum Vitae.

Section D: Local Plan for Data Collection (20 Points)

Describe the applicant's plan for gathering local data, submitting data requirements, and document the applicant's ability to ensure accurate data tracking and reporting.

Funded projects are required to coordinate data collection efforts with a regional (IHS Area) evaluator. The regional evaluators will be identified and funded by IHS and coordinated with each local project and will feed the regional and national evaluation for MSPI. Awardees will work with the regional evaluator(s) to evaluate the core processes, outcomes, impacts, and benefits associated with the MSPI. Awardees shall collect local data related to the project and submit it in semi-annual progress reports. The data collected and submitted through the progress reports will be made available to the regional and national evaluator(s) for MSPI. The purpose of the regional and national evaluation is to assess the extent to which the projects are successful in achieving project goals and objectives and to determine the impact of MSPI-related activities on individuals and the larger community.

Progress reporting will be required on national and regionally selected data elements related to program outcomes and financial reporting for all awardees. Progress reports will be collected semi-annually throughout the project on a web-based portal. Progress reports include the compilation of quantitative (numerical) data (*e.g.,* number served; screenings completed, etc.) and of qualitative or narrative (text) data. The regional and national evaluators will also coordinate the narrative data

collection and provide an analysis of the funded project's responses to open-ended questions about ''program accomplishments,'' ''barriers to implementation,'' and description of partnership and coalition work.

The reporting portal will be open to project staff on a 24 hour/7 day week basis for the duration of each reporting period. Reporting form formats allow awardees to report outcomes and include open-ended questions about current accomplishments and barriers during the reporting period. In addition, financial report forms (SF–425), which document funds received and expended during the semi-annual reporting period, will be available. All materials will be provided on the portal and are to be submitted online. Technical assistance for web-based data entry and for the completion of required fiscal documents will be timely and readily available to awardees by assigned IHS Project Officers.

Section E: Budget and Budget Narrative (10 Points)

The applicant is required to include a line item budget for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative for *Project Year 1 only*. The budget should match the scope of work described in the project narrative for the first project year expenses only. The page limitation should not exceed four single-spaced pages.

The applicant must provide a narrative justification of the items included in the proposed line item budget supporting the mission and goals of MSPI, as well as a description of existing resources and other support the applicant expects to receive for the proposed project. Other support is defined as funds or resources, whether Federal, non-Federal or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions or non-Federal means. (This should correspond to Item #18 on the applicant's SF–424, Estimated Funding.) Provide a narrative justification supporting the development or continued collaboration with other partners regarding the proposed activities to be implemented.

Additional documents can be uploaded as Appendix Items in Grants.gov

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of Tribal, urban and Federal reviewers appointed by the IHS program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.,* budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required. To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by DGM in our grant system, GrantSolutions (*https://www.grantsolutions.gov*). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 65 points, and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application submitted. The IHS program office will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum score of 65 points and were deemed by the ORC to be ''Approved,'' but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2015, the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS Grants Management Official announcing to the Project Director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

Grants are administered in accordance with the following regulations, policies, and OMB cost principles:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements HHS Awards, located at 45 CFR part 75.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' located at 45 CFR part 75, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of IDC in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate

agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of Interior (Interior Business Center) *http://www.doi.gov/ibc/services/Indirect_Cost_Services/index.cfm*. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under ''Agency Contacts'' or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Reports must be submitted electronically via GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Progress reports are required semi-annually/annually through the national MSPI online progress report data portal, within thirty (30) days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the reporting period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within ninety (90) days of expiration of the budget/project period.

B. Financial Reports

Federal Financial Report FFR (SF–425), Cash Transaction Reports are due thirty (30) days after the close of every calendar quarter to the Payment Management Services, HHS at: *http://www.dpm.psc.gov*. It is recommended that the applicant also send a copy of the FFR (SF–425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report (SF–425).

C. Federal Subaward Reporting System (FSRS)

This award may be subject to the Transparency Act subaward and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 subaward obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a $25,000 subaward obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit DGM Grants Policy Web site at: *https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics*.

Telecommunication for the hearing impaired is available at: TTY (301) 443–6394.

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Audrey Solimon, Health System Specialist, 5300 Homestead Rd. NE., Albuquerque, NM 87110, Phone: (505) 248–4330, Fax: (505) 248–4257, Email: *Audrey.Solimon@ihs.gov*.

2. Questions on grants management and fiscal matters may be directed to: Cherron Smith, GMS, IHS Division of Grants Management, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20874, Phone: (301) 443–2192, Fax: (301) 443–9602, Email: *Cherron.Smith@ihs.gov*.

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, Phone: (301) 443–2114; or the DGM main line (301) 443–5204, Fax: (301) 443–9602, E-Mail: *Paul.Gettys@ihs.gov*.

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: June 30, 2015.

Robert G. McSwain,

Acting Director, Indian Health Service.

[FR Doc. 2015–16744 Filed 7–7–15; 8:45 am]

BILLING CODE 4160–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Presentation

SUMMARY: The National Institute on Alcohol Abuse and Alcoholism (NIAAA) will host an online presentation to enable public discussion of the Institute's proposal to create a new division; Division of Medications Development. The proposal seeks to better reflect the NIAAA priorities by increasing the emphasis on medications development efforts on treating alcohol use disorders (AUD). The change is budget neutral and will use existing

resources within the institute. The information was discussed at the public portion of the National Advisory Council on Alcohol Abuse and Alcoholism held on June 10, 2015.

DATES: This online presentation will be available at *http://www.niaaa.nih.gov/sites/default/files/Reorg_creationMedDevDivCouncil_June2015final_Accessible.pdf* on July 8, 2015 at 8:00 a.m. Members of the public wishing to provide comments must do so by 5:00 p.m. EDT July 17, 2015 by sending an email to *NIAAAReOrgComments@mail.nih.gov.* The email should include your name and, when applicable, your professional affiliation. NIAAA will respond to your email by July 24, 2015.

FOR FURTHER INFORMATION CONTACT: Keith Lamirande, Executive Officer, *Keith.Lamirande@nih.gov* (301) 443–2238 or Vicki Buckley, Deputy Executive Officer, *Vicki.Buckley@nih.gov* (301) 443–1269, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION: The NIH Reform Act of 2006 (42 U.S.C. 281 (d)(4)) requires public notice of proposed reorganization plans. Information about those plans are available on the Institute's Web site, *http://www.niaaa.nih.gov/.*

Dated: July 1, 2015.

George Koob,

Director, National Institute on Alcohol Abuse and Alcoholism.

[FR Doc. 2015–16708 Filed 7–7–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Disordered Eating.

Date: July 30, 2015.

Time: 1:30 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–2242, *jerkinsa@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA–DK–14–023 Elucidating HIV and HIV-treatment Associated Metabolic/Endocrine Dysfunction (R01).

Date: July 31, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–2242, *jerkinsa@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 1, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–16704 Filed 7–7–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Clinical Evaluation of Adjuncts to Opioid Therapies for the Treatment of Chronic Pain.

Date: July 30, 2015.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: M. Catherine Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7846, Bethesda, MD 20892, 301–435–1766, *bennettc3@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 1, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–16706 Filed 7–7–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Mobile Health: Technology and Outcomes in Low and Middle Income Countries.

Date: July 13–14, 2015.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301–435–1180, *ruvinser@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 1, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–16705 Filed 7–7–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Assay Validation for High Quality Markers.

Date: July 29, 2015.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W602, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Delia Tang, MD, Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W602 Bethesda, MD 20892–9750, 240–276–6456, *tangd@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 2, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–16707 Filed 7–7–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, ZAA1 DD (01) 2015/10 NIAAA Member Conflict Applications-Biomedical Sciences.

Date: July 31, 2015.

Time: 1:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA, NIH, 5635 Fishers Lane, Room CR2098, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, NIH, 5635 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov*.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, ZAA1 GG (50) 2015/10 NIAAA Alcohol Research Center Reviews.

Date: August 11, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA, NIH, 5635 Fishers Lane, Room CR2098, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Richard A. Rippe, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, NIH, 5635 Fishers Lane, Room 2109, Rockville, MD 20852, (301) 443–8599, *rippera@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 92.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Supports Awards, National Institutes of Health, HHS)

Dated: July 1, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–16702 Filed 7–7–15; 8:45 am]

BILLING CODE 4140–01–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.

This meeting is open to the public but is being held by teleconference only. No physical meeting location is provided for any interested individuals to listen to and/or participate in the meeting. Any individual interested in listening to the meeting discussions must call: 800–779–9002 and use Passcode: 3336961 for access to the meeting. Individuals who plan to attend and need special assistance, 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: July 20, 2015.

Time: 5:00 p.m. to 6:00 p.m.

Agenda: Evaluation and analysis of the NIH Strategic Plan.

Place: National Institutes of Health, (Telephone Conference Call), Dial in Number 800–779–9002, Passcode: 3336961.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, Telephone: 301–496–4272, Email: *woodgs@od.nih.gov*.

Any interested person may file written comments with the committee by forwarding their statement electronically to the Contact Person at *woodgs@od.nih.gov*. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested of the interested person.

Information will also available on the committee's home page: *http://*

acd.od.nih.gov, where any additional information for the meeting will be posted when available.

This notice is being published less than 15 days prior to the meeting due to the timing limitations of receiving input from committee members prior to presenting the plan to other audiences for comment and meeting a legislative reporting deadline.

Dated: July 1, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–16703 Filed 7–7–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[156A2100DD/AAKC001030/A0A501010.999900 253G]

Final Decision on Remand Against Federal Acknowledgment of the Duwamish Tribal Organization

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of final decision on remand.

SUMMARY: The Department of the Interior (Department) gives notice that the Assistant Secretary—Indian Affairs (AS–IA) declines to acknowledge that the Duwamish Tribal Organization (DTO), c/o Cecile Maxwell-Hansen, is an Indian tribe within the meaning of Federal law. This notice follows a Final Decision on Remand (FD on Remand) that the petitioner does not satisfy all seven mandatory criteria in the either the 1978 or 1994 regulations, 25 CFR part 83. Therefore, the DTO does not meet the requirements for a government-to-government relationship with the United States. The Department issues the FD on Remand in response to judicial review in *Hansen* v. *Salazar,* 2013 U.S. Dist. LEXIS 40622 (3/22/2013).

DATES: This decision is final for the Department on publication of this notice.

ADDRESSES: Requests for a copy of this FD on Remand should be addressed to the Office of the Assistant Secretary—Indian Affairs, Attention: Office of Federal Acknowledgment, 1951 Constitution Avenue NW., MS 34B–SIB, Washington, DC 20240. The FD on Remand is also available through *www.bia.gov/WhoWeAre/AS–IA/OFA/RecentCases/index.htm.*

FOR FURTHER INFORMATION CONTACT: Mr. R. Lee Fleming, Director, Office of Federal Acknowledgment, (202) 513–5650.

SUPPLEMENTARY INFORMATION: This FD on Remand determines that the petitioner does not satisfy all seven mandatory criteria in the either the 1978 or 1994 regulations, 25 CFR part 83. It affirms the conclusions of the 1996 Proposed Finding (PF) notice of which was published in the **Federal Register**, 61 FR 33762 (1996), that found the DTO did not meet all seven of the mandatory criteria for Federal acknowledgment as an Indian tribe under the regulations 25 CFR part 83 published in 1978.

This FD on Remand concludes the administrative process during which the AS–IA issued a PF against acknowledgment and a Final Determination against acknowledgment on September 25, 2001, notice of which was published in the **Federal Register**, 66 FR 49966 (2001). On December 31, 2001, the DTO, as the ''Duwamish Tribe of Washington,'' filed a request for reconsideration with the Interior Board of Indian Appeals (IBIA). The IBIA docketed the petitioner's request, dismissed it for lack of jurisdiction and referred two issues, not within its purview, to the Secretary of the Interior as possible grounds for reconsideration (37 IBIA 95). The two issues concerned a January 19, 2001 draft decision by the Acting AS–IA that proposed to acknowledge the DTO under the 1994 regulations.

On May 8, 2002, in response to the IBIA referral, the Secretary declined to request that the AS–IA reconsider the FD against acknowledgment of the DTO. The FD declining to acknowledge the DTO as an Indian tribe became final and effective May 8, 2002.

On May 7, 2008, the DTO petitioned for judicial review and other relief in the U.S. District Court for the Western District of Washington. On March 22, 2013, the Court vacated the FD of September 25, 2001, and remanded the decision to the Department, ordering it to ''consider the Duwamish petition under the 1994 acknowledgment regulations or explain why it declines to do so.'' The court referred to the unsigned draft of the former Acting AS–IA and provided that ''Whatever the significance of that document, it clearly gave decision makers in the Department notice that consideration of the Duwamish petition under both sets of regulations might be appropriate'' (Coughenour 3/22/2013, 18). The Court did not address the merits of the decision under the criteria in the FD.

The United States filed a notice of appeal and following settlement, the Ninth Circuit granted the motion to dismiss the appeal voluntarily on June 9, 2014. This FD on Remand addresses the Court's procedural concerns by reevaluating the evidence in the record under the provisions of the 1994 revised regulations. It also evaluates the evidence under the 1978 regulations and refers to those regulations to explain or clarify how the Department evaluated evidence in the PF and FD, now superseded by this FD on Remand. Finally, the FD on Remand refers to the Acting AS–IA draft document.

This FD on Remand is made following a review of the DTO's response to the PF, the public comments on the PF, the documents submitted in court proceedings, and it incorporates the evidence considered in the 1996 PF and the 2001 FD. This notice declining to acknowledge the DTO is based on a determination that of the seven mandatory criteria for Federal acknowledgment as an Indian tribe, the petitioner has met criteria 83.7(d), (e), (f), and (g), but has failed to meet criteria 83.7(a), (b), and (c) under both the 1978 and 1994 regulations.

Documentary sources describe a historical Duwamish tribe comprising Indians living at the confluence of the Black, Cedar, and Duwamish Rivers south of Lake Washington as well as along the Green and White Rivers, around Lake Washington, and along the eastern shore of Puget Sound in the area of Elliott Bay. Federal negotiators combined the Duwamish with other allied tribes and bands into confederated ''treaty tribes'' to make a treaty in 1855, and continued to deal with these treaty tribes as the ''D'Wamish and other allied tribes.'' These treaty tribes moved to four reservations and the separate tribes and bands eventually consolidated as four reservation tribes that continue today as the Lummi Tribe of the Lummi Reservation, Suquamish Indian Tribe of the Port Madison Reservation, Swinomish Indian Tribal Community, and Tulalip Tribes of Washington. A few Duwamish tribal members moved to the Muckleshoot Reservation after its creation in 1857. The petitioner's ancestors, primarily Duwamish Indian women who married non-Indian settlers, did not go to the reservations with the treaty tribes. Rather, before and after the treaty, they left the tribes as individuals and families and, by the 1880s, lived dispersed throughout western Washington. There is no evidence that their descendants, who are the DTO's ancestors, maintained tribal relations with the ''D'Wamish and other allied tribes'' on the reservations or that they were a part of a community of similarly situated Duwamish descendants.

The DTO petitioner first came into existence in 1925 when eight men

announced their ''intention of forming'' an organization. No evidence indicates this new organization was a continuation of the historical ''D'Wamish and other allied tribes'' on the reservations or that it evolved as a group from them. Nor does the evidence show that the 1925 organization continued activities of a previous group of Duwamish Indians listed by Charles Satiacum in 1915 in his efforts to identify ''the true Duwamish'' as part of an intertribal organization's pursuit of claims for unallotted Indians in Washington State. Having formed only in 1925, the petitioner cannot show any identifications before its formation and, therefore, does not meet criterion 83.7(a), requiring identifications as ''American Indian,'' or ''aboriginal'' since historical times to the present, under the 1978 regulations, and as an Indian entity since 1900, under the 1994 regulations. Outside observers first identified the DTO in 1939 and Federal officials have identified the petitioner intermittently since 1940 as an Indian organization. Contemporary Government officials and American settlers, and later ethnographers, historians, and the Indian Claims Commission identified a historical Duwamish tribe, which existed at the time of first sustained contact with non-Indians. External observers also identified a Duwamish community at a traditional location near the junction of the Black and Cedar Rivers as late as 1900, but DTO's ancestors were not part of that community. Multiple sources, including congressional appropriations, have identified the ''D'Wamish and other allied tribes'' on the reservations, and the subsequently consolidated reservation tribes, continuously since the treaty in 1855, but these identifications are not of the petitioner. Because the petitioner was created only in late 1925 and is not a continuation of any earlier Duwamish entity, the various identifications of a Duwamish tribe before 1925 do not identify the petitioner. The petitioner has not meet criterion 83.7(a) at any time before 1939, and, therefore, it does not meet it under either the 1978 or 1994 regulations.

The petitioner does not meet criterion 83.7(b) for community under either the 1978 or the 1994 regulations. Under the former, although the members descend from a historical Duwamish tribe, the petitioner's members and their ancestors have not inhabited a specific area or lived in a community distinct from other populations at any time. Under the latter regulation, a predominant portion of the petitioner has never formed a distinct social or geographical community. The petitioner did not present evidence showing a majority of its members undertook joint social or cultural activities, married one another, spoke the Duwamish language, participated in cooperative economic activities, or undertook informal social activities together, the types of evidence described in the 1994 regulations that may be used to show a community exists. The petitioner described families living in isolated households as typical of the petitioner's ancestors, but did not show that these geographically dispersed families interacted in social networks involving most of the members at any time. Since 1925, other than the organization's annual meetings, social activities between members took place within their own extended families, not among a broader DTO membership. The petitioner's current members do not maintain a community that is distinct from the surrounding non-Indian population. The group's geographical dispersion is consistent with other evidence showing that members do not maintain, and have not maintained, significant social contact with each other. Before 1925, the petitioner's ancestors, primarily descendants of marriages between Duwamish Indians and pioneer settlers, had little or no interaction either with the Indians of the historical Duwamish settlements or with those Duwamish who moved to reservations. Because the petitioner has not maintained a community that is socially distinct from the general populations from historical contact to the present it has not met the requirements of criterion (b) under either the 1978 or the 1994 regulations.

The petitioner does not meet criterion 83.7(c) under the 1978 and 1994 regulations requiring a petitioner to show political influence or other political authority over its members. The DTO formed in late 1925 and since then it has not exercised political influence or authority over its members. It has limited itself, in general, to pursuing Federal acknowledgment and claims against the United States for its dues-paying members. The petitioner did not submit any evidence to show the group's leaders mobilized members to undertake group activities and that members were involved in making decisions for the group at any time. Because the petitioner formed in 1925 and has not maintained tribal political influence or authority over its members, there is insufficient evidence in the record that it exercised political influence of authority over its members ''throughout history until the present'' under the 1978 regulations or ''from historical times until the present'' under the 1994 regulations. The DTO does not meet the requirements of criterion (c) under the 1978 and 1994 regulations.

The petitioner has met criterion (d) by providing copies of the constitution and by-laws the DTO adopted in 1925 and are still in effect today. These governing documents also describe the petitioner's membership criteria. The petitioner has satisfied criterion (e), under the 1978 and 1994 regulations, because the available evidence demonstrates that about 99 percent (386 of 390) of its members on the 1992 list descend from historical Duwamish Indians. Evidence submitted to the court in *Hansen* v. *Salazar* relates to criterion 83.7(f). One exhibit, ''Combination of 1942 and 1979 Suquamish rolls compared with 1971 Duwamish Judgment Roll and Lane Report,'' shows DTO Chairwoman Cecile Ann (Oliver) Hansen and her brother Charles ''Manny'' Oliver, Jr., on both the 1942 and 1979 Suquamish rolls, which also identifies their great-grandmother, Jane Garrison, as their ''Duwamish Ancestor.''

To confirm or refute Muckleshoot's allegation that at least some members of DTO, including its leaders, may be enrolled in Federal tribes, the Department reviewed BIA censuses of Tulalip, Muckleshoot, and Quinault Reservations for Ms. Hansen's ancestors who were considered members of federally recognized tribes. Her father (Quinault-Cowlitz) and her paternal grandparents were allotted lands on Quinault Reservation. Her mother (''Snohomish-Duwamish'') was recorded on Tulalip Reservation censuses with her parents and is buried on the Tulalip Reservation. Hansen's maternal grandfather (Snohomish) was also allotted land on Tulalip; however, his wife, Hansen's maternal grandmother, Anna Garrison, was not allotted land. It is through Jane Garrison, mother of Anna (nee Garrison) Henry, that Cecile Hansen claims descent from the historical Duwamish Indian tribe. Thus, it appears that the Oliver siblings were eligible to enroll, or were enrolled, with the Suquamish Indian Tribe. Only 11 individuals (less than 3 percent of 390 DTO members) descend from Jane Garrison.

The PF did not find a ''significant percentage'' of the DTO are enrolled in federally recognized tribes. There is no evidence that a significant percentage of the petitioner's members belong to any federally-recognized tribe, or that the petitioner was subject to legislation terminating or forbidding a Federal relationship. Thus, the petitioner has met criteria (f) and (g), under both the 1978 and 1994 regulations.

The 1994 regulations clarified the 1978 regulations, but did not change the standard of proof for weighing evidence to determine whether a petitioner has demonstrated the required continuity of tribal existence from historical times to the present. As the preamble to the 1994 regulations states, ''additional language has been added to clarify the standard of proof,'' which would continue to be that ''facts are considered established if the available evidence demonstrates a reasonable likelihood of their validity'' (59 FR 9280). ''[P]etitioners that were not recognized under the previous regulations would not be recognized by these revised regulations'' (59 FR 9282).

The 1994 regulations included a new provision for previously recognized tribes at section 83.8. To qualify for evaluation under 83.8, a group must provide substantial evidence of unambiguous Federal acknowledgment, and must provide evidence that it is a continuation of a previously acknowledged tribe or evolved from that entity by showing it is a group comprised of members who together left the acknowledged tribe. The DTO ancestors, however, did not leave the treaty tribe as a group and the dispersed ancestors did not form DTO until 1925. Therefore, the DTO does not qualify for evaluation under 83.8 of the 1994 regulations, for previously acknowledged tribes. Since DTO ancestors were not part of the D'Wamish and other allied tribes, the evidence of government-to-government relations between the reservation tribes and the United States cannot be used to demonstrate the DTO meets either the 1978 or the 1994 regulations.

Based on the evaluation of the evidence, the AS–IA concludes that the Duwamish Tribal Organization should not be granted Federal acknowledgment as an Indian tribe under 25 CFR part 83.

A report summarizing the evidence, reasoning, and analyses that are the basis for the FD on Remand will be provided to the petitioner and interested parties, will be available to other parties upon written request, and will be available on the Department of the Interior's Web site at *http://www.doi.gov.* Requests for a copy of the summary evaluation of the evidence should be addressed to the Federal Government as instructed in the **ADDRESSES** section of this notice.

This decision is final for the Department on publication of this notice in the **Federal Register**.

Dated: July 2, 2015.

Kevin K. Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2015–16710 Filed 7–2–15; 4:15 pm]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[156A2100DD/AAKC001030/A0A501010.999900 253G]

Final Determination for Federal Acknowledgment of the Pamunkey Indian Tribe

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of final determination.

SUMMARY: The Department of the Interior (Department) gives notice the Assistant Secretary—Indian Affairs (AS–IA) has determined to acknowledge the Pamunkey Indian Tribe (Petitioner #323) as an Indian tribe within the meaning of Federal law. This notice is based on a determination that affirms the reasoning, analysis, and conclusions in the Proposed Finding (PF), as modified by additional evidence. The petitioner has submitted more than sufficient evidence to satisfy each of the seven mandatory criteria for acknowledgment set forth in the regulations under 25 CFR 83.7, and, therefore, meets the requirements for a government-to-government relationship with the United States. Based on the limited nature and extent of comments and consistent with prior practices, the Department did not produce a separate detailed report or other summary under the criteria pertaining to this final determination (FD). The proposed finding, as supplemented by this notice, is affirmed and constitutes the FD.

DATES: This determination is final and will become effective on October 6, 2015, pursuant to 25 CFR 83.10(l)(4), unless the petitioner or an interested party files a request for reconsideration under § 83.11.

ADDRESSES: Requests for a copy of the **Federal Register** notice should be addressed to the Office of the Assistant Secretary—Indian Affairs, Attention: Office of Federal Acknowledgment, 1951 Constitution Avenue NW., MS: 34B–SIB, Washington, DC 20240. The **Federal Register** notice is also available through *www.bia.gov/WhoWeAre/AS-IA/OFA/RecentCases/index.htm.*

FOR FURTHER INFORMATION CONTACT: R. Lee Fleming, Director, Office of Federal Acknowledgment (OFA), (202) 513–7650.

SUPPLEMENTARY INFORMATION: The Department publishes this notice in the exercise of authority the Secretary of the Interior delegated to the AS–IA by 209 DM 8. The Department issued a PF to acknowledge Petitioner #323 on January 16, 2014, and published notice of that preliminary decision in the **Federal Register** on January 23, 2014, pursuant to part 83 of title 25 of the Code of Federal Regulations (25 CFR part 83) (79 FR 3860). This FD affirms the PF and concludes that the Pamunkey Indian Tribe, c/o Mr. Kevin M. Brown, 331 Pocket Road, King William, VA 23086, fully satisfies the seven mandatory criteria for acknowledgment as an Indian tribe. Since the promulgation of the Department's regulations in 1978, the Department has reviewed over 50 complete petitions for Federal acknowledgment. OFA experts view this petition and the voluminous and clear documentation as truly extraordinary. Based on the facts and evidence, Petitioner #323 easily satisfies the seven mandatory criteria.

Publication of the PF in the **Federal Register** initiated the 180-day comment period provided in the regulations at § 83.10(i). The comment period closed July 22, 2014. Neither the Pamunkey petitioner nor other parties asked for an on-the-record technical assistance meeting under § 83.10(j)(2). The petitioner submitted comments certified by its governing body, and a third party submitted comment on the PF during the comment period. The Department also received 10 letters from trade associations and businesses that raised concerns over the potential impact acknowledgment of the petitioner might have on tax revenues to the Commonwealth and on their own economic interests should the petitioner venture into commercial enterprises. Three of these letters were received after the close of the comment period. Not all of the correspondence was copied to the petitioner as is required for comment under § 83.10(i). The correspondence did not address the evidence or analysis in the PF, is not substantive comment on whether the petitioner meets the mandatory criteria, and is therefore not further addressed in this FD. Further, as provided under § 83.10(l)(1), untimely comment cannot be considered. The petitioner submitted its response to the third-party comment and some of the correspondence before the close of the 60-day response period on September 22, 2014.

As part of the consultation process provided by the regulations at § 83.10(k)(1), the OFA wrote a letter to the petitioner and interested parties on October 16, 2014, followed by contact

with the petitioner's attorney. These communications informed the petitioner and interested parties that the Department planned to begin active consideration of all comments and the petitioner's response on November 3, 2014, and to issue a FD on or before March 31, 2015. The Department received no objections to this schedule. On March 27, 2015, the Department notified the petitioner and interested parties that the deadline for issuing the FD was extended 90 days to on or before July 29, 2015, to allow the Office of the AS–IA additional time based on the AS–IA's overall workload and travel schedule.

In addition to the record for the PF, this FD reviews and considers the arguments and evidence submitted as comments by the petitioner and third parties as well as the petitioner's response to the third-party comment. This FD addresses the third-party arguments under the appropriate criteria below. Because the PF addressed in detail the wealth of evidence showing how it is more than sufficient to fully satisfy the criteria, as well as some of the arguments presented in the third-party comment, this FD supplements, and must be read in conjunction with, the PF.

The third party comment that specifically addresses the PF was co-authored by the organizations ''Stand Up for California!'' and MGM National Harbor (Stand Up for California! and MGM 2014). Its Attachment 1 contains documents that are the same as, similar to, or related to documents that were already in the record and considered in the Department's PF. This commenter presents three issues in particular that do not relate to any specific criterion. None of these three issues merits a revision in the evaluation and conclusions under the criteria nor justifies the delay in issuing the FD. First, the commenter discussed the Department's proposed changes to the acknowledgment regulations (79 FR 30766, May 29, 2014) and proposes that the Department should not proceed with the issuance of the Pamunkey FD until the Department ''resolves what standards are sufficiently 'objective' for establishing that an American Indian group exists as an Indian Tribe '' (Stand Up for California! and MGM 2014, 3). The comment does not challenge the existing regulations, and in fact refers to the existing regulatory criteria as ''longstanding, clearly defined criteria that have been in effect since 1978.'' (Stand Up for California! and MGM 2014, 3–4). This issue does not merit delay in issuing the FD. The existing regulations remain in effect until July 30, 2015, and the Department's authority to promulgate them has been universally affirmed by the courts. *Miami Nation of Indians of Indiana* v. *Babbitt,* 255 F.3d 342 (7th Cir. 2001); *James* v. *United States Dep't of Health & Human Servs.,* 824 F.2d 1132 (D.C. Cir. 1987); *Western Shoshone Business Council* v. *Babbitt,* 1 F.3d 1052 (10th Cir. 1993). In *Miami Nation of Indians of Indiana,* the unanimous opinion authored by Judge Posner squarely rejected a challenge to the Department's authority to promulgate the Federal acknowledgment regulations, explaining ''Recognition is, as we have pointed out, traditionally an executive function. When done by treaty it requires the Senate's consent, but it never requires legislation, whatever power Congress may have to legislate in the area.'' In addition, as a general matter, a proposed rule does not preclude action under existing regulatory authority. Delay, therefore, is not appropriate. This decision is issued under the rules in effect at the time of this decision. The revisions to the federal acknowledgment regulations have now been finalized and published, but they are not effective until July 31, 2015. (80 FR 37862, July 1, 2015). In any event, the Pamunkey petitioner had the choice to suspend review pending revision of the regulations, and they chose to proceed under the regulations as they currently exist.

Second, the commenter maintains that the Pamunkey petitioner is in violation of the Indian Civil Rights Act (ICRA) because its membership standards specifically prohibit its members from marrying African-Americans (Stand Up for California! and MGM 2014, 5–7). The commenter maintains that prohibiting female members from voting and holding office are violations of the ICRA as well. The ICRA applies to federally recognized tribes, and thus does not apply to a petitioner, which by definition is not a federally recognized tribe. Further, the petitioner's submission in response to the PF and third-party comment indicates that it has removed the designation ''male'' with regard to voting members, changed all male pronouns in this document to include both male and female pronouns, and deleted the first section of its ''Ordinances'' document, which had mandated that members marry only persons of ''white or Indian blood.'' These changes address the specific concerns raised by the third party. Finally, the Department notes that it examines the evidence in its historical context for purposes of the evaluation under the criteria. The Commonwealth of Virginia's history is relevant to the historical context. For example, interracial marriage was a crime in the Commonwealth of Virginia until the United States Supreme Court struck down that law in 1967. *Loving* v. *Virginia,* 388 U.S. 1 (1967). Although such historical evidence often offends today's sensibilities, it is, nonetheless, evidence to be analyzed. This argument does not merit a revision to the evaluation or conclusions under the criteria.

Finally, the commenter takes issue with the 2008 notice issued by the AS–IA providing guidance and direction to OFA on an interpretation of the acknowledgment regulations. The commenter objects that this notice allows petitioners to document their claims of continuous tribal existence only since 1789, rather than at first sustained contact, which in this case would have been nearly 200 years prior with the founding of the Jamestown colony in 1607 (72 FR 30146). According to the commenter, the AS–IA's ''illegal guidance'' resulted in an improper finding by the Department (Stand Up for California! and MGM 2014, 7–11). The AS–IA's 2008 directive is an interpretation of the regulations, not a change to the regulations, and it is within the authority of the AS–IA to make such interpretations and offer such guidance., *Perez* v. *Mortgage Bankers Assn.,* 135 S. Ct. 1199 (2015). The commenter did not provide evidence that the petitioner did not exist before 1789, and other evidence in the record actually supports the finding of continued existence since first sustained contact. In fact, even though it was not required to do so, the petitioner submitted considerable evidence that the 1789 population at Indian Town connects to the Pamunkey population described by politicians, travelers, and the Colony of Virginia from the mid-1600s onward (PIT PF 2014, 4–6, 22–23). The commenter did not challenge this evidence ''show[ing] that a Pamunkey Indian tribe or settlement continued throughout the colonial period,'' nor the documented connection between the 1789 and mid-1600s ''first contact'' population (PIT PF 2014, 5). This general comment without any evidence does not merit a revision in the evaluation or conclusions under the criteria.

Although the PF found that the petitioner satisfied all seven mandatory criteria, the petitioner submitted even more evidence as part of its comment on the PF. The petitioner's timely comments on the PF included a 93-page narrative and 4 appendices of exhibits.

These exhibits included historical documents related to the Pamunkey church; an updated and separately certified membership list identifying 208 members as of July 19, 2014; an updated genealogical database of the petitioner's members and their ancestry; 99 ancestor files; and 208 member files (PIT Comments 2014). The petitioner's timely response to third-party comments included 59 pages of explanatory information on how it satisfies the criteria and 31 pages of exhibits, primarily genealogical in content (PIT Response 2014).

The petitioner provided additional new evidence and analyses addressing community, some revisions to its governing document, and additional documentation tracing descent from the historical Indian tribe. The third-party comment provided no new evidence and their arguments did not merit revision of the PF's conclusions. Although the PF found that petitioner satisfied the criteria, the petitioner submitted even more evidence. This FD finds that the general arguments against the conclusions of the PF are not persuasive and do not necessitate a change in the reasoning, analyses, and conclusions for the FD. This FD modifies only a few specific findings in the PF concerning criterion 83.7(e), based on the information submitted by the petitioner, but these revised calculations, based on updated and newly submitted membership information, only strengthen the PF's overall conclusion that the petitioner meets all seven mandatory criteria. In summary, the amount and quality of evidence submitted by the petitioner both prior to and after the PF sets this petition apart as one of the most well documented petitions ever reviewed by OFA and the Department. Petitioner's extraordinary amount of quality evidence and documentation easily satisfies the mandatory criteria for acknowledgment. Therefore, this FD affirms the PF.

Evaluation Under the Criteria

Criterion 83.7(a) requires that external observers have identified the petitioner as an American Indian entity on a substantially continuous basis since 1900. Neither the petitioner's nor third-party comments explicitly addressed the PF's conclusions that the petitioner met criterion 83.7(a). The evidence in the record is voluminous and extraordinary. The evidence identifies Pamunkey as an American Indian entity by various external observers, including newspaper articles, state and local officials, and scholars. This evidence shows external observers identified the Pamunkey petitioner as an American Indian entity on a substantially continuous basis since 1900; therefore, this FD affirms the PF's conclusions that the petitioner meets criterion 83.7(a).

Criterion 83.7(b) requires that a predominant portion of the petitioning group has comprised a distinct community since historical times. The petitioner met this criterion in the PF from 1789 until 1899 with a combination of evidence under criterion 83.7(b)(1). From 1900 to the present, the high level of evidence available under criterion 83.7(c)(2) was used to demonstrate community under criterion 83.7(b), using the ''crossover'' evidence provision under 83.7(b)(2)(v). The PF did not request additional evidence to demonstrate criterion 83.7(b), as the comprehensive evidence in the record for the PF more than satisfies the criterion. Taking nothing for granted, the petitioner submitted additional new information concerning the Pamunkey Baptist Church and its role in the historical Pamunkey community. This new evidence documented that the ''body of individuals residing at Indian Town'' petitioned the organization to form a new church (the future Colosse Church) after a theological schism had resulted in the expulsion of the Lower College Church from the Dover Baptist Association, circa 1835. Further, when the Dover representatives came to visit, they met non-Pamunkeys who sought to establish a new congregation, as well as the Pamunkey group, who had actually initiated the investigation. The Pamunkey group agreed to attach itself to this new congregation. The petitioner also referenced some mid-19th century documents from the chancery court records of Petersburg, VA., that contain additional information about Lavinia Sampson, a Pamunkey woman who was discussed in the PF (PIT PF 2014, 38–39). Such information, although not needed to meet any of the criteria, further described and corroborated the role of the church in the petitioner's community before and after the Civil War, and also provided some additional discussion about Lavinia Sampson's relationship with some of the Pamunkey still living in King William County. This information strengthened the conclusions reached in the PF under criterion 83.7(b).

Other new evidence further supports the conclusions reached in the PF. Department researchers located a copy of the 1864 U.S. Navy court-martial of William Terrill Bradby, who was convicted of manslaughter for killing his brother Sterling Bradby in February of that year (NARA, Court Martial Case Files 1809–1894, NN1665). Previous researchers had known of the court-martial, but none had been able to locate a copy of the documents, possibly because it had been filed under the erroneous name ''Gerrill.'' According to the court-martial documents, several men elsewhere identified as Indians from King William County lived in a temporary settlement off the reservation for a short time during the Civil War (all but one are known to have returned to their homes in King William County immediately after the war ended). The settlement was located on Mumford's Island, near Gloucester Point in Gloucester County, about 50 miles from the Pamunkey reservation. Four other men (two named on censuses of the Pamunkey reservation and two associated with the neighboring Mattaponi state Indian reservation) testified that they also lived on Mumford's Island in 1864. The older men likely served as civilian boat pilots for the Union Army during their stay there. Sterling Bradby's wife, Ellen, is specifically identified as having been at Mumford's Island. This document provides additional information describing the relations among Pamunkey members and some of their relatives from the Mattaponi reservation during the 19th century, and further demonstrates that these members left the reservation as a group and later returned to it. This new evidence and analysis further supports the conclusions regarding the social relationships among group members reached in the PF for criterion 83.7(b).

Stand Up for California! and MGM maintained that the petitioner should not have been able to satisfy criterion 83.7(b) for a number of reasons. The commenter maintained that the ''crossover'' evidence from criterion 83.7(c)(2) used to satisfy criterion 83.7(b) should not have been used for the period from 1900 to the present because the reservation population was less than a ''predominant proportion'' of the group (Stand Up for California! and MGM 2014, 11–12). The regulations, 83.7(b), define community using the terms ''predominant portion.'' Section 83.7(b)(2) further provides that a petitioner ''shall be considered to have provided sufficient evidence of community'' at a given point in time if ''the group has met the criterion in § 83.7(c) using evidence described in § 83.7(c)(2).'' The regulations under § 83.7(c) or § 83.7(c)(2), however, do not require that a ''predominant proportion'' of members live within a limited area, and § 83.7(b)(2) defines the § 83.7(c)(2) evidence as ''sufficient'' to meet § 83.7(b). Therefore, the third-party

argument that less than a predominant portion lived on the reservation does not merit a change in the analysis or conclusions reached in the PF under criterion 83.7(b). The § 83.7(c)(2) evidence included multiple relevant and remarkably exceptional examples of the group's leadership allocating reservation land, determining residence rights, collecting taxes and fines from residents, and resolving disputes between members. The third party does not provide any evidence; instead it argues that the regulations should be applied in an unconventional manner contrary to the language of the regulations. In summary, the third party comment does not in any substantive manner undermine the sufficiency of this substantial body of evidence.

Further, the commenter characterized the migration of members away from the reservation as the ''steady and deliberate abandonment of the reservation by Petitioner's members'' (Stand Up for California! and MGM 2014, 13) and maintained that ''there is evidence that affirmatively establishes that a substantial portion of the petitioner ceased to participate in the group'' (Stand Up for California! and MGM 2014, 11). These broad statements are contrary to the truly exceptional evidence in the record. First, the PF described a core reservation population throughout the 19th and 20th centuries (PIT PF 40–42, 46–47, 72–79); at no time was the reservation itself ever ''abandoned,'' even if some people moved away. Most, if not every, federally recognized Indian tribe has citizens who do not reside on the tribe's reservation. Indeed, some federally recognized Indian tribes do not have a reservation. Second, the PF acknowledged that some people left the community permanently; however, the PF also noted that other people left the reservation for various economic opportunities over the years and described how some of those who left stayed in contact with those still on the reservation, as well as with others who also left for economic reasons. This pattern of behavior is entirely consistent with that of citizens of federally recognized Indian tribes. The PF noted that members who moved to cities such as Philadelphia often sought out other Pamunkey who had moved there earlier to help them obtain employment or a place to live. It also noted that people who moved away from the reservation returned to visit when they could, and often returned to live there years later (PIT PF 2014, 54–55).

Indeed, most successful petitioners do not have a state reservation or a land base. Notwithstanding this basic fact, past Department findings have noted other communities where people moved away from the area where a number of members resided for work or other opportunities, but remained in contact with those relatives still living in a core community (see findings for Huron Potawatomi and Match-E-Be-Nash-She-Wish Band of Pottawatomi), and the evidence in the record indicates that this pattern also occurred with the Pamunkey. In many respects, it is irrelevant that people left the Pamunkey reservation. What is relevant for purposes of community is the evidence in the record that other members knew where they were, and often stayed in contact with them (PIT PF 2014,74–75; 77–78). Likewise, there is no requirement that all descendants of historical members remain in the membership at present. Current rules for membership in the group specify a social connection to the community as well as to current members living on the reservation (PIT PF 2014, 83–84). That the present membership consists of members whose families have remained in contact with each other demonstrates that the group is more than just a group of descendants with little in common other than a distant genealogical connection. It is inaccurate to describe the economic migration of members as ''abandonment'' of the group. Virtually every federally recognized Indian tribe has members who do not live on the reservation. Like those members of federally recognized Indian tribes, Pamunkey members remain a part of the community, even though they may no longer live on the reservation.

The Department finds that the third-party comments do not change the analysis of the PF's substantial body of evidence and overall conclusions that a distinct Pamunkey community has existed from historical times to the present. The evidence in the record is more than sufficient to satisfy this criterion. Therefore, the Pamunkey petitioner meets criterion 83.7(b).

Criterion 83.7(c) requires that the petitioning group has maintained political influence over its members as an autonomous entity since historical times. ''Autonomous'' is defined in terms of political influence or authority independent of the control of any other Indian governing entity. The petitioner met this criterion in the PF. Stand Up for California! and MGM argued, ''It is impossible to determine from the evidence in the PF that the Indian community at Pamunkey Island actually meets the criteria for tribal acknowledgment in 1789, *i.e.,* that it existed as a self-governing tribe, rather than simply as an increasingly assimilated community of Indian families'' (Stand Up for California! and MGM 2014, 9–10). The commenter contends that the evidence in the record indicated the Pamunkey were not politically autonomous in the late 18th and early 19th centuries because of the involvement of the Pamunkey trustees, whom the commenter describes as ''non-Indians appointed by the Commonwealth'' (Stand Up for California! and MGM 2014, 10).

While there is some indication that the Commonwealth of Virginia appointed the trustees before 1799, the legislature then passed an act specifically authorizing the Indians to directly elect trustees. Even prior to 1799, there is evidence that the Pamunkey still had some input into those decisions, and that the choice of trustees was not a matter for the Assembly alone. The Department also rejects the commenter's argument because there is more than sufficient evidence in the record to determine that the Commonwealth considered the Pamunkey a tribe in 1789, and not just a collection of families. That the Commonwealth established the procedure by which the Pamunkeys themselves selected trustees to deal with issues specific to the Pamunkey, including the disposition of land and the resolution of residency rights, indicates that Virginia recognized the Pamunkey as a political entity.

Further, the extensive evidence demonstrates that the Pamunkey consulted the trustees on a variety of matters over the years and valued their advice and recommendations, but the Pamunkey themselves made the ultimate decisions. The historical record demonstrates that the trustees served as intermediaries and advisors on legal affairs between the Pamunkey and the outside world (see, for example, PIT PF 2014, 38 and 60). While various states may have historically passed laws or appointed trustees for state tribes, the regulations in this regard simply require that the petitioner exercise political authority independent of the control of another Indian tribe. In any event, there is no evidence in the record that the Pamunkey trustees ever exercised any political authority over the group. The extensive record provided significant evidence of regular elections of chiefs and councils throughout the 19th and 20th centuries. The highly detailed records from the 20th century also demonstrate that the group managed its own affairs and exercised political influence and authority over its members. Previous acknowledgment decisions establish that the presence of non-Indian trustees, justices of the

peace or overseers does not prevent a petitioner from meeting criterion 83.7(c) (Mashpee PF 2006, 14, 37, 89, 98).

The commenter also questioned the PF's description of the Pamunkey Indian reservation (alternately referred to as ''Pamunkey Island,'' ''Indian Island,'' and ''Indian Town'') as a distinctly Pamunkey community because of the presence of some other Indian individuals and an unspecified number of non-Indians (Stand Up for California! and MGM 2014, 9–11). Even if other Indians or non-Indians lived on the reservation, the petitioner has submitted more than sufficient evidence demonstrating that it maintained a distinct community. The PF did note that there were other individual Indians and some non-Indians living among the Pamunkey, and described the Pamunkey settlement as ''very nearly exclusive,'' although not completely exclusive in the late 18th and early 19th centuries (PIT PF 2014, 23). The regulations have never required complete or nearly complete exclusivity. Further, the PF acknowledged the presence of unauthorized squatters living on the reservation, but specifically noted that there was no indication that these squatters ever became part of the Pamunkey community. The PIT response to the Stand Up for California! and MGM comments stated that the squatters did not live on Indian Island proper, but lived on other lands that were then owned by the Pamunkey and later sold (PIT Response 2014, 23). However, there is no indication there was ever an Indian entity on Indian Island or on any of the land owned by the Pamunkey separate from the Pamunkey itself. In the case of the families living on the nearby Mattaponi state Indian reservation, individuals did go back and forth between the two communities, particularly when they married a member of the opposite group. The overwhelming evidence in the record easily demonstrates that there was a distinct self-governing community residing on the Pamunkey Indian Reservation, which was autonomous and separate entity from the Mattaponi on its separate state Indian reservation. All evidence in the record indicates that some Indian individuals from other tribes lived with or married into the Pamunkey, but that the Pamunkey reservation remained a distinctly Pamunkey settlement under the authority of the Pamunkey leaders. This situation is extraordinarily analogous to many federally recognized Indian tribes and Indian reservations throughout the United States. As further support, the regulations provide in § 83.6(e), that evaluations of petitions shall take into account the limitation inherent in demonstrating the historical existence of community and political influence or authority.

Other new evidence further supports the conclusions reached in the PF. Department researchers located a document within the chancery court records of King William County, Virginia, which described how the Pamunkey administered affairs on the reservation at the turn of the 20th century (*Miles* v. *Miles* 1907). The reservation treasurer, Pamunkey member J. T. Dennis, testified in this case and explained that the Pamunkey council served as a judicial body, adjudicating disputes on the reservation, and also explained that the council had the authority to regulate the behavior of members on the reservation. Dennis stated that the council would allow aggrieved members to take their cases to the courts of the Commonwealth if the other party did not comply with the rulings issued by the reservation council, and that the council had threatened to exercise this authority against the young man in this particular case if he did not abide by their dictates. Two other reservation residents also testified that the young man had obeyed the dictates of the council. Dennis also stated that reservation law did allow people to be ''put out'' of the tribe if they did not obey the dictates of the tribal council, and characterized this as ''a pretty severe punishment.'' Dennis did not say if the young man had been threatened with being ''put out'' of the tribe, although the plaintiff's lawyer seems to intimate that he had feared that might happen if he did not obey the council. This new evidence supplements the already voluminous and substantial evidence and further underscores the authority the Pamunkey council held over the reservation residents even in personal matters, and demonstrates that the members living there recognized this authority.

The commenter's arguments are unsupported by the voluminous, substantial evidence in the record, not persuasive, and new evidence in the record further supports the conclusions reached in the PF that the petitioning group has maintained political influence and authority over its members since historical times. This FD affirms the PF's conclusions. Therefore, the Pamunkey petitioner meets criterion 83.7(c).

Criterion 83.7(d) requires that the petitioning group provide a copy of its governing document, including its membership criteria. For the PF, the petitioner submitted a copy of its governing document which included its membership criteria, satisfying the requirements of criterion 83.7(d). In its response to comments, the petitioner submitted an amended governing document, entitled ''Laws of the Pamunkey Indians,'' and an amended secondary governing document, entitled ''Ordinances of the Pamunkey Indian Reservation'' (PIT Response 2014, 60–78, Exhibit 1). The petitioner revised its governing document (''Laws'') on July 12, 2012, to remove the designation ''male'' with regard to voting members, to modify the qualification for service on the group's governing body, and to revise rights to residence on the Pamunkey reservation. On September 4, 2014, the petitioner changed all male pronouns in this document to include both male and female pronouns. On August 27, 2014, the petitioner deleted the first section of its ''Ordinances'' document, which had mandated that members marry only persons of ''white or Indian blood.''

The documents submitted for the FD provide new evidence under criterion 83.7(d) concerning how the Pamunkey petitioner governs itself and determines its membership, supporting the conclusions in the PF. This FD affirms the PF's conclusions. Therefore, the Pamunkey petitioner meets criterion 83.7(d).

Criterion 83.7(e) requires that the petitioner's members descend from a historical Indian tribe or from historical Indian tribes which combined and functioned as a single autonomous political entity. The PF found the petitioner met criterion 83.7(e) because it submitted a separately certified membership list and because 162 of its 203 members (80 percent) demonstrated descent from members of the historical Pamunkey Indian tribe. During the comment period, the petitioner submitted an updated membership list, separately certified by its governing body, and additional genealogical evidence, that demonstrates that all of its current 208 members (100 percent) document descent from members of the historical Pamunkey Indian tribe as of July 19, 2014 (PIT Comment 2014, Appendix 4). Accordingly, the evidence in the record is more than sufficient to establish that petitioner has satisfied this criterion. Supplemental genealogical evidence included certified birth records for 11 members and one member's parent, and parentage documentation for deceased forebears Robert W. Miles, Ezekiel Langston, and Daizy/Hazie Bloomfield Allmond (PIT Comment 2014, Appendix 4, Item 5, 47–93).

The PF found that 41 of the petitioner's 203 members either had not documented descent from their claimed Pamunkey ancestor, or claimed ancestors who were not documented as historical Pamunkey Indians. Of these 41 members, 18 (9 percent of the petitioner's members) did not document descent from a member of the historical Pamunkey Indian tribe. This FD finds that of these 18, all have now documented their generation-by-generation descent from a member of the historical Pamunkey Indian Tribe. The residual 23 members claimed descent from Robert W. Miles, whose ancestry had not been traced to a member of the historical Pamunkey Indian tribe at the time of the PF. With new evidence submitted by the petitioner for the FD, it is now demonstrated that Robert W. Miles is the grandson of Pleasant Miles, a documented member of the historical Indian tribe. All of the residual 23 members have documented their generation-by-generation descent from Pleasant Miles through Robert W. Miles for this FD.

Materials the petitioner submitted in the comment period demonstrated also that some current members descend from an additional historical Pamunkey Indian individual who was not claimed as their ancestor for the PF (PIT Comment 2014, Appendix 4, Item 5, 76–82). This historical individual, known to be a member of the historical Pamunkey Indian tribe, is Pleasant Miles (b.bef.1815–d.aft.1836), listed on the 1836 petition, and now demonstrated to be the father of Isaac Miles (b.abt.1828–d.aft.1852) and the grandfather of Robert W. Miles (b.1852–d.1930). As a result of this new evidence, 40 members of the petitioner are able to claim descent from Pleasant Miles, and 33 of those 40 have documented that descent. Of the remaining seven members, one has documented his descent from Edward Bradby, and the other six have documented their descent from Edward Bradby and Isaac Miles, Jr., other qualifying historical Pamunkey Indian ancestors.

Stand Up for California! and MGM argued that the PF did not satisfactorily document Matilda Brisby (aka Brisley or Bradby) as a historical Pamunkey Indian (Stand Up for California! and MGM 2014, 14–16). The PF reported that Matilda Brisby was listed on the 1835 Colosse Baptist Church ''Island List'' of Indians associated with the Pamunkey Indian community on ''Indian Island,'' which the PF considered as a list identifying members of the historical Pamunkey Indian tribe (PIT PF 2014, App. A). The Southern Claims Commission testimony of Matilda Brisby's grandson, son-in-law, and numerous others, all of whom were identified as members of the Pamunkey Indian tribe, implied that she was considered a member of the Pamunkey community (PIT PF 2014, 97–98; see also discussion under criterion 83.7(b)). The PF concluded this evidence was sufficient under the reasonable likelihood standard to identify her as a historical Pamunkey Indian, whether she was born Pamunkey or was married to a Pamunkey Indian. The commenter argues that ''at most'' the Church record ''establishes that the listed individuals were Indians and residents of the state reservation'' and further questions whether Martha A. (Brisby) Page Sampson and Matilda A. (Brisby) Langston were her daughters. The marriage records of these two individuals, however, specifically identify Matilda Brisby as their mother. The commenter does not present any evidence that Matilda Brisby was non-Indian or other Indian, surmising based on secondary sources that she may be Mattaponi ''based on close relationship between Pamunkey and Mattaponi.'' Without any direct evidence, the commenter's argument is not persuasive. The evidence in the record affirms the Department's conclusion that Matilda Brisby is Pamunkey Indian.

Of the 164 members of the petitioner claiming descent from Matilda Brisby, 157 have demonstrated that descent. However, even if Matilda Brisby were not Pamunkey Indian, it would not change the finding that petitioner has satisfied this criterion. Based on the evidence submitted by the petitioner in the comment period, all 164 of those members also demonstrate descent from one or more of six other historical Pamunkey Indians—Edward ''Ned'' Bradby (Sr.) (122), William Bradby (30), James Langston (131), Isaac Miles, Jr. (108), Pleasant Miles (5), and John Sampson (65). The commenter provides no primary evidence that these individuals are not Pamunkey Indian, and under the regulations, the evidence demonstrates they are Pamunkey. Thus, the commenter's argument regarding Matilda Brisby, even if true, does not require a change in the conclusions of the PF that the petitioner meets criterion 83.7(e).

In summary, the petitioner's evidence for 100 percent of its membership is more than sufficient to demonstrate that it descends from a historical Indian tribe. For all of the above reasons, the argument presented by the third party does not result in a change in the conclusion that Matilda Brisby was a member of the historical Pamunkey Indian tribe. (This FD notes and corrects an error in the PF that gave ''1850'' instead of ''1820'' as the approximate date of Matilda Brisby's marriage to Edward Brisby; PIT PF 2014, 97).

The commenter Stand Up for California! and MGM also argued that demonstrating Matilda Brisby's non-Indian status would result in the group's failure to meet criterion 83.7(e) because too many members would no longer have descent from the historical Pamunkey Indian tribe (Stand Up for California! and MGM 2014, 13). Because evidence the petitioner submitted for the FD demonstrates all 208 current members descend from the historical Pamunkey Indian tribe through individuals other than Matilda Brisby, this argument does not require a change in the analysis for the FD (PIT Comment 2014, Appendix 4, Membership Files and Item 5, 47–93; PIT Response 2014, Narrative, 48–50).

The Department's evaluation of new evidence submitted for the FD further strengthens the overall conclusions reached in the PF under criterion 83.7(e). For the FD, the Pamunkey petitioner has demonstrated that 100 percent of its members descend from the historical Pamunkey Indian tribe, with every member having generation-to-generation documentation of descent from a member of the historical Pamunkey Indian tribe. This evidence is more than sufficient to satisfy this criterion. Therefore, the Pamunkey petitioner fully satisfies criterion 83.7(e).

Criterion 83.7(f) requires the petitioner's membership be composed principally of persons who are not members of another federally recognized Indian tribe. The petitioner met this criterion in the PF. All five of the new members added since the PF stated on consent forms that they are not enrolled with any federally recognized Indian tribe. The evidence in the record demonstrates the membership of the petitioner is composed principally of persons who are not members of any acknowledged North American Indian tribe. The petitioner and third party did not submit comments on this criterion. Therefore, the FD affirms the PF's conclusions that the Pamunkey petitioner meets criterion 83.7(f).

Criterion 83.7(g) requires that the petitioner not be subject to congressional legislation that has terminated or forbidden the Federal relationship. The PF concluded the petitioner met criterion 83.7(g) because the petitioner did not submit and the Department did not locate any evidence that Congress has either terminated or forbidden a Federal relationship with

the petitioner or its members. The petitioner and third party did not submit comments on this criterion. Therefore, this FD affirms the PF's conclusion that the Pamunkey petitioner meets criterion 83.7(g).

This notice is the FD to extend Federal acknowledgment under 25 CFR part 83 to the Pamunkey Indian Tribe. Under § 83.10(h) of the regulations, this FD summarizes the evidence, reasoning, and analyses that form the basis for this decision. In addition to its publication in the **Federal Register**, this notice will be posted on the Bureau of Indian Affairs Web site at *http://www.bia.gov/WhoWeAre/AS-IA/OFA/RecentCases/index.htm.* Requests for a copy of the FD should be addressed to the Federal Government as instructed in the **ADDRESSES** section of this notice.

After the publication of the FD in the **Federal Register**, the Pamunkey petitioner or any interested party may file a request for reconsideration with the Interior Board of Indian Appeals (IBIA) under the procedures in § 83.11 of the regulations. The IBIA must receive this request no later than 90 days after the publication of the FD in the **Federal Register**. The FD will become effective as provided in the regulation 90 days after the **Federal Register** publication unless a request for reconsideration is received within that time.

Dated: July 2, 2015.

Kevin K. Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2015–16711 Filed 7–2–15; 4:15 pm]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCON04000. L16100000.DR0000]

Notice of Availability of the Record of Decision for the Colorado River Valley Field Office Approved Resource Management Plan

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) and Approved Resource Management Plan (RMP) for the Colorado River Valley Field Office located in portions of Eagle, Garfield, Mesa, Pitkin, Rio Blanco, and Routt counties in northwest Colorado. The Colorado State Director signed the ROD on June 11, 2015, which constitutes the BLM's final decision and makes the approved RMP effective immediately.

ADDRESSES: Copies of the ROD/approved RMP are available upon request from the Field Manager, BLM Colorado River Valley Field Office, 2300 River Frontage Road, Silt, CO 81652 or via the Internet at *http://www.blm.gov/co/st/en/fo/crvfo.html.* Copies of the Colorado River Valley Field Office ROD and approved RMP are available for public inspection at the Colorado River Valley Field Office.

FOR FURTHER INFORMATION CONTACT: Brian Hopkins, Planning and Environmental Coordinator; telephone: 970–876–9073; address: 2300 River Frontage Road in Silt, CO 81652; email: *bhopkins@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, seven 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 field office has worked with the public, interest groups, stakeholders, cooperating agencies, tribes, the Northwest Colorado Resource Advisory Council, neighboring BLM offices, the Environmental Protection Agency, the U.S. Forest Service, and the U.S. Fish and Wildlife Service to craft the revised RMP. The result is an approved RMP that seeks to provide an overall balance between the protection, restoration, and enhancement of natural and cultural values, while allowing resource use and development in identified areas. Goals and objectives focus on environmental, economic, and social outcomes achieved by strategically addressing them on a landscape scale. Management direction is broad to accommodate a variety of interests and uses.

The BLM initiated scoping for the RMP in 2007 and collected information and public input via public meetings and interviews in order to develop the Draft RMP/Environmental Impact Statement (EIS) in September 2011. Based on public and agency comments, the BLM carried forward the preferred alternative with some edits as the Proposed RMP/Final EIS. The BLM published the Proposed RMP/Final EIS in March 2014 and made it available for a 30-day public protest period beginning on March 24, 2014. During the protest period, the BLM received protests on a variety of issues. Following the protest resolution, the BLM made minor editorial modifications to the approved RMP to provide further clarification of some decisions.

BLM regulations also require a 60-day Governor's Consistency Review period for the Proposed RMP/Final EIS to ensure consistency with State government plans or policies. The Governor did not identify any inconsistencies with State government plans or policies. The response letter stated that the State is grateful that the BLM has chosen to rely upon the Upper Colorado River Wild and Scenic Stakeholder Group Management Plan in concert with BLM management authorities to protect Colorado River segments. This approach is consistent with Colorado policy and law to support stakeholder efforts to develop protection of river-dependent resources as alternatives to Wild and Scenic River designation.

Management decisions outlined in the approved RMP apply only to BLM-managed surface lands (approximately 505,200 acres) and BLM-managed Federal mineral estate (approximately 701,200 acres) that lies beneath other Federal, State and private surface ownership with the exception of National Forest lands. The approved RMP will replace the 1984 Glenwood Springs Resource Area RMP. The approved RMP outlines goals, objectives, management actions, and allowable uses for resources and land uses including: Air, soil, water, upland and riparian vegetation, fish and wildlife, cultural resources, visual resources, forestry, livestock, grazing, minerals, energy development and recreation. While the RMP also proposes conservation management for Greater Sage-grouse habitat, the Northwest Colorado BLM Greater Sage-Grouse Plan Amendment and EIS will fully analyze the applicable Greater Sage-grouse conservation measures, consistent with BLM Instruction Memorandum No. 2012–044. The BLM expects to make a comprehensive set of decisions for managing Greater Sage-grouse on lands administered by the Colorado River Valley Field Office in the ROD for the Northwest Colorado BLM Greater Sage-Grouse Plan Amendment and EIS.

The approved RMP includes some implementation decisions designating routes of travel which are appealable to the Interior Board of Land Appeals under 43 CFR part 4. The route decisions are displayed by travel zone in Appendix A of the approved RMP. Any party adversely affected by the proposed route designations may appeal within 30 days of publication of this Notice of Availability pursuant to 43 CFR part 4, subpart E. The appeal should state the specific route(s), as

identified in Appendix A of the approved RMP, on which the decision is being appealed.

The appeal must be filed with the Colorado River Valley Field Manager at the above listed address. Please consult the appropriate regulations (43 CFR part 4, subpart E) for further appeal requirements.

Authority: 40 CFR 1506.6

Ruth Welch,

BLM Colorado State Director.

[FR Doc. 2015–16431 Filed 7–7–15; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCOS00000 L10100000.BN0000 15X]

Notice of Public Meetings, Southwest Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Southwest Resource Advisory Council (RAC) is scheduled to meet as indicated below.

DATES: The Southwest RAC meeting will be held on August 14, 2015, in Gunnison, Colorado.

ADDRESSES: The Southwest RAC meeting will be held August 14 at the Gunnison High School, 800 W. Ohio Ave., Gunnison, CO 81230. The meeting will begin at 9 a.m. and adjourn at approximately 4 p.m. A public comment period regarding matters on the agenda will be held at 11:30 a.m.

FOR FURTHER INFORMATION CONTACT: Shannon Borders, Public Affairs Specialist, 970–240–5300; 2505 S. Townsend Ave., Montrose, CO 81401. 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, seven 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 Southwest RAC advises the Secretary of the Interior, through the BLM, on a variety of public land issues in Colorado. Topics of discussion for all Southwest RAC meetings may include field manager and working group reports, recreation, fire management, land use planning, invasive species management, energy and minerals management, travel management, wilderness, land exchange proposals, cultural resource management and other issues as appropriate. These meetings are open to the public. The public may present written comments to the RACs. Each formal RAC meeting will also have time, as identified above, allocated for hearing public comments. Depending on the number of people wishing to comment and time available, the time for individual oral comments may be limited.

Greg Shoop,

BLM Colorado Associate State Director.

[FR Doc. 2015–16677 Filed 7–7–15; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[15X.LLAZ956000.L14400000.BJ0000. LXSSA225000.241A]

Notice of Filing of Plats of Survey; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey; Arizona.

SUMMARY: The plats of survey of the described lands were officially filed in the Arizona State Office, Bureau of Land Management, Phoenix, Arizona, on dates indicated.

SUPPLEMENTARY INFORMATION:

The Gila and Salt River Meridian, Arizona

The plat representing the survey and subdivision of certain sections, Township 39 North, Range 9 East, accepted June 11, 2015, and officially filed June 12, 2015, for Group 1136, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The plat, in two sheets, representing the dependent resurvey, survey and subdivision of certain sections, Township 35 North, Range 14 East, accepted May 1, 2015, and officially filed May 5, 2015, for Group 1128, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The plat representing the dependent resurvey and subdivision of certain sections, Township 24 North, Range 19 East, accepted May 28, 2015, and officially filed May 29, 2015, for Group 1127, Arizona.

This plat was prepared at the request of the Bureau of Indian Affairs.

The supplemental plat showing amended lotting in section 29, Township 12 North, Range 9 West, accepted May 1, 2015, and officially filed May 6, 2015, for Group 9107, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The supplemental plat showing amended lotting and revisions to the Table Top Wilderness boundary in section 21, Township 7 South, Range 3 East, accepted May 1, 2015, and officially filed May 6, 2015, for Group 9108, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The supplemental plat showing amended lotting and revisions to the Table Top Wilderness boundary in section 5, Township 8 South, Range 3 East, accepted May 1, 2015, and officially filed May 6, 2015, for Group 9108, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The plat representing the dependent resurvey and subdivision of section 23, Township 23 South, Range 20 East, accepted May 13, 2015, and officially filed May 14, 2015, for Group 1112, Arizona.

This plat was prepared at the request of the United States Forest Service.

The plat representing the dependent resurvey of Mineral Survey No. 3550 and Mineral Survey No. 4281, Township 24 South, Ranges 20 and 21 East, accepted May 13, 2015, and officially filed May 14, 2015, for Group 1112.

This plat was prepared at the request of the United States Forest Service.

The plat representing the dependent resurvey and subdivision of sections 31 and 32, Township 23 South, Range 21 East, accepted May 13, 2015, and officially filed May 14, 2015, for Group 1112, Arizona.

This plat was prepared at the request of the United States Forest Service.

The plat representing the dependent resurvey and subdivision of section 5, Township 24 South, Range 21 East, accepted May 13, 2015, and officially filed May 14, 2015, for Group 1112, Arizona.

This plat was prepared at the request of the United States Forest Service.

The plat representing the dependent resurvey and subdivision of section 6, Township 20 South, Range 22 East, accepted June 17, 2015, and officially filed June 18, 2015, for Group 1143, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The plat representing the dependent resurvey of Homestead Entry Survey No. 234, Township 2 South, Range 31 East, accepted June 17, 2015, and officially filed June 18, 2015, for Group 1139, Arizona.

This plat was prepared at the request of the United States Forest Service.

A person or party who wishes to protest against any of these surveys must file a written protest with the Arizona State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within thirty (30) days after the protest is filed.

FOR FURTHER INFORMATION CONTACT: These plats will be available for inspection in the Arizona State Office, Bureau of Land Management, One North Central Avenue, Suite 800, Phoenix, Arizona, 85004–4427. 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.

Gerald T. Davis,

Chief Cadastral Surveyor of Arizona.

[FR Doc. 2015–16679 Filed 7–7–15; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCON02000.L16100000.DR0000]

Notice of Availability of the Kremmling Field Office Record of Decision and Approved Resource Management Plan, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) and approved Resource Management Plan (RMP) for the Kremmling Field Office located in Grand, Eagle, Summit, Jackson, Larimer, and Routt counties in northwest Colorado. The Colorado State Director signed the ROD on June 19, 2015, which constitutes the BLM's final decision and makes the approved RMP effective immediately.

ADDRESSES: Copies of the ROD/approved RMP are available upon request from the Field Manager, BLM Kremmling Field Office, 2103 E. Park Ave, Kremmling CO 80459 or via the Internet at *http://www.blm.gov/co/st/en/fo/kfo.html.* Copies of the ROD/approved RMP are available for public inspection at the Kremmling Field Office.

FOR FURTHER INFORMATION CONTACT: Stephanie Odell, Field Manager; telephone 970–724–3001; address 2103 E. Park Ave, Kremmling CO 80459; email *sodell@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 Ms. Odell during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question for Ms. Odell. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The approved RMP provides management for approximately 377,900 BLM-administered surface acres and 653,500 acres of mineral estate in northwest Colorado. It describes the actions needed to meet the desired resource conditions for upland and riparian vegetation, fish and wildlife habitats, water resources, air quality, cultural, paleontological and visual resources as well as livestock grazing, minerals, energy development, and recreation. While the approved RMP also proposes some conservation management for Greater Sage-Grouse habitat, the Northwest Colorado BLM Greater Sage-Grouse Plan Amendment and Environmental Impact Statement (EIS) will fully analyze applicable Greater Sage-Grouse conservation measures. The BLM expects to make a comprehensive set of decisions for managing Greater Sage-Grouse on land administered by the Kremmling Field Office in the Record of Decision for the Northwest Colorado BLM Greater Sage-Grouse Plan Amendment and EIS, which when final will amend this RMP.

The BLM initiated scoping for the RMP in 2007, and collected information and public input via public meetings and interviews in order to develop the draft RMP/EIS in September 2011. Based on public comments, the BLM made edits and carried forward the preferred alternative into the proposed RMP/final EIS with some modifications. The Environmental Protection Agency and the BLM published their respective Notices of Availability of the proposed RMP/final EIS in the **Federal Register** on March 21, 2014 (79 FR 15741 and 15772), initiating the protest period. During the protest period for the proposed RMP, the BLM received five valid protest submissions. All protests were dismissed; however, the BLM made minor editorial modifications to the approved RMP to provide further clarification of some of the decisions. There was also a 60-day Governor's consistency review period for the proposed RMP; no inconsistencies were identified during the review.

The decisions designating routes of travel for motorized vehicles are implementation decisions and are appealable under 43 CFR part 4. These decisions are contained in Appendix A of the approved RMP. These route designations will be evaluated for consistency with the Northwest Colorado BLM Greater Sage-Grouse Plan Amendment and EIS, when final; and if needed, additional NEPA will occur, with public involvement, to address any inconsistencies. Any party adversely affected by the proposed route designations may appeal within 30 days of publication of this Notice of Availability pursuant to 43 CFR part 4, subpart E. The appeal should state the specific route(s), as identified in Appendix A of the approved RMP, on which the decision is being appealed. The appeal must be filed with the Kremmling Field Manager at the above listed address. Please consult the appropriate regulations (43 CFR part 4, subpart E) for further appeal requirements.

Authority: 40 CFR 1506.6.

Ruth Welch,

BLM Colorado State Director.

[FR Doc. 2015–16432 Filed 7–7–15; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2015–0010; OMB Control Number 1014–0017; 15XE1700DX EEEE500000 EX1SF0000.DAQ000]

Information Collection Activities: Safety and Environmental Management Systems (SEMS); Proposed Collection; Comment Request

ACTION: 60-day notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), BSEE is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval.

The information collection request (ICR) concerns a renewal to the paperwork requirements in the regulations under Subpart S, *Safety and Environmental Management Systems (SEMS).*

DATES: You must submit comments by September 8, 2015.

ADDRESSES: You may submit comments by either of the following methods listed below.

- Electronically go to *http://www.regulations.gov.* In the Search box, enter BSEE–2015–0010 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- Email *cheryl.blundon@bsee.gov.* Mail or hand-carry comments to the Department of the Interior; Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch; ATTN: Cheryl Blundon; 45600 Woodland Road, Sterling, VA 20166. Please reference ICR 1014–0017 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Cheryl Blundon, Regulations and Standards Branch at (703) 787–1607 to request additional information about this ICR.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR part 250, subpart S, *Safety and Environmental management Systems (SEMS).*

Form(s): BSEE–0131.

OMB Control Number: 1014–0017.

Abstract: The Outer Continental Shelf (OCS) Lands Act at 43 U.S.C. 1334 authorizes the Secretary of the Interior (Secretary) to prescribe rules and regulations necessary for the administration of the leasing provisions of that Act related to mineral resources on the OCS. Such rules and regulations will apply to all operations conducted under a lease. Operations on the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition. These responsibilities are among those delegated to the Bureau of Safety and Environmental Enforcement (BSEE).

In addition to the general rulemaking authority of the OCSLA at 43 U.S.C. 1334, section 301(a) of the Federal Oil and Gas Royalty Management Act (FOGRMA), 30 U.S.C. 1751(a), grants authority to the Secretary to prescribe such rules and regulations as are reasonably necessary to carry out FOGRMA's provisions. While the majority of FOGRMA is directed to royalty collection and enforcement, some provisions apply to offshore operations. For example, section 108 of FOGRMA, 30 U.S.C. 1718, grants the Secretary broad authority to inspect lease sites for the purpose of determining whether there is compliance with the mineral leasing laws. Section 109(c)(2) and (d)(1), 30 U.S.C. 1719(c)(2) and (d)(1), impose substantial civil penalties for failure to permit lawful inspections and for knowing or willful preparation or submission of false, inaccurate, or misleading reports, records, or other information. Because the Secretary has delegated some of the authority under FOGRMA to BSEE, 30 U.S.C. 1751 is included as additional authority for these requirements.

Regulations governing Safety and Environmental Management Systems (SEMS) are covered in 30 CFR 250, Subpart S and are the subject of this collection. This request also covers any related Notices to Lessees and Operators (NTLs) that BSEE issues to clarify, supplement, or provide additional guidance on some aspects of our regulations.

We consider the information to be critical for us to monitor industry's operations record of safety and environmental management of the OCS. The Subpart S regulations hold the operator accountable for the overall safety of the offshore facility, including ensuring that all employees, contractors, and subcontractors have safety policies and procedures in place that support the implementation of the operator's SEMS program and align with the principles of managing safety. The SEMS program describes management commitment to safety and the environment, as well as policies and procedures to assure safety and environmental protection while conducting OCS operations (including those operations conducted by all personnel on the facility). BSEE will use the information obtained by submittals and observed via SEMS audits to ensure that operations on the OCS are conducted safely, as they pertain to both human and environmental factors, and in accordance with BSEE regulations, as well as industry practices. The UWA and other recordkeeping will be reviewed diligently by BSEE during inspections/audits, etc., to ensure that industry is correctly implementing the documentation and that the requirements are being followed properly.

Information on Form BSEE–0131 includes company identification, number of company/contractor injuries and/or illnesses suffered, company/contractor hours worked, EPA National Pollutant Discharge Elimination System (NPDES) permit noncompliances, and oil spill volumes for spills less than 1 barrel. All pieces of information are reported annually as collected during 1 calendar year and the information broken out quarterly. The information is used to develop industry average incident rates that help to describe how well the offshore oil and gas industry is performing. Using the produced data allows BSEE to better focus our regulatory and research programs on areas where the performance measures indicate that operators are having difficulty meeting our expectations. BSEE will be more effective in leveraging resources by redirecting research efforts, promoting appropriate regulatory initiatives, and shifting inspection program emphasis based on performance results.

However, this ICR has removed form BSEE–0130. BSEE has found that there have been no instances of organizations using form BSEE–0130 and that equivalent information can be submitted by organizations following the instructions in § 250.1922(a)(1), ''. . . submit documentation to BSEE describing the process for assessing an ASP for accreditation and approving, maintaining, and withdrawing the accreditation of an ASP.'' BSEE's Office of Offshore Regulatory Programs will then review the information, request other supporting documents as needed, and propose terms of BSEE oversight, in order to ensure conformance with the entirety of § 250.1922. Therefore, BSEE believes the intent of the form BSEE–0130 is already incorporated in the regulations and will remove the duplicate information collection burden represented by form BSEE–0130.

No questions of a sensitive nature are asked. We protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and DOI's implementing regulations (43 CFR 2); 30 CFR 250.197, *Data and information to be made available to the public or for limited inspection*; and 30 CFR part 252, *OCS Oil and Gas Information Program.* Responses are mandatory.

Frequency: Varies by section but is primarily on occasion.

Description of Respondents: Potential respondents comprise Federal oil, gas, or sulphur lessees and/or operators.

Estimated Reporting and Recordkeeping Hour Burden: The currently approved annual reporting

burden for this collection is 651,728 hours and $9,444,000 non-hour cost burdens. In this submission, we are requesting a total of 2,238,164 burden hours and $5,220,000 non-hour cost burdens. The following chart details the individual components and respective hour burden estimates of this ICR. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

Citation 30 CFR 250 subpart S	Reporting and recordkeeping requirement +	Hour burden	Average number of annual responses	Additional annual burden hours (rounded)
1900–1933	High Activity Operator: Have a SEMS program, and maintain all documentation and records pertaining to your SEMS program, according to API RP 75, ISO 17011 in their entirety, the COS–2–01, 03, and 04 documents as listed in § 250.198, and all the requirements as detailed in 30 CFR 250, Subpart S. Make your SEMS available to BSEE upon request.	27,054	15 operators	405,810.
1900–1933	Moderate Activity Operator: Have a SEMS program, and maintain all documentation and records pertaining to your SEMS program, according to API RP 75, the three COS documents in their entirety, and all the requirements as detailed in 30 CFR 250, Subpart S. Make your SEMS available to BSEE upon request.	11,625	40 operators	465,000.
1900–1933	Low Activity Operator: Have a SEMS program, and maintain all documentation and records pertaining to your SEMS program, according to API RP 75, the three COS documents in their entirety, and all the requirements as detailed in 30 CFR 250, Subpart S. Make your SEMS available to BSEE upon request.	1,525	75 operators	114,375.
1911(b)	Immediate supervisor must conduct a JSA, sign the JSA, and ensure all personnel participating sign the JSA. The individual designated as being in charge of facility approves and signs all JSAs before job starts. NOTE: If activity is repeated, the 1st signed JSA is allowed.	15 mins.	130 operators × 365 days × 50 JSA's per day = 2,372,500 *.	593,125.
1914(e); 1928(d), (e); 1929.	Submit Form BSEE–0131. Maintain a contractor employee injury/illness log in the operation area, retain for 2 years, and make available to BSEE upon request (this requirement is included in the form burden). Inform contractors of hazards.	15	130 operators	1,950.
1920(a), (b); 1921	ASP audit for High Activity Operator	15 operators × $217,000 audit = $3,255,000/3 = $1,085,000.		
	ASP audit for Moderate Activity Operator	40 operators × $108,000 audit = $4,320,000/3 = $1,440,000.		
	ASP audit for Low Activity Operator	75 operators × $62,000 audit = $4,650,000/3 = $1,550,000.		
	NOTE: An audit is done once every 3 years.			
1920(b)	Notify BSEE with audit plan/schedule 30 days prior to conducting your audit.	1	130 operators/once every 3 years = 44.	44 (rounded).
1920(c); 1925(a);	Submit to BSEE after completed audit, an audit report of findings and conclusions, including deficiencies and required supporting information/documentation.	4	44 operators	176.
1920(d); 1925(b);	Submit/resubmit a copy of your CAP that will address deficiencies identified in audit within 60 days of audit completion.	10	170 submissions	1,700.
1922(a)	Organization requests approval for AB; submits documentation for assessing, approving, maintaining, and withdrawing accreditation of ASP.	15	3 requests	45.
1922(b)	Make available to BSEE upon request, conflict of interest procedures.	20 mins.	12 requests	4.
1924(b)	Make available to BSEE upon request, evaluation documentation and supporting information relating to your SEMS.	5	130 operators	650.
1924(c)	Explain and demonstrate your SEMS during site visit if required; provide evidence supporting your SEMS implementation.	12	12 explanations	144.

Citation 30 CFR 250 subpart S	Reporting and recordkeeping requirement +	Hour burden	Average number of annual responses	Additional annual burden hours (rounded)
1925(a);	Pay for all costs associated with BSEE directed ASP audit approximately 10 percent per operator per category: 1 required audit for high operator ($217,000 per audit × 1 audit = $217,000); 4 required audits for moderate operator ($108,000 per audit × 4 audits = $432,000; and 8 required audits for low operator ($62,000 per audit per 8 audits = $496,000) = 13 required audits per year.	13 BSEE directed ASP audits—for a total of $1,145,000.		
1928	(1) Document and keep all SEMS audits for 6 years (at least two full audit cycles) at an onshore location.	6	130 operators	780.
	(2) JSAs must have documented results in writing and kept onsite for 30 days or until release of the MODU; retain records for 2 years. (3) All MOC records (API RP Sec 4) must be documented, dated, and retained for 2 years. (4) SWA documentation must be kept onsite for 30 days; retain records for 2 years. (5) Documentation of employee participation must be retained for 2 years.	62 hrs/mo × 12 mos/yr = 744 hrs	838 manned facilities.	623.472.
	(6) All documentation included in this requirement must be made available to BSEE upon request.	2	1,620 unmanned facilities.	3,240.
1930(c)	Document decision to resume SWA activities	8	130 operators once every 2 wks = 130 × 52/2 = 3,380.	27,040.
1933(a)	Personnel reports unsafe practices and/or health violations	Burden covered under 30 CFR 250, Subpart A 1014–0022		0.
1933(c)	Post notice where personnel can view their rights for reporting unsafe practices.	15 mins.	2,435 facilities	609 (rounded).
Total Subpart S			2,381,721 Responses.	2,238,164 Hours.
			$5,220,000 Non-Hour Cost Burdens	

* We calculated operators conducting 50 JSAs a day (25 JSAs for each 12 hour shift). Some contractors may perform none for a particular day, whereas others may conduct more than 50 per day. This estimate is an average. Also, in Alaska, the Alaska Safety Handbook or ASH is followed on the North Slope, which is a book containing both safety standards and the permit to work process for North Slope operations. The ASH includes work permits which include a hazards analysis and mitigation measures section on the back of the permit.

+ In the future, BSEE may require electronic filing of some submissions.

Estimated Reporting and Recordkeeping Non-Hour Cost Burden

We have identified four non-hour cost burdens:

§ 250.1925(a)—Pay for all costs associated with a BSEE directed audit due to deficiencies.

§ 250.1920(a)—ASP audits for High, Moderate, and Low Activity Operator.

We estimate a total reporting non-hour cost burden to industry of $5,220,000 for this collection of information. We have not identified any other non-hour cost burdens associated with this collection of information.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency ''. . . to provide notice . . . and otherwise consult with members of the public and affected agencies concerning each proposed collection of information . . .''. Agencies must specifically solicit comments to: (a) Evaluate whether the collection is necessary or useful; (b) evaluate the accuracy of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of technology.

Agencies must also estimate the non-hour paperwork cost burdens to respondents or recordkeepers resulting from the collection of information. Therefore, if you have other than hour burden costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. For further information on this burden, refer to 5 CFR 1320.3(b)(1) and (2), or contact the Bureau representative listed previously in this notice.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make any necessary adjustments to the burden in our submission to OMB.

Public Comment Procedures: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: July 1, 2015.

Robert W. Middleton,

Deputy Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2015–16675 Filed 7–7–15; 8:45 am]

BILLING CODE 4310–VH–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–418P]

Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to adjust the 2015 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13(c) and 1315.13(d). Electronic comments must be submitted, and written comments must be postmarked, on or before August 7, 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.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–418P'' on all correspondence, including any attachments. 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 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 that duplicate electronic submissions 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, Attention: DEA **Federal Register** Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record and will be made available 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 posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all 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 the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made available in the public docket. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority and Background

Section 306 of the Controlled Substances Act (CSA), 21 U.S.C. 826, requires the Attorney General to determine the total quantity and establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA. 28 CFR 0.100(b).

The DEA established the 2015 aggregate production quotas for substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on September 8, 2014 (79 FR 53216). That notice stipulated that, in accordance with 21 CFR 1303.13 and 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

Analysis for Proposed Adjusted 2015 Aggregate Production Quotas and Assessment of Annual Needs

The DEA proposes to adjust the established 2015 aggregate production quotas for certain schedule I and II controlled substances to be manufactured in the United States in 2015 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes. The DEA is not proposing to adjust the established 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in and imported into the United States in 2015 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks.

In proposing the adjustment, the DEA has taken into account the criteria that the DEA is required to consider in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The DEA determines whether to propose an adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances and assessment of annual needs for ephedrine, pseudoephedrine,

and phenylpropanolamine by considering: (1) Changes in the demand for that class or chemical, changes in the national rate of net disposal of the class or chemical, and changes in the rate of net disposal of the class or chemical by registrants holding individual manufacturing quotas for the class; (2) whether any increased demand for that class or chemical, the national and/or individual rates of net disposal of that class or chemical are temporary, short term, or long term; (3) whether any increased demand for that class or chemical can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota; (4) whether any decreased demand for that class or chemical will result in excessive inventory accumulation by all persons registered to handle that class or chemical; and (5) other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Acting Administrator finds relevant.

The DEA also considered updated information obtained from 2014 year-end inventories, 2014 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to the DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors the DEA considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed adjusted 2015 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 established assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

As previously described in the published notice establishing the 2015 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers, 21 CFR 1303.24, may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA has included in all proposed adjusted schedule II controlled substance aggregate production quotas, and certain proposed adjusted schedule I controlled substance aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting adjusted established aggregate production quotas will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

The Acting Administrator, therefore, proposes to adjust the 2015 aggregate production quotas for certain schedule I and II controlled substances expressed in grams of anhydrous acid or base, as follows:

Basic class	Established 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
Schedule I		
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR–144)	15	25
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15	25
[1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ–2201)	15	no change
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15	25
1-(1-Phenylcyclohexyl)pyrrolidine	10	no change
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45	no change
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45	no change
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	no change
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200)	45	no change
1-Butyl-3-(1-naphthoyl)indole (JWH–073)	45	no change
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45	no change
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45	no change
1-Methyl-4-phenyl-4-propionoxypiperidine	2	no change
1-Pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678)	45	no change
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45	no change
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45	no change
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45	no change
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45	no change
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45	no change
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45	no change
2-(2,5-Dimethoxy-4-*n*-propylphenyl)ethanamine (2C–P)	30	no change
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30	no change
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30	no change
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	30	no change
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	30	no change
2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B–NBOMe; 2C–B–NBOMe; 25B; Cimbi-36).	15	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	30	no change

Basic class	Established 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C–NBOMe; 2C–C–NBOMe; 25C; Cimbi-82).	15	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	30	no change
2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I–NBOMe; 2C–I–NBOMe; 25I; Cimbi-5).	15	no change
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	15	no change
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25	no change
2,5-Dimethoxy-4-*n*-propylthiophenethylamine	25	no change
2,5-Dimethoxyamphetamine	25	no change
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	30	no change
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	30	no change
3,4,5-Trimethoxyamphetamine	25	no change
3,4-Methylenedioxyamphetamine (MDA)	55	no change
3,4-Methylenedioxymethamphetamine (MDMA)	50	no change
3,4-Methylenedioxy-*N*-ethylamphetamine (MDEA)	40	no change
3,4-Methylenedioxy-*N*-methylcathinone (methylone)	50	no change
3,4-Methylenedioxypyrovalerone (MDPV)	35	no change
3-Fluoro-*N*-methylcathinone (3–FMC)	15	25
3-Methylfentanyl	2	no change
3-Methylthiofentanyl	2	no change
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25	no change
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	25	no change
4-Fluoro-*N*-methylcathinone (4–FMC)	15	25
4-Methoxyamphetamine	100	no change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change
4-Methylaminorex	25	no change
4-Methyl-*N*-ethylcathinone (4–MEC)	15	25
4-Methyl-*N*-methylcathinone (mephedrone)	45	no change
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15	25
5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol	68	no change
5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog).	53	no change
5-Methoxy-3,4-methylenedioxyamphetamine	25	no change
5-Methoxy-*N,N*-diisopropyltryptamine	25	no change
5-Methoxy-*N,N*-dimethyltryptamine	25	no change
Acetyl-*alpha*-methylfentanyl	2	no change
Acetyldihydrocodeine	2	no change
Acetylmethadol	2	no change
Allylprodine	2	no change
Alphacetylmethadol	2	no change
alpha-Ethyltryptamine	25	no change
Alphameprodine	2	no change
Alphamethadol	2	no change
alpha-Methylfentanyl	2	no change
alpha-Methylthiofentanyl	2	no change
alpha-Methyltryptamine (AMT)	25	no change
alpha-Pyrrolidinobutiophenone (α-PBP)	15	25
alpha-Pyrrolidinopentiophenone (α-PVP)	15	25
Aminorex	25	no change
Benzylmorphine	2	no change
Betacetylmethadol	2	no change
beta-Hydroxy-3-methylfentanyl	2	no change
beta-Hydroxyfentanyl	2	no change
Betameprodine	2	no change
Betamethadol	4	no change
Betaprodine	2	no change
Bufotenine	3	no change
Cathinone	70	no change
Codeine methylbromide	5	no change
Codeine-*N*-oxide	305	no change
Desomorphine	5	25
Diethyltryptamine	25	no change
Difenoxin	11,000	no change
Dihydromorphine	3,990,000	no change
Dimethyltryptamine	35	no change
Dipipanone	5	no change
Fenethylline	5	no change
gamma-Hydroxybutyric acid	70,250,000	no change
Heroin	25	50
Hydromorphinol	2	no change

Basic class	Established 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
Hydroxypethidine	2	no change
Ibogaine	5	no change
Lysergic acid diethylamide (LSD)	35	no change
Marihuana	658,000	no change
Mescaline	25	no change
Methaqualone	10	no change
Methcathinone	25	no change
Methyldesorphine	5	no change
Methyldihydromorphine	2	no change
Morphine methylbromide	5	no change
Morphine methylsulfonate	5	no change
Morphine-*N*-oxide	350	no change
N-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	15	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB–PINACA)	15	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB–FUBINACA).	15	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB–CHMINACA).	15	no change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB–PINACA)	15	no change
N,N-Dimethylamphetamine	25	no change
Naphthylpyrovalerone (naphyrone)	15	25
N-Benzylpiperazine	25	no change
N-Ethyl-1-phenylcyclohexylamine	5	no change
N-Ethylamphetamine	24	no change
N-Hydroxy-3,4-methylenedioxyamphetamine	24	no change
Noracymethadol	2	no change
Norlevorphanol	52	no change
Normethadone	2	no change
Normorphine	18	40
Para-fluorofentanyl	zero	5
Parahexyl	zero	5
Phenomorphan	2	no change
Pholcodine	zero	5
Psilocybin	30	no change
Psilocyn	30	no change
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB–22; 5F–PB–22)	15	25
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB–22; QUPIC)	15	25
Tetrahydrocannabinols	497,500	511,250
Thiofentanyl	2	no change
Tilidine	10	25
Trimeperidine	2	no change
Schedule II		
1-Phenylcyclohexylamine	5	no change
1-Piperidinocyclohexanecarbonitrile	5	no change
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,687,500	no change
Alfentanil	17,750	no change
Alphaprodine	3	no change
Amobarbital	25,125	no change
Amphetamine (for conversion)	21,875,000	no change
Amphetamine (for sale)	37,500,000	no change
Carfentanil	19	no change
Cocaine	275,000	no change
Codeine (for conversion)	50,000,000	no change
Codeine (for sale)	49,500,000	63,900,000
Dextropropoxyphene	19	45
Dihydrocodeine	226,375	no change
Diphenoxylate (for conversion)	75,000	no change
Diphenoxylate (for sale)	1,337,500	no change
Ecgonine	174,375	no change
Ethylmorphine	3	no change
Fentanyl	2,150,000	2,300,000
Glutethimide	3	no change
Hydrocodone (for conversion)	137,500	no change
Hydrocodone (for sale)	99,625,000	no change
Hydromorphone	7,000,000	no change
Isomethadone	5	no change
Levo-alphacetylmethadol (LAAM)	4	no change
Levomethorphan	5	30
Levorphanol	7,125	no change

Basic class	Established 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
Lisdexamfetamine	29,750,000	no change
Meperidine	6,250,000	no change
Meperidine Intermediate-A	6	no change
Meperidine Intermediate-B	11	32
Meperidine Intermediate-C	6	no change
Metazocine	19	no change
Methadone (for sale)	31,875,000	no change
Methadone Intermediate	34,375,000	no change
Methamphetamine	2,061,375	no change
[1,250,000 grams of *levo*-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]		
Methylphenidate	83,750,000	87,500,000
Morphine (for conversion)	91,250,000	no change
Morphine (for sale)	62,500,000	no change
Nabilone	18,750	no change
Noroxymorphone (for conversion)	17,500,000	no change
Noroxymorphone (for sale)	1,475,000	no change
Opium (powder)	112,500	no change
Opium (tincture)	687,500	no change
Oripavine	35,000,000	no change
Oxycodone (for conversion)	8,350,000	no change
Oxycodone (for sale)	137,500,000	139,150,000
Oxymorphone (for conversion)	29,000,000	no change
Oxymorphone (for sale)	7,750,000	no change
Pentobarbital	35,000,000	no change
Phenazocine	6	no change
Phencyclidine	19	38
Phenmetrazine	3	no change
Phenylacetone	9,375,000	no change
Racemethorphan	3	no change
Remifentanil	3,750	4,200
Secobarbital	215,003	no change
Sufentanil	6,255	no change
Tapentadol	12,500,000	no change
Thebaine	125,000,000	no change
List I Chemicals		
Ephedrine (for conversion)	1,000,000	no change
Ephedrine (for sale)	4,000,000	no change
Phenylpropanolamine (for conversion)	44,800,000	no change
Phenylpropanolamine (for sale)	8,500,000	no change
Pseudoephedrine (for conversion)	7,000	no change
Pseudoephedrine (for sale)	224,500,000	no change

The Acting Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Acting Administrator may further adjust the 2015 aggregate production quotas and assessment of annual needs as needed.

Comments

In accordance with 21 CFR 1303.13(c) and 1315.13(d), any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this notice, the Acting Administrator may hold a public hearing on one or more issues raised. 21 CFR 1303.13(c) and 1315.13(e). In the event the Acting Administrator decides to hold such a hearing, the Acting Administrator will publish a notice of the hearing in the **Federal Register**. After consideration of any comments or objections, or after a hearing, if one is held, the Acting Administrator will issue and publish in the **Federal Register** a final order establishing any adjustment of the 2015 aggregate production quota for each basic class of controlled substance and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. 21 CFR 1303.13(c) and 1315.13(f).

Dated: July 1, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015–16699 Filed 7–7–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Employment and Training Administration

Comment Request for Information Collection for the Evaluation of the Young Parents Demonstration Program, Reinstatement With Change

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 [44 U.S.C. 3506 (c) (A)] (PRA). The PRA helps ensure that respondents can provide requested data in the desired format with minimal reporting burden (time and financial resources), collection instruments are clearly understood and the impact of collection requirements on respondents can be properly assessed.

Currently, ETA is soliciting comments concerning the information collection request (ICR) to collect data for the Evaluation of the Young Parents Demonstration Program (YPDP).[1]

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for Office of Management and Budget (OMB) approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB 1205–0494.

DATES: Submit written comments to the office listed in the addresses section below on or before September 8, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free by contacting Michelle Ennis, Office of Policy Development and Research, Employment and Training Administration, U.S. Department of Labor, Room N–5641, 200 Constitution Avenue NW., Washington, DC 20210, Phone: 202–693–3636 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD). Fax: 202–693–2766. Email: *ennis.michelle@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michelle Ennis, 202–693–3636, or *ennis.michelle@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The proposed reinstatement with change of information collection is for an evaluation of the YPDP. The YPDP is sponsored by ETA to test innovative strategies that can improve the skills and education of young parents and, ultimately their employment and earnings.

The YPDP grantees are required to develop a ''bump-up'' intervention providing an additional level of services above and beyond the existing services currently provided that are specifically intended to increase an individual's education, job training and employment. A key factor in the bump-up design is having a single, persistent intervention for the treatment group that is substantially different from what the control group receives. Each of the grantees is implementing one of the following two bump-up interventions:

- *Mentoring Models*—Intensive professional staff mentoring specifically for education, employment, and training; and specifically for pregnant and parenting teens and young parents; or
- *Employment/Education/Training Models*—Guided employment, education, training and related supports specifically for pregnant and parenting teens and young parents.

Individuals enrolling in YPDP have a 50/50 chance of receiving this additional level of services. Those individuals not receiving the bump-up services receive the existing services offered by the grantee.

To evaluate the YPDP bump-up interventions, we will compare the education, employment, and other outcomes for the two groups over various points in time. The evaluation will estimate the success in providing educational and occupational skills training that fosters family economic self-sufficiency to young parents (both mothers and fathers) and expectant parents ages 16–24.

II. Review Focus

The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions

- *Agency:* DOL–ETA.
- *Type of Review:* Reinstatement with change.
- *Title of Collection:* Evaluation of the Young Parents Demonstration Program.
- *OMB Control Number:* 1205–0494.
- *Affected Public:* Individuals (Young Parents) and community-based organizations.
- *Estimated Number of Respondents:* 2,971.
- *Frequency:* Six (6) Participant Tracking System entries, two (2) site visit interviews, and one (1) survey response.
- *Total Estimated Annual Responses:* 11,168.
- *Estimated Average Time per Response:* 11.4 minutes or 0.19 hours.
- *Estimated Total Annual Burden Hours:* 2,119 hours.
- *Total Estimated Annual Other Cost Burden:* $44,276.

[1] U.S. Department of Labor, Employment and Training Administration. 2008. ''Young Parents Demonstration Program (YPDP) SGA/DFA PY 08–08,'' **Federal Register**, Vol. 73, No. 193, October 3, 2008 (available over the Internet at: *http://edocket.access.gpo.gov/2008/pdf/E8–23319.pdf*).

Type of respondent	Data collection activity	Number of respondents	Number of responses per respondent (frequency)	Total number of responses	Response time per response (in hours)	Total annual burden (in hours)	Average hourly wage (Jan 2015) *	Total annualized cost
Study Participant ...	Participant Tracking System—Data Collection.	1,633	6	9,798	0.167	1,636	$20.81	$34,051
Program Staff	Site Visit Interviews.	32	2	64	0.750	48	$24.48	$1,175
Study Participant ...	18-Month Follow-Up Survey.	1,306	1	1,306	0.333	435	$20.81	$9,050
Total	.....	2,971	.....	11,168	.....	2,119	.....	$44,276

* For the wage rate used for the ''study participant,'' see U.S. Department of Labor, Bureau of Labor Statistics, Table B–8. Average hourly and weekly earnings of production and nonsupervisory employees on private nonfarm payrolls by industry sector, seasonally adjusted (accessed from the following website as of January 2015: *http://www.bls.gov/news.release/empsit.t24.htm*). For the wage rate for ''program staff,'' see U.S. Department of Labor, Bureau of Labor Statistics, Table B–3. Average hourly and weekly earnings of all employees on private nonfarm payrolls by industry sector, seasonally adjusted (accessed from the following website as of January 2015: *http://www.bls.gov/news.release/empsit.t19.htm*).

We will summarize and/or include the comments received in response to this request for comments in our request for OMB approval of the ICR. They will also become a matter of public record.

Portia Wu,

Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2015–16717 Filed 7–7–15; 8:45 am]

BILLING CODE 4510–FT–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (15–051)]

Notice of Intent To Grant Exclusive License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of intent to grant exclusive license.

SUMMARY: This notice is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). NASA hereby gives notice of its intent to grant a partially exclusive license in the United States to practice the inventions described and claimed in USPN 8,255,079, Human Grasp Assist Device and Method of Use, NASA Case No. MSC–24741–1; USSN 13/408,675, Control of a Glove-Based Grasp Assist Device, NASA Case No. 25320–1; USSN 13/408,668, Human Grasp Assist Device Soft Good, NASA Case No. MSC–25318–1; Japanese Patent Application No. 2014–064953, Human Grasp Assist Soft, NASA Case No. MSC–25318–2; USPN 8,849,453, Human Grasp Assist Device with Exoskeleton, NASA Case No. 25319–1 and USSN 14/175,094, Grasp Assist Device with Shared Tendon Actuator Assembly, NASA Case No. MSC–25783–1 to CSSDP Investments, Inc., having its principal place of business in Newport Coast, California. The fields of use may be limited to assistive wearable devices for humans. The patent rights in these inventions have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective partially exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

DATES: The prospective partially exclusive license may be granted unless within fifteen (15) days from the date of this published notice, NASA receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7. Competing applications completed and received by NASA within fifteen (15) days of the date of this published notice will also be treated as objections to the grant of the contemplated exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

ADDRESSES: Objections relating to the prospective license may be submitted to Patent Counsel, Office of Chief Counsel, NASA Johnson Space Center, 2101 NASA Parkway, Mail Code AL, Houston, Texas 77058, Phone (281) 483–3021; Fax (281) 483–6936.

FOR FURTHER INFORMATION CONTACT: Ms. Michelle P. Lewis, Johnson Space Center, 2101 NASA Parkway, Technology Transfer and Commercialization Office, Mail Code AO52, Houston, TX 77058, (281) 483–8051. Information about other NASA inventions available for licensing can be found online at *http://technology.nasa.gov.*

Mark P. Dvorscak,

Agency Counsel for Intellectual Property.

[FR Doc. 2015–16641 Filed 7–7–15; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

[NRC–2013–0225]

Physical Security—Review of Physical Security System Designs—Standard Design Certification and Operating Reactor Licensing Applications

AGENCY: Nuclear Regulatory Commission.

ACTION: Standard review plan-final section revision; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a final revision to the following section of NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,'' Section 13.6.2, ''Physical Security—Review of Physical Security System Designs—Standard Design Certification and Operating Reactor Licensing Applications.''

DATES: The effective date of this Standard Review Plan (SRP) update is August 7, 2015.

ADDRESSES: Please refer to Docket ID NRC–2013–0225 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0225. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463;

email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *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*. The ADAMS accession number for each document referenced (if it available in ADAMS) is provided the first time that a document is referenced. The final revision for SRP Section 13.6.2, ''Physical Security—Review of Physical Security System Designs—Standard Design Certification and Operating Reactor Licensing Applications'' is available in ADAMS under Accession No. ML14140A210.

• *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.

• The NRC posts its issued staff guidance on the NRC's external Web page (*http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/*).

FOR FURTHER INFORMATION CONTACT: Mark Notich, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–6992, email: *Mark.Notich@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On September 30, 2013 (78 FR 59981), the NRC published for public comment draft Revision 2 of SRP Section 13.6.2, ''Physical Security—Review of Physical Security System Designs—Standard Design Certification and Operating Reactor Licensing Applications.'' This section has been developed to assist the NRC staff with the review of the physical security system designs for design certification and operating reactor license applications and to inform applicants and other affected entities of guidance regarding an acceptable method by which to evaluate the affected portions of part 73 of Title 10 of the *Code of Federal Regulations* (10 CFR).

The NRC staff received comment submissions on the proposed revision. The NRC staff made several changes to the proposed revision after consideration of the comments. The comments are documented alongside the NRC staff's responses are available in ADAMS under Accession No. ML14140A207. A redline strikeout comparing the proposed draft and final revision can be found in ADAMS under Accession No. ML14140A208.

II. Backfitting and Issue Finality

Issuance of this final SRP section does not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and is not otherwise inconsistent with the issue finality provisions in 10 CFR part 52. The NRC staff's position is based upon the following considerations:

1. *The SRP positions do not constitute backfitting, inasmuch as the SRP is internal guidance directed at the NRC staff with respect to their regulatory responsibilities*.

The SRP provides guidance to the staff on how to review an application for NRC regulatory approval in the form of licensing. Changes in internal staff guidance are not matters for which either nuclear power plant applicants or licensees are protected under either the Backfit Rule or the issue finality provisions of 10 CFR part 52.

2. *Backfitting and issue finality—with certain exceptions discussed below—do not protect current or future applicants*.

Applicants and potential applicants are not, with certain exceptions, protected by either the Backfit Rule or any issue finality provisions under 10 CFR part 52. This is because neither the Backfit Rule nor the issue finality provisions were intended to apply to every NRC action which substantially changes the expectations of current and future applicants.

The exceptions to the general principle are applicable whenever an applicant references a 10 CFR part 52 license (*e.g.,* an early site permit) and/or NRC regulatory approval (*e.g.,* a design certification rule) with specified issue finality provisions. The staff does not currently intend to impose the positions represented in this SRP section in a manner that is inconsistent with any issue finality provisions of 10 CFR part 52. If in the future the NRC staff does indeed intend to impose positions inconsistent with these issue finality provisions, the NRC staff must address the regulatory criteria for avoiding issue finality.

3. *The NRC staff has no intention to impose the SRP positions on existing nuclear power plant licenses or regulatory approvals either now or in the future (absent a voluntary request for change from the licensee, holder of a regulatory approval, or a design certification applicant).*

The staff does not intend to impose or apply the positions described in the SRP section to existing (already issued) licenses (*e.g.,* operating licenses and combined licenses) and regulatory approvals—in this case, design certifications. Hence, the issuance of this SRP guidance even if considered guidance which is within the purview of the issue finality provisions in 10 CFR part 52—need not be evaluated as if it were a backfit or as being inconsistent with issue finality provisions. If, in the future, the staff seeks to impose a position in the SRP on holders of already issued licenses in a manner which does not provide issue finality as described in the applicable issue finality provision, then the staff must make the showing as set forth in the Backfit Rule, or address the criteria for avoiding issue finality as described applicable issue finality provision, as applicable.

III. Congressional Review Act

This action is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

Dated at Rockville, Maryland, this 29th day of June, 2015.

For the Nuclear Regulatory Commission.

Lawrence Burkhart,

Acting Chief, New Reactor Rulemaking and Guidance Branch, Division of Advanced Reactors and Rulemaking, Office of New Reactors.

[FR Doc. 2015–16741 Filed 7–7–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2013–0124]

Strategies and Guidance To Address Loss of Large Areas of the Plant Due to Explosions and Fires

AGENCY: Nuclear Regulatory Commission.

ACTION: Standard review plan-final section revision; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a final revision to the following section of NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition'': Section 19.4, ''Strategies and Guidance to Address Loss of Large Areas of the Plant due to Explosions and Fires.''

DATES: The effective date of this Standard Review Plan (SRP) update is August 7, 2015.

ADDRESSES: Please refer to Docket ID NRC–2013–0124 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0124. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The final revision for SRP Section 19.4, ''Strategies and Guidance to Address Loss of Large Areas of the Plant due to Explosions and Fires'' is available under ADAMS Accession No. ML13316B202.
- *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.
- The NRC posts its issued staff guidance on the NRC's external Web page (*http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/*).

FOR FURTHER INFORMATION CONTACT: Mark Notich, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555 0001; telephone: 301–415–3053, email: *Mark.Notich@nrc.gov* or Nishka Devaser, telephone: 301–415–5196, email: *Nishka.Devaser@nrc.gov* Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Background

On June 11, 2013 (78 FR 35072), the NRC published for public comment the initial issuance of SRP Section 19.4, ''Strategies and Guidance to Address Loss of Large Areas of the Plant Due to Explosions and Fires.'' This section has been developed to assist NRC staff with the review of applications for certain construction permits, operating licenses, license amendments, certain standard design certifications, and combined licenses under parts 50 and 52 of Title 10 of the *Code of Federal Regulations* (10 CFR). It also informs new reactor applicants and other affected entities of SRP guidance regarding an acceptable method by which staff performs its review of the subject of loss of large areas of the plant due to explosions and fires.

The NRC staff made several changes to the final revision of the subject guidance since issuance of the proposed revision. The staff clarified its expectations with Nuclear Energy Institute (NEI) 06–12, ''B.5.b Phase 2 & 3 Submittal Guideline,'' in the SRP Acceptance Criteria subsection of the guidance. Additionally, some content previously seen in the proposed revision under Appendix A, ''Experience Gained from Implementation of Temporary Instruction 2515/171, Verification of Site Specific Implementation of B.5.b Phase 2 & 3 Mitigating Strategies at Currently Licensed Power Reactor Sites and Related Staff Positions,'' was integrated into the Areas of Review and SRP Acceptance Criteria subsections. The remainder of the content from the proposed Appendix A was removed from the final guidance. Finally, the staff updated the SRP section's list of review interfaces to include additional interfacing SRP sections.

The NRC staff received comment submissions on the proposed revision. Public comments are documented alongside the NRC staff's respective response in ADAMS under Accession No. ML13295A535. A redline strikeout comparing the proposed draft and final revisions can be found in ADAMS under Accession No. ML13316B153.

Revision to this SRP section will supercede the staff guidance presented in Interim Staff Guidance DC/COL–ISG–016, ''Compliance with 10 CFR 50.54(hh)(2) and 10 CFR 52.80(d), Loss of Large Areas of the Plant due to Explosions or Fires from a Beyond-Design Basis Event.'' As a result, the NRC staff will be retiring DC/COL–ISG–016 in a subsequent **Federal Register** notice.

II. Backfitting and Issue Finality

Issuance of this final SRP section does not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and is not otherwise inconsistent with the issue finality provisions in 10 CFR part 52. The NRC staff's position is based upon the following considerations:

1. *The SRP positions do not constitute backfitting, inasmuch as the SRP is internal guidance directed at the NRC staff with respect to their regulatory responsibilities.*

The SRP provides guidance to the staff on how to review an application for NRC regulatory approval in the form of licensing. Changes in internal staff guidance are not matters for which either nuclear power plant applicants or licensees are protected under either the Backfit Rule or the issue finality provisions of 10 CFR part 52.

2. *Backfitting and issue finality—with certain exceptions discussed below—do not protect current or future applicants.*

Applicants and potential applicants are not, with certain exceptions, protected by either the Backfit Rule or any issue finality provisions under 10 CFR part 52. This is because neither the Backfit Rule nor the issue finality provisions were intended to apply to every NRC action that substantially changes the expectations of current and future applicants.

The exceptions to the general principle are applicable whenever an applicant references a 10 CFR part 52 license (*e.g.,* an early site permit) and/or NRC regulatory approval (*e.g.,* a design certification rule) with specified issue finality provisions. The staff does not currently intend to impose the positions represented in this SRP section in a manner that is inconsistent with any issue finality provisions of 10 CFR part 52. If in the future the NRC staff does indeed intend to impose positions inconsistent with these issue finality provisions, the NRC staff must address the regulatory criteria for avoiding issue finality.

3. *The NRC staff has no intention to impose the SRP positions on existing nuclear power plant licenses or regulatory approvals either now or in the future (absent a voluntary request for change from the licensee, holder of a regulatory approval, or a design certification applicant).*

The staff does not intend to impose or apply the positions described in the SRP section to existing (already issued) licenses (*e.g.,* operating licenses and combined licenses) and regulatory approvals—in this case, design certifications. Hence, the issuance of this SRP guidance—even if considered guidance that is within the purview of the issue finality provisions in 10 CFR part 52—need not be evaluated as if it were a backfit or as being inconsistent with issue finality provisions. If, in the future, the staff seeks to impose a position in the SRP on holders of already issued licenses in a manner that does not provide issue finality as described in the applicable issue finality provision, then the staff must make the

showing as set forth in the Backfit Rule, or address the criteria for avoiding issue finality as described applicable issue finality provision, as applicable.

III. Congressional Review Act

This action is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

Dated at Rockville, Maryland, this 25th day of June, 2015.

For the Nuclear Regulatory Commission.

Lawrence Burkhart,

Acting Chief, New Reactor Rulemaking and Guidance Branch, Division of Advanced Reactors and Rulemaking, Office of New Reactors.

[FR Doc. 2015–16736 Filed 7–7–15; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Civil Service Retirement System Board of Actuaries Meeting

AGENCY: Office of Personnel Management.

ACTION: Notice of meeting.

SUMMARY: The Civil Service Retirement System Board of Actuaries plans to meet on Friday, July 24, 2015. The meeting will start at 10:00 a.m. EDT and will be held at the U.S. Office of Personnel Management (OPM), 1900 E Street NW., Room 1350, Washington, DC 20415.

The purpose of the meeting is for the Board to review the actuarial methods and assumptions used in the valuations of the Civil Service Retirement and Disability Fund (CSRDF). The Board will also review OPM's computation of the supplemental liability of the CSRDF with respect to current and former employees of the Postal Service in the Federal Employees Retirement System (FERS).

Agenda

1. Summary of recent and proposed legislation;
2. Review of actuarial assumptions;
3. Reconsideration of the Postal Service supplemental liability under FERS. Persons desiring to attend this meeting of the Civil Service Retirement System Board of Actuaries, or to make a statement for consideration at the meeting, should contact OPM at least 5 business days in advance of the meeting date at the address shown below. The manner and time for any material presented to the Board may be limited.

FOR FURTHER INFORMATION CONTACT: Gregory Kissel, Senior Actuary for Retirement Programs, U.S. Office of Personnel Management, 1900 E Street NW., Room 4307, Washington, DC 20415. Phone (202) 606–0722 or email at *actuary@opm.gov.*

For the Board of Actuaries.

Katherine Archuleta,

Director.

[FR Doc. 2015–16692 Filed 7–7–15; 8:45 am]

BILLING CODE 6325–63–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review; Health Benefits Election Form, OPM 2809, 3206–0141

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day Notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revised information collection request (ICR) 3206–0141, Health Benefits Election Form. As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection.

DATES: Comments are encouraged and will be accepted until September 8, 2015. 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 Retirement Services, Operations Support, Office of Personnel Management, Room 2347–E, 1900 E Street NW., Washington, DC 20415, Attention: Alberta Butler, or sent via email to *Alberta.Butler@opm.gov.*

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW., Room 3316–AC, Washington, DC 20503, Attention: Cyrus S. Benson or sent via email to *Cyrus.Benson@opm.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget is particularly interested in comments that:

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.

OPM 2809, is used by annuitants and former spouses to elect, cancel, suspend, or change health benefits enrollment during periods other than open season.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Health Benefits Election Form.

OMB Number: 3206–0141.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 30,000.

Estimated Time per Respondent: 30 minutes.

Total Burden Hours: 11,667 hours.

U.S. Office of Personnel Management.

Katherine Archuleta,

Director.

[FR Doc. 2015–16694 Filed 7–7–15; 8:45 am]

BILLING CODE 6325–38–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2015–91; Order No. 2557]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an additional Foreign Postal Operators 1 negotiated service agreement with Hongkong Post. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 9, 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

On June 30, 2015, the Postal Service filed notice that it has entered into an additional Foreign Postal Operators 1 negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2015–91 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than July 9, 2015. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints James F. Callow to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2015–91 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, James F. Callow is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than July 9, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–16645 Filed 7–7–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of United States Postal Service of Filing Functionally Equivalent Inbound Competitive Multi-Service Agreement with a Foreign Postal Operator, June 30, 2015 (Notice).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75349; File No. SR–NASDAQ–2015–049]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Order Granting Approval of Proposed Rule Change, as Modified by Amendment Nos. 1 and 2 Thereto, Relating to the Listing and Trading of the Shares of the PowerShares DB Optimum Yield Diversified Commodity Strategy Portfolio, PowerShares Agriculture Commodity Strategy Portfolio, PowerShares Precious Metals Commodity Strategy Portfolio, PowerShares Energy Commodity Strategy Portfolio, PowerShares Base Metals Commodity Strategy Portfolio and PowerShares Bloomberg Commodity Strategy Portfolio, Each a Series of PowerShares Actively Managed Exchange-Traded Commodity Fund Trust

July 1, 2015.

I. Introduction

On April 30, 2015, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change relating to the listing and trading of shares (''Shares'') of the PowerShares DB Optimum Yield Diversified Commodity Strategy Portfolio, PowerShares Agriculture Commodity Strategy Portfolio, PowerShares Precious Metals Commodity Strategy Portfolio, PowerShares Energy Commodity Strategy Portfolio, PowerShares Base Metals Commodity Strategy Portfolio and PowerShares Bloomberg Commodity Strategy Portfolio (individually, ''Fund,'' and collectively, ''Funds''), each a series of the PowerShares Actively Managed Exchange-Traded Commodity Fund Trust (''Trust'') [3] under Nasdaq Rule 5735. The proposed rule change was published for comment in the **Federal Register** on May 21, 2015.[4] On June 30, 2015, the Exchange filed Amendment No. 1 to the proposed rule change, and on July 1, 2015, the Exchange filed Amendment No. 2 to the proposed rule change.[5] The Commission received no comments on the proposal. This order grants approval of the proposed rule change, as modified by Amendment Nos. 1 and 2 thereto.

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] According to the Exchange, the Trust is registered with the Commission as an investment company and has filed a registration statement on Form N–1A with the Commission. A description of each Fund's investment strategy is set forth in the Trust's registration statement (''Registration Statement''). *See* Pre-effective Amendment No. 1 to the Registration Statement for the Trust, dated May 20, 2014 (File Nos. 333–193135 and 811–22927).

[4] *See* Securities Exchange Act Release No. 74979 (May 15, 2015), 80 FR 29359 (''Notice'').

[5] In Amendment No. 1 to the proposed rule change, the Exchange: (a) Made a technical typographical correction to the citation in its filing referencing an exemptive order issued under the Investment Company Act of 1940 (''1940 Act''); and (b) clarified that only the Subsidiary (as defined herein) will hold Commodity-Linked Instruments (as defined herein) by removing the following statement in the filing: ''in addition, each Fund may hold instruments that its respective Subsidiary is entitled to hold, and vice versa, to the extent consistent with federal tax requirements.''. In Amendment No. 2 to the proposed rule change, the Exchange further clarified that (a) each Fund, through its respective Subsidiary (but not directly), will only invest in those commodity-linked notes, OTC Swaps, Forwards, or other over-the-counter instruments that are based on the price of relevant Commodities Futures, as applicable, and tend to exhibit trading prices or returns that correlate with any Commodities Futures and that will further the investment objective of such Fund (each ''OTC Swaps,'' ''Forwards,'' and ''Commodities Futures,'' as defined herein); and (b) each Subsidiary (not each Fund) will enter into swap agreements and other over-the-counter transactions only with large, established, and well capitalized financial institutions that meet certain credit quality standards and monitoring policies, and each Subsidiary (not each Fund) will use various techniques to minimize credit risk, including early termination, or reset and payment of such investments, the use of different counterparties, or limiting the net amount due from any individual counterparty. Because Amendment Nos. 1 and 2 to the proposed rule change seek to make certain clarifications and technical corrections, and do not materially affect the substance of the proposed rule change or raise unique or novel regulatory issues, Amendment Nos. 1 and 2 to the proposed rule change do not require notice and comment. The text of Amendment Nos. 1 and 2 is available at: *http://www.sec.gov/rules/sro/nasdaq.shtml.*

[6] *See* Securities Exchange Act Release Nos. 73078 (Sept. 11, 2014), 79 FR 55851 (Sept. 17, 2014) (SR–NASDAQ–2014–80) (''Prior Notice''); and 73471 (Oct. 30, 2014), 79 FR 65751 (Nov. 5, 2014) (SR–NASDAQ–2014–080) (''Prior Order,'' and, together with the Prior Notice, collectively, ''Prior Release'').

II. Description of the Proposed Rule Change

The Commission previously approved the listing and trading of the Shares on the Exchange under Nasdaq Rule 5735, which governs the listing and trading of Managed Fund Shares.[6] According to the Exchange, the Shares of the PowerShares DB Optimum Yield Diversified Commodity Strategy

Portfolio have commenced trading on the Exchange; the Shares of the other Funds have not. The Exchange proposes to permit the listing or continued listing, as the case may be, of the Shares based on certain proposed revisions to their investment strategies, as described in more detail below.[7]

A. Principal Investments

As stated in the Prior Release, each Fund's investment objective is to seek long-term capital appreciation. The Prior Release states that each Fund seeks to achieve its investment objective by investing, under normal circumstances,[8] in a combination of: (i) A wholly-owned subsidiary organized under the laws of the Cayman Islands (individually, ''Subsidiary,'' and collectively, ''Subsidiaries''); (ii) exchange-traded products or exchange-traded commodity pools; [9] and (iii) U.S. Treasury Securities, money market mutual funds, high quality commercial paper, and similar instruments (''Collateral Instruments'').[10]

The Prior Release also states that each Subsidiary will invest in exchange-traded futures contracts linked to commodities (''Commodities Futures'') to provide its parent Fund with additional indirect exposure to the commodities markets. Each Fund's investment in its Subsidiary is designed to help the Fund obtain exposure to Commodities Futures returns in a manner consistent with the federal tax requirements applicable to regulated investment companies, such as the Funds, which limit the ability of investment companies to invest directly in derivative instruments such as Commodities Futures.

In this proposed rule change, the Exchange seeks to make certain revisions to the investment strategy described in the Prior Release. Specifically, the proposal seeks to allow the Funds and the Subsidiaries, as applicable, to also invest in a variety of other securities and instruments beyond those set forth in the Prior Release, as follows:

- Each Fund, which already may invest in ETFs, ETNs, and Commodity Pools, seeks to also invest in: (i) Other investment companies,[11] to the extent permitted under the 1940 Act; [12] and (ii) exchange-traded commodity-linked equity securities [13] (''Equity Securities'') (collectively, ''Commodity-Related Assets'').
- each Subsidiary, which already may invest in Commodities Futures, now also seeks to invest in: (i) Exchange-traded futures contracts on commodity indices; (ii) commodity-linked notes; [14] (iii) ETNs; (iv) exchange-traded options on Commodities Futures (''Options''); [15] (v) centrally-cleared or over the counter (''OTC'') swaps on commodities (''Swaps''); and (vi) commodity-related forward contracts (''Forwards'') (collectively, ''Commodity-Linked Instruments''), which provide exposure to the investment returns of the commodities markets, without investing directly in physical commodities.

The Prior Release notes that all of the exchange-traded securities held by a Fund will be traded in a principal trading market that is a member of ISG or a market with which the Exchange has a comprehensive surveillance sharing agreement. The Funds propose to invest in Equity Securities, closed-end funds, ETFs, ETNs, Commodity Pools, and non-U.S. investment companies that are not traded in a principal trading market that is a member of ISG or a market with which the Exchange has a comprehensive surveillance sharing agreement; however, not more than 10% of each Fund's investments in these investments (in the aggregate) will be invested in instruments that trade in markets that are not members of the ISG or that are not parties to a comprehensive surveillance sharing agreement with the Exchange.

According to the Exchange, these additional instruments are intended to support each Fund's principal investment strategy by providing each Fund with the flexibility to obtain additional exposure to the investment returns of the commodities markets within the limits of applicable federal tax requirements and without investing directly in physical commodities. Each Fund, through its respective Subsidiary, will only invest in those commodity-linked notes, OTC Swaps, Forwards, or other over-the-counter instruments that are based on the price of relevant Commodities Futures, as applicable, and tend to exhibit trading prices or returns that correlate with any Commodities Futures and that will further the investment objective of such Fund.[16] The Funds represent that the

[7] The Exchange states that the changes described herein will be effective contingent upon effectiveness of a post-effective amendment to the Registration Statement of the Trust, on behalf of each Fund.

[8] The term ''under normal circumstances'' includes, but is not limited to, the absence of extreme volatility or trading halts in the equity, commodities and futures markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or manmade disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.

[9] Specifically, the Prior Release noted that the Funds will invest in: (1) Exchange-traded funds (''ETFs'') that provide exposure to commodities, as would be listed under Nasdaq Rules 5705 and 5735; (2) exchange-traded notes (''ETNs'') that provide exposure to commodities, as would be listed under Nasdaq Rule 5710; or (3) exchange-traded pooled investment vehicles that invest primarily in commodities and commodity-linked instruments, as would be listed under Nasdaq Rules 5711(b), (d), (f), (g), (h), (i), and (j) (''Commodity Pool'' or ''Commodity Pools'').

[10] The Exchange represents that, for a Fund's purposes, money market instruments will include: Short-term, high quality securities issued or guaranteed by non-U.S. governments, agencies, and instrumentalities; non-convertible corporate debt securities with remaining maturities of not more than 397 days that satisfy ratings requirements under Rule 2a–7 of the 1940 Act; money market mutual funds; and deposits and other obligations of U.S. and non-U.S. banks and financial institutions.

[11] In addition to ETFs, the other investment companies will consist of non-exchange traded U.S. registered open-end investment companies (mutual funds), closed-end investment companies traded on U.S. exchanges, or exchange-traded non-U.S. investment companies traded on foreign exchanges.

[12] According to the Exchange, each Fund's investment in securities of other investment companies may exceed the limits permitted under the 1940 Act, in accordance with certain terms and conditions set forth in a Commission exemptive order issued to an affiliate of the Trust (which applies equally to the Trust) pursuant to Section 12(d)(1)(J) of the 1940 Act. *See* Investment Company Act Release No. 30238 (Oct. 23, 2012) (File No. 812–13820) or, in the case of non-U.S. investment companies, pursuant to Commission No-Action relief. *See* Red Rocks Capital, LLC (pub. avail. June 3, 2011).

[13] Equity Securities will be comprised of exchange-traded common stocks of companies that operate in commodities, natural resources, and energy businesses, and in associated businesses, as well as companies that provide services or have exposure to such businesses.

[14] According to the Exchange, such commodity-linked notes generally will not be exchange-traded; however it is possible that in the future some of those instruments could be listed for trading on an exchange.

[15] The Prior Release noted that with respect to Commodities Futures held indirectly through a Subsidiary, not more than 10% of the weight of such Commodities Futures in the aggregate shall consist of instruments whose principal trading market is not a member of the Intermarket Surveillance Group (''ISG'') or a market with which the Exchange does not have a comprehensive surveillance sharing agreement. The Exchange now clarifies that Options and commodity index futures will be subject to the same restrictions as Commodities Futures, and that Options and commodity index futures will be considered in the aggregate with Commodities Futures. Therefore, with respect to Commodities Futures, commodity index futures, and Options, not more than 10% of the weight of such Commodities Futures, commodity index futures, and Options, in the aggregate, shall consist of instruments whose principal trading market is not a member of the ISG or a market with which the Exchange does not have a comprehensive surveillance sharing agreement. The Exchange states that this 10% limitation applicable to Commodities Futures, commodity index futures, and Options, in the aggregate, is separate from the 10% limitation applicable to exchange traded equity securities described herein, and is determined separately from this other limitation.

[16] Each Subsidiary will enter into swap agreements and other over-the-counter transactions

Continued

descriptions of the original asset types included in the Prior Release remain otherwise unchanged and that the Funds and their Subsidiaries will adhere to all investment restrictions set forth in the Prior Release as they apply to the original asset types. The Funds also represent that the investments in these additional asset types will be consistent with each Fund's investment objective.

The Exchange represents that, except for these changes described herein, all other facts presented and representations made in the Prior Release remain unchanged and in full effect. Additional information regarding the Trust, Fund, and Shares, including investment strategies and restrictions, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, distributions and taxes, calculation of net asset value (''NAV''), availability of information, trading rules and halts, and surveillance procedures, among other things, can be found in the Registration Statement, Notice, and Prior Release, as applicable.[17]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1 and 2 thereto, is consistent with the requirements of Section 6 of the Act [18] and the rules and regulations thereunder applicable to a national securities exchange.[19] In particular, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1 and 2 thereto, is consistent with the requirements of Section 6(b)(5) of the Act,[20] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in 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 Commission also finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act,[21] which sets forth the finding of Congress that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities.

The Exchange represents that not more than 10% of each Fund's investments in Equity Securities, closed-end funds, ETFs, ETNs, Commodity Pools, and non-U.S. investment companies, in the aggregate, will be invested in instruments that trade in markets that are not members of the ISG or that are not parties to a comprehensive surveillance sharing agreement with the Exchange. In addition, the Exchange represents that, with respect to Commodities Futures, commodity index futures, and Options, not more than 10% of the weight of such Commodities Futures, commodity index futures, and Options, in the aggregate, will consist of instruments whose principal trading market is not a member of the ISG or a market with which the Exchange does not have a comprehensive surveillance sharing agreement. The Commission further notes that: (1) Commodity-Linked Instruments will only be held at the Fund's Subsidiary level; [22] and (2) according to the Prior Release, each Fund's investment in a Subsidiary may not exceed 25% of the Fund's total assets.[23]

With respect to the calculation of NAV, in addition to the information set forth in the Prior Release, the Exchange represents that: (i) Equity Securities, ETNs, and futures on commodity indices will be valued at the last sales price or the official closing price on the exchange where such securities principally trade; (ii) investment companies will be valued using such company's end of the day NAV per share, unless the shares are exchange-traded, in which case they will be valued at the last sales price or official closing price on the exchanges on which they primarily trade; (iii) Options generally will be valued at the closing price (and, if no closing price is available, at the mean of the last bid/ask quotations) generally from the exchange where such instruments principally trade; and (iv) Swaps, commodity-linked notes and Forwards generally will be valued based on quotations from a pricing vendor (such quotations being derived from available market- and company-specific data), all in accordance with valuation procedures adopted by the Board of Trustees of the Trust. All other valuation procedures pertaining to the Funds, and as set forth in the Prior Release, are unchanged.

On each business day, before commencement of trading in Shares in the Regular Market Session on the Exchange, each Fund will disclose on its Web site the identities and quantities of its portfolio of securities and other assets (''Disclosed Portfolio,'' as defined in Nasdaq Rule 5735(c)(2)) held by such Fund and its Subsidiary, which will form the basis for each Fund's calculation of NAV at the end of the business day. In addition to the information set forth in the Prior Release, the Funds will disclose on a daily basis on the Funds' Web site the following information regarding each portfolio holding, as applicable to the type of holding: ticker symbol, CUSIP number or other identifier, if any; a description of the holding (including the type of holding), the identity of the security or other asset or instrument underlying the holding, if any; for options, the option strike price; for Swaps, a description of the type of Swap; quantity held (as measured by, for example, par value, notional value or number of shares, contracts or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and percentage weighting of the holding in the Fund's portfolio. The Web site information will be publicly available at no charge. Intra-day price information on the exchange-traded assets held by the Fund and the Subsidiary, including the Equity Securities, ETNs, Options, exchange-traded investment companies (including closed-end funds), and exchange-traded futures contracts on commodity indices will be available via the quote and trade service of the respective exchanges on

only with large, established, and well capitalized financial institutions that meet certain credit quality standards and monitoring policies. Each Subsidiary will use various techniques to minimize credit risk, including early termination, or reset and payment of such investments, the use of different counterparties, or limiting the net amount due from any individual counterparty.

[17] *See* Registration Statement, Notice, and Prior Release, *supra* notes 3, 4, and 6, respectively, and accompanying text.

[18] 15 U.S.C. 78(f).

[19] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[22] *See* Amendment No. 1, *supra* note 5.

[23] *See* Prior Release, *supra* note 6. The Commission further notes that, according to the Prior Release, because each Fund will wholly own and control its respective Subsidiary, and the Fund and the Subsidiary will be managed by Invesco PowerShares Capital Management LLC (''Adviser''), the Subsidiary will not take action contrary to the interests of the Fund or the Fund's shareholders. The Board of Trustees of the Trust has oversight responsibility for the investment activities of each Fund, including its expected investments in its Subsidiary, and that Fund's role as the sole shareholder of such Subsidiary. In managing a Subsidiary's portfolio, the Adviser will be subject to the same investment restrictions and operational guidelines that apply to the management of a Fund. *See* Prior Release, *supra* note 6, 79 FR at 55853.

which they principally trade. Additionally, price information on Swaps, commodity-linked notes, Forwards, and non-exchange traded investment companies will be available from major broker-dealer firms or through subscription services, such as Bloomberg, Markit, and Thomson Reuters, which can be accessed by entities that have entered into an authorized participant agreement with the Trust and other investors.

In addition to the information set forth in the Prior Release, the Exchange represents that: (i) FINRA, on behalf of the Exchange, will communicate as needed regarding trading information it can obtain relating to exchange-traded or centrally-cleared equity securities and assets held by a Fund or its Subsidiary, as applicable, which include exchange-traded Commodity-Related Assets and exchange-traded or centrally-cleared Commodity-Linked Instruments, with other markets and other entities that are members of the ISG; (ii) FINRA may obtain trading information regarding trading in exchange-traded equity securities and other assets held by each Fund and each Subsidiary, as applicable, from such markets and other entities; and (iii) the Exchange may obtain information regarding trading in exchange-traded equity securities and other assets held by each Fund and each Subsidiary from such markets and other entities (as long as such markets and other entities are members of ISG or have in place a comprehensive surveillance sharing agreement with the Exchange). The Exchange has a general policy prohibiting the distribution of material, non-public information by its employees.

The Commission notes that, beyond the changes described herein, the Exchange represents that there are no changes to any other information included in the Prior Release, and all other facts presented and representations made in the Prior Release remain true and in effect. The Commission further notes that the Funds and the Shares must comply with the requirements of Nasdaq Rule 5735 to be initially and continuously listed and traded on the Exchange. This approval order is based on all of the Exchange's representations and description of the Funds, including those set forth above, in the Prior Release, and in the Notice.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[24] that the proposed rule change (SR–NASDAQ–2015–049), as modified by Amendment Nos. 1 and 2 thereto, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–16652 Filed 7–7–15; 8:45 am]

BILLING CODE 8011–01–P

[24] 15 U.S.C. 78s(b)(2).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75350; File No. SR–BOX–2015–24]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Market LLC Options Facility

July 1, 2015.

Pursuant to Section 19(b)(1) under the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 29, 2015, BOX Options Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with 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 the Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the Fee Schedule on the BOX Market LLC (''BOX'') options facility. While changes to the fee schedule pursuant to this proposal will be effective upon filing, the changes will become operative on July 1, 2015. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com.*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make a number of changes to Section I.A of the BOX Fee Schedule, Exchange Fees for Non-Auction Transactions.

First, the Exchange proposes to amend certain credits in the pricing model outlined in Section I.A. (Non-Auction Transactions).[5] In this section, fees and credits are assessed depending on upon three factors: (i) The account type of the Participant submitting the order; (ii) whether the Participant is a liquidity provider or liquidity taker; and (iii) the account type of the contra party. Non-Auction Transactions in Penny Pilot Classes are assessed different fees or credits than Non-Auction Transactions in Non-Penny Pilot Classes. The Exchange recently adopted this pricing model[6] and now proposes to amend certain credits in this section.

Specifically, the Exchange proposes to eliminate the Maker and Taker credits for Public Customers interacting with Professional Customers/Broker Dealers or Market Makers in both Penny Pilot and Non-Penny Pilot Classes. Public Customers currently receive a $0.10 credit (Penny Pilot Classes) and $0.45 credit (Non-Penny Pilot Classes) when interacting with Professional Customers, Broker Dealers or Market Makers, regardless of whether they are adding or removing liquidity. The Exchange proposes to eliminate both these credits.

These transactions will remain exempt from the Liquidity Fees and Credits outlined in Section II of the BOX Fee Schedule. The revised fee structure

[5] Non-Auction Transactions are those transactions executed on the BOX Book.

[6] *See* Securities Exchange Act Release No. 73547 (November 6, 2014), 79 FR 67520 (November 13, 2014) (Notice of Filing and Immediate Effectiveness of SR–BOX–2014–25).

for Non-Auction Transactions will be as follows:

Account type	Contra party	Penny pilot classes		Non-penny pilot classes	
		Maker fee/ credit	Taker fee/ credit	Maker fee/ credit	Taker fee/ credit
Public Customer	Public Customer	$0.00	0.00	0.00	0.00
	Professional Customer/Broker Dealer	0.00	0.00	0.00	0.00
	Market Maker	0.00	0.00	0.00	0.00
Professional Customer or Broker Dealer.	Public Customer	0.60	0.64	0.95	0.99
	Professional Customer/Broker Dealer	0.25	0.40	0.35	0.40
	Market Maker	0.25	0.44	0.35	0.44
Market Maker	Public Customer	0.51	0.55	0.85	0.90
	Professional Customer/Broker Dealer	0.00	0.05	0.00	0.10
	Market Maker	0.00	0.29	0.00	0.29

For example, if a Public Customer submitted an order to the BOX Book in a Penny Pilot Class (making liquidity), the Public Customer would now be charged no fee if the order interacted with a Market Maker's order and the Market Maker (taking liquidity) would be charged $0.55. To expand on this example, if the Market Maker instead submitted an order to the BOX Book in a Penny Pilot Class (making liquidity), the Market Maker would be charged $0.51 if the order interacted with a Public Customer's order and the Public Customer (taking liquidity) would again be charged no fee.

In Section I.A.1., the Tiered Volume Rebate for Non-Auction Transactions, the Exchange gives a per contract rebate to Market Makers and Public Customers based on their average daily volume (''ADV'') considering all transactions executed on BOX by the Market Maker or Public Customer, respectively, as calculated at the end of each month. In the Public Customer's Monthly ADV section the Exchange proposes to adjust the volume tiers and adopt different per contract rebates for Penny Pilot Classes and Non-Penny Pilot Classes. The new per contract rebates for Public Customers in Non-Auction Transactions as set forth in Section I.A.1. of the BOX Fee Schedule will now be as follows:

Public customer monthly ADV	Per contract rebate	
	Penny pilot classes	Non-penny pilot classes
65,001 contracts and greater	($0.40)	($0.70)
40,001 contracts to 65,000 contracts	($0.25)	($0.50)
15,001 contracts to 40,000 contracts	($0.15)	($0.40)
1 contract to 15,000 contracts	$0.00	$0.00

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5)of the Act,[7] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among BOX Participants and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers. The proposed changes will allow the Exchange to be competitive with other exchanges and to apply fees and credits in a manner that is equitable among all BOX Participants. Further, the Exchange operates within a highly competitive market in which market participants can readily direct order flow to any other competing exchange if they determine fees at a particular exchange to be excessive.

The Exchange believes amending the Non-Auction Transaction credits for Public Customers is reasonable, equitable and not unfairly discriminatory. The fee structure for Non-Auction Transactions has been well received by Participants and the industry since it was adopted last year, and the Exchange believes it is now appropriate to eliminate the credits for Public Customers.[8] The proposed fee structure is intended to attract order flow to the Exchange by offering all market participants incentives to submit their Non-Auction orders to the Exchange. The practice of providing additional incentives to increase order flow is, and has been, a common practice in the options markets.[9] Further, the Exchange believes it is appropriate to provide incentives for market participants which will result in greater liquidity and ultimately benefit all Participants trading on the Exchange.

The Exchange also believes it is equitable, reasonable and not unfairly discriminatory to assess fees according to the account type of the Participant

[7] 15 U.S.C. 78f(b)(4) and (5).

[8] *See supra,* note 6. Prior to adopting the Non-Auction Transaction fee structure, Public Customers were charged $0.07 for each Non-Auction transaction.

[9] *See* BATS Exchange, Inc. (''BATS'') BATS Options Exchange Fee Schedule ''Standard Rates''; Chicago Board Options Exchange, Inc. (''CBOE'') Fee Schedule ''Volume Incentive Program'' (page 4); ISE Gemini, LLC (''Gemini'') Schedule of Fees, Section I. Regular Order Fees and Rebates ''Penny Symbols and SPY, and Non-Penny Symbols'' (page 4); Miami International Securities Exchange, LLC (''MIAX'') Fee Schedule Section I(a)(i) ''Market Maker Transaction Fees'' and ''Market Maker Sliding Scale'', and Section I(a)(iii) ''Priority Customer Rebate Program''; NASDAQ OMX BX, Inc. (''BX Options'') Chapter XV, Section 2 BX Options Market—Fees and Rebates; NASDAQ OMX PHLX,(''PHLX''), Pricing Schedule Section B, ''Customer Rebate Program''; NASDAQ Stock Market LLC (''NOM'') Chapter XV, Section 2 NASDAQ Options Market—Fees and Rebates; NYSE Amex, Inc. (''AMEX'') Fee Schedule Section I.C. NYSE Amex Options Market Maker Sliding Scale—Electronic; and NYSE Arca, Inc (''Arca'') Options Fees and Charges, ''Customer and Professional Customer Monthly Posting Credit Tiers and Qualifications for Executions in Penny Pilot Issues''(page 4).

originating the order and the contra party. This fee structure has been in place on the Exchange since last year and the Exchange is simply adjusting certain credits within the structure.[10] The result of this structure is that a Participant does not know the fee it will be charged when submitting certain orders. Therefore, the Participant must recognize that it could be charged the highest applicable fee on the Exchange's schedule, which may, instead, be lowered or changed to a credit depending upon how the order interacts.

The Exchange believes that the proposed fees for Public Customers in Non-Auction Transactions are reasonable. Under the proposed Non-Auction Transaction fee structure Public Customers will never pay a fee for their Non-Auction transactions and may be eligible for a per contract rebate depending on their monthly ADV for all transactions executed on BOX. Therefore the Exchange believes that it is appropriate and therefore consistent with the Act to eliminate the credits for Public Customers in Section 1.A. The Exchange believes the Non-Auction transaction fees for Public Customers are reasonable as they are in line with the current fees assessed by other competing exchanges.[11]

Tiered Volume Rebate for Non-Auction Transactions

BOX believes it is reasonable, equitable and not unfairly discriminatory to adjust the tiered volume based rebates for Public Customers in Non-Auction Transactions. The volume thresholds and applicable rebates are meant to incentivize Public Customers to direct order flow to the Exchange to obtain the benefit of the rebate, which will in turn benefit all market participants by increasing liquidity on the Exchange. Other exchanges employ similar incentive programs; [12] and the Exchange believes that the proposed changes to the volume thresholds and rebates are reasonable and competitive when compared to incentive structures at other exchanges.

The Exchange continues to believe it is equitable and not unfairly discriminatory to offer these rebate structures to Public Customers in Non-Auction transactions. The practice of incentivizing increased Public Customer order flow is common in the options markets. The Exchange believes the proposed changes to the tiers and per contract rebates are reasonable, as Public Customers will benefit from the opportunity to obtain a greater rebate in most situations. For example, under the current schedule a Public Customer with an ADV of 17,000 would receive a per contract rebate of $0.12. Under the proposed schedule this same Public Customer would receive a per contract rebate of $0.15 for Penny Pilot Classes and $0.40 for Non-Penny Pilot Classes.

The Exchange believes it is reasonable to offer a higher per contract rebate for transactions in Penny Pilot Classes [sic] compared to Non-Penny Pilot Classes [sic] because Non-Penny Pilot Classes are typically less actively traded and have wider spreads. The Exchange believes that offering a higher rebate will incentivize Public Customer order flow in Non-Penny Pilot issues on the Exchange, ultimately benefitting all Participants trading on BOX.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes that the proposed adjustments to fees and rebates in the Non-Auction Transactions fee structure will not impose a burden on competition among various Exchange Participants. Rather, BOX believes that the changes will result in the Participants being charged appropriately for these transactions and are designed to enhance competition in Non-Auction transactions on BOX. Submitting an order is entirely voluntary and Participants can determine which type of order they wish to submit, if any, to the Exchange. Further, the Exchange believes that this proposal will enhance competition between exchanges because it is designed to allow the Exchange to better compete with other exchanges for order flow.

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 Exchange Act [13] and Rule 19b–4(f)(2) thereunder,[14] because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further 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–BOX–2015–24 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–BOX–2015–24. 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

[10] *See supra,* note 6.

[11] Many U.S. Options Exchanges do not differentiate their fees between auction and non-auction transactions. However, Public Customers are charged anywhere from $0.00 to $0.85 within the following options exchange fee schedules. *See* NASDAQ OMX BX (''BX'') Options Pricing, Chapter XV, Sec. 2; NYSE Arca Options (''Arca'') Fees and Charges page 3; International Securities Exchange (''ISE'') Schedule of Fees, Section I.

[12] *See* Section B of the PHLX Pricing Schedule entitled ''Customer Rebate Program;'' ISE Gemini's Qualifying Tier Thresholds (page 6 of the ISE Gemini Fee Schedule); and CBOE's Volume Incentive Program (VIP). CBOE's Volume Incentive Program (''VIP'') pays certain tiered rebates to Trading Permit Holders for electronically executed multiply-listed option orders which include AIM orders. Note that some of these exchanges base these rebate programs on the percentage of total national Public Customer volume traded on their respective exchanges, which the Exchange is not proposing to do.

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 240.19b–4(f)(2).

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–BOX–2015–24, and should be submitted on or before July 29, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–16653 Filed 7–7–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75346; File No. SR–CHX–2015–03]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing of Proposed Rule Change To Implement CHX SNAP℠, an Intra-Day and On-Demand Auction Service

July 1, 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 June 23, 2015, the Chicago Stock Exchange, Inc. (''CHX'' 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

CHX proposes to adopt and amend rules to implement CHX SNAP℠, an intra-day and on-demand auction service. The text of this proposed rule change is available on the Exchange's Web site at *http://www.chx.com/rules/proposed_rules.htm,* 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 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt and amend rules to implement CHX SNAP℠ (Sub-second Non-displayed Auction Process), an innovative intra-day and on-demand auction service that could occur numerous times throughout a regular trading session [3] at the request of Participants seeking to trade securities in bulk. SNAP Cycles are designed to transition seamlessly from, and back to, automated trading in the subject security, and to occur simultaneously with automated trading in the subject security elsewhere in the national market system. SNAP is designed to address a specific market need for bulk trading of securities on an exchange, which will operate efficiently within the national market system.

On June 5, 2014, Chair White noted, among other things, that a key question concerning trading venues is whether they have sufficient opportunity and flexibility to innovate successfully with initiatives that seek to deemphasize speed as a key to trading success in order to further serve the interests of investors.[4] Chair White specifically noted possible solutions to include frequent batch auctions designed to minimize speed advantages.[5]

Consistent with Chair White's statement, the Exchange proposes SNAP, an innovative solution that *deemphasizes* speed as a hallmark of its functionality, which will operate consistently with Regulation NMS [6] and Rule 201 of Regulation SHO or applicable exemptive relief.[7] As discussed in detail below, the SNAP Cycle has several characteristics specifically designed to minimize speed advantages, which include, among other things, the following:

- SNAP Cycles will never be scheduled and will always be driven by market demand for bulk trading in a security.
- The order acceptance period for SNAP Eligible Orders will always be randomized.
- Order cancellations during a SNAP Cycle will be prohibited.
- New order modifiers, such as SNAP Auction Only Order—Pegged, will permit market participants to take advantage of the most recent market data in competitively pricing their SNAP Eligible Orders, regardless of their respective speed capabilities.

As such, the Exchange proposes to adopt Article 18, Rule 1 (SNAP) to outline the proposed SNAP Cycle; amend Article 1, Rule 2 (Order Types, Modifiers and Related Terms) to adopt several new order modifiers related to SNAP; and amend Article 20, Rule 8 (Operation of the Matching System) to support a new order ranking plan for SNAP executions. The Exchange also proposes to amend various other rules to harmonize with SNAP.

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] CHX Article 20, Rule 1(b) provides that the ''regular trading session—shall begin at 8:30 a.m. and shall end at 3:00 p.m. each day for all securities.'' All times are in central time, unless noted otherwise.

[4] *See* Mary Jo White, Chair, Securities and Exchange Commission, Speech at Sandler O'Neil & Partners L.P. Global Exchange and Brokerage Conference (June 5, 2014).

[5] *See id.*

[6] 17 CFR 242.611.

[7] 17 CFR 242.201. As discussed in detail below, SNAP executions may be delayed up to 200 milliseconds from the market snapshot utilized for determining the single auction price (*i.e.,* SNAP Price), if the SNAP Price would require, among other things, the routing of one or more orders to away markets for Rule 611 of Regulation NMS compliance purposes. *See infra* Section 5. The purpose of the routing delay is to give away markets sufficient to time to respond to the routed orders, so that any unexecuted routed orders would be included in the SNAP execution within the Matching System. However, the SNAP execution delay may render the national best bid ascertained from the aforementioned market snapshot no longer ''current,'' as required during a short sale price test restriction in a covered security, pursuant to Rule 201(b)(1)(i) of Regulation SHO. Accordingly, the Exchange will be submitting separately a request for no-action relief or exemptive relief from certain requirements of Rule 201 of Regulation SHO to address this issue.

Section 1: SNAP Cycle—Generally

Proposed Article 18, Rule 1(a) provides a general overview of the scope of SNAP. Specifically, SNAP is a fully-hidden on-demand auction that may be initiated in a security (''subject security'') within the Matching System, pursuant to the provisions of proposed Article 18, Rule 1. Participants that submit valid limit orders marked Start SNAP will initiate a SNAP Cycle and, thus, SNAP Cycles are always on-demand and never scheduled or initiated by the Exchange.[8] Also, the entire SNAP Cycle is designed to be completed in less than one second. Except for specified time frames noted in the proposed rules, all other processes in the SNAP Cycle are virtually instantaneous.[9]

In addition, SNAP Cycles may only occur during the regular trading session, but may occur more than once during a regular trading session and may occur in different securities concurrently.[10] However, during a SNAP Cycle, automated trading in the subject security shall be suspended. It is important to note that the Exchange operates only one book and, thus, automated execution of orders in a subject security will never occur simultaneously with a SNAP Cycle in the same security. However, given the fundamental differences between automated execution of orders and auctions, as discussed in detail below, the Exchange proposes a distinction between the CHX book during the Open Trading State [11] and the CHX book during a SNAP Cycle (''SNAP CHX book'').

The Exchange also reserves the right to enable or disable SNAPs, per security, pursuant to notice to its Participants. On initial operation, the Exchange anticipates making the SNAP functionality available for all securities that are traded within the Matching System.[12]

In sum, the SNAP Cycle is comprised of the following five stages detailed under proposed Article 18, Rule 1(b), all of which are discussed comprehensively under Section 5 and illustrated through numerous examples under Section 6:

- Stage One: Initiating the SNAP Cycle.
- Stage Two: SNAP Order Acceptance Period.
- Stage Three: Pricing and Satisfaction Period.
- Stage Four: Order Matching Period.
- Stage Five: Transition to the Open Trading State.

Section 2: Proposed Defined Terms

The Exchange proposes new defined terms related to SNAPs. Proposed Article 1, Rule 1(qq) defines ''Open Trading State,'' as the period of time during the regular trading session when orders are eligible for automatic execution.[13] As discussed in detail below, the SNAP Cycle and the Open Trading State are mutually exclusive in a subject security as the automated trading of securities in a subject security is always suspended during the SNAP Cycle in the same security.

Proposed Article 1, Rule 1(rr) defines ''SNAP Price'' as a single price at which the greatest number of shares may be executed during a SNAP Cycle, as described under proposed Article 18, Rule 1(b), without trading-through any more aggressively priced orders on either side of the market, in compliance with all CHX Rules and relevant securities laws and regulations, including Regulation NMS [14] and Rule 201 of Regulation SHO, and any applicable exemptive relief therefrom;[15] provided the following:

(1) Where two or more price points are identified above, the SNAP Price shall be the price closest to the last reported sale in the security from the same trading day that was not permitted to trade-through the National Best Bid and Offer (''NBBO'') at the time the last sale was executed (''eligible same day last sale''). Where two or more price points are equally close to the eligible same day last sale price, the SNAP Price shall be the eligible same day last sale price.

(2) If an eligible same day last sale cannot be ascertained, pursuant to proposed paragraph (rr)(1) above, the SNAP Price shall be the price closest to the NBBO midpoint. Where two or more price points are equally close to the NBBO midpoint, the SNAP Price shall be the NBBO midpoint.

As discussed in detail below, the SNAP Price will only be determined after the SNAP CHX book has been established during the stage three Pricing and Satisfaction Period and the SNAP Price will always be based on a single market snapshot in the subject security at the time the SNAP Price is determined.[16] Example 6 below illustrates the process for determining the SNAP Price.[17]

Proposed Article 1, Rule 1(ss) defines ''SNAP Eligible Order'' as a limit order, as defined under Article 1, Rule 2(a)(1), not marked by, or handled as, any one of the following modifiers:

(1) Cancel On SNAP, as defined under proposed Article 1, Rule 2(h)(4).

(2) Fill Or Kill, as defined under Article 1, Rule 2(d)(2).

(3) Immediate Or Cancel (''IOC''), as defined under Article 1, Rule 2(d)(4).

(4) Start SNAP, as defined under proposed Article 1, Rule 2(h)(1), except where the limit order marked Start SNAP is eligible for SNAP AOO—One And Done handling, pursuant to proposed Article 1, Rule 2(h)(1)(B).[18]

In sum, aside from modifiers that require the immediate execution or cancellation of the order (*i.e.,* Fill Or Kill and IOC) or explicitly prohibit the order from participating in SNAPs (*i.e.,* Cancel On SNAP or Start SNAP), all other limit orders shall be considered SNAP Eligible Orders.[19] Moreover, to ensure that modifiers attached to SNAP Eligible Orders do not conflict with the SNAP Cycle, the Exchange proposes to deactivate certain modifiers for the subject security during the SNAP Cycle, pursuant to proposed Article 18, Rule 1(b)(2)(D).[20]

Section 3: Proposed Orders Modifiers Related to SNAP

The Exchange proposes to adopt the following new limit order modifiers related to SNAP, which are listed and defined under proposed Article 1, Rule 2(h):

- Start SNAP, under proposed paragraph (h)(1);
- Cancel On SNAP, under proposed paragraph (h)(2);
- SNAP Auction Only Order (''SNAP AOO'')—Day, under paragraph (h)(3)(A);
- SNAP AOO—One And Done, under paragraph (h)(3)(B); and
- SNAP AOO—Pegged, under paragraph (h)(3)(C).

Proposed Article 1, Rule 2(h) provides that the valid use of a modifier is subject to the modifier being compatible with other applicable order modifiers or terms related to the order. The compatibility of the order modifier with other modifiers is either explicitly noted in the definition of the proposed modifier or implied by the definition itself.

[8] *See infra* Sections 3 and 5.

[9] *See infra* Section 5.

[10] *See supra* note 3.

[11] *See infra* Section 2.

[12] Any changes to the list of SNAP eligible securities shall be announced via Information Memorandum and shall be effective no sooner than the trading day after the Information Memorandum has been issued.

[13] *See supra* note 3; *see also supra* note 7.

[14] 17 CFR 242.611.

[15] 17 CFR 242.201; *see supra* note 7.

[16] *See infra* Section 4.

[17] *See infra* Section 6.

[18] *See infra* Section 3.

[19] Cross and market orders are never SNAP Eligible Orders as cross orders are always handled IOC and market orders are required to be marked IOC. *See* CHX Article 1, Rule 2(a)(2) and (3).

[20] *See infra* Section 4.

Proposed paragraph (h)(1) defines ''Start SNAP'' as a limit order modifier that -1- initiates a SNAP Cycle in a specified security, as described under proposed Article 18, Rule 1(b), if the limit order marked Start SNAP meets the requirements of proposed subparagraph (A) or, -2- joins a SNAP Cycle in progress, if it does not meet the requirements of proposed subparagraph (A), but meets the requirements of proposed subparagraph (C). Also, a limit order marked Start SNAP is not executable during the Open Trading State, as defined under proposed Article 1, Rule 1(qq). Consequently, a limit order marked Start SNAP will never be permitted to post to the CHX book or be executed otherwise than during a SNAP Cycle. A limit order marked Start SNAP that does not meet the requirements of either proposed subparagraph (A) or (C) shall be cancelled.

Thereunder, proposed subparagraph (A) details the requirements for a limit order marked Start SNAP to initiate a SNAP Cycle. If the limit order marked Start SNAP does not meet all of the conditions under proposed subparagraph (A), the limit order marked Start SNAP will be cancelled, unless it meets the requirements for special handling pursuant to proposed subparagraph (C).

Proposed subparagraph (A)(i) provides that a limit order marked Start SNAP must meet the following minimum size requirement attributed to its limit price; provided, however, that certain issues specified below have special minimum size requirements:

Limit price		Minimum size
From	To	
0.0001	0.9999	100,000
1.00	4.99	50,000
5.00	24.99	25,000
25.00	49.99	20,000
50.00	99.99	10,000
100.00	499.99	5,000
500.00	.....	2,500

Special issue	Minimum size
Berkshire Hathaway, Inc. (BRK–A)[21]	100

Proposed subparagraph (A)(ii) details the pricing requirement of the limit order marked Start SNAP. Specifically, the limit price of the buy (sell) order marked Start SNAP must be priced at or through the National Best Offer (National Best Bid) at the time the order was received by the Matching System. That is, the limit order marked Start SNAP must be priced at the market or more aggressively. The Exchange believes that this pricing requirement will maximize the size of the SNAP execution by encouraging aggressive pricing. In light of this aggressive pricing requirement, a SNAP Cycle will not be initiated if the National Best Bid and Offer (''NBBO'') in the subject security is crossed or a two-sided NBBO does not exist at the time the limit order marked Start SNAP is received by the Matching System.

Proposed subparagraph (A)(iii) details the timing requirement of the limit order marked Start SNAP. Specifically, a limit order marked Start SNAP will only initiate a SNAP Cycle if it is received during the regular trading session; provided, however, that it will not initiate a SNAP if it is received (a) within five minutes of the first two-sided quote in the subject security having been received by the Exchange from the primary market disseminated after either the beginning of the regular trading session or after a halt or pause that required the Exchange to suspend trading in the subject security; (b) within five minutes of the end of the regular trading session; (c) during a SNAP Cycle; or (d) within one minute after the completion of the previous SNAP Cycle. With respect to proposed subparagraph (A)(iii)(a), the Exchange believes that requiring five minutes to have passed after the dissemination of the first two-sided quote from the primary market in the subject security before permitting a SNAP Cycle to be initiated is necessary to ensure that sufficient time has passed for the market in the subject security to have been established.

Proposed subparagraph (A)(iv) provides a general condition that a SNAP Cycle shall not be initiated if the CHX Routing Services, the Exchange's outbound routing service, is not operational.[22] Given the aggressive pricing requirement for limit orders marked Start SNAP, it is possible that one or more orders would have to be routed away to execute against contra-side Protected Quotations of external markets for purposes of Regulation NMS compliance. Thus, the Exchange proposes to prohibit a SNAP Cycle from initiating when outbound routing is not available at time of receipt of a limit order marked Start SNAP.[23]

Proposed subparagraph (B) provides an optional minimum SNAP execution size condition that may be selected by the Participant that submitted the limit order marked Start SNAP. Specifically, an order sender may instruct that the SNAP Cycle be cancelled, without any executions, if the sum -1- of the minimum number of shares that may be executed within the Matching System at the SNAP Price, as defined under proposed Article 1, Rule 1(rr), and -2- the number of shares that would be routed away, pursuant to proposed Article 19, Rule 3(a)(4) and (5), is less than the minimum number of shares required for the Start SNAP order to have initiated the current SNAP Cycle, pursuant to proposed subparagraph (A)(i). The optional minimum size condition provides the Start SNAP order sender with a tool to minimize information leakage concerning orders that participated in the SNAP. That is, without a minimum size condition, the Participant that submitted the limit order marked Start SNAP may give up crucial information concerning its order, without receiving the benefit of a substantial execution. Thus, the minimum size condition is intended to minimize the probability and magnitude of such information leakage.

Proposed subparagraph (C) provides a default handling for a limit order marked Start SNAP that does not meet the requirements to initiate a SNAP Cycle. Specifically, by default, a limit order marked Start SNAP that does not meet the requirements of proposed subparagraph (A) and is received by the Matching System during a SNAP Order Acceptance Period, as described under proposed Article 18, Rule 1(b)(2), shall be handled as SNAP AOO—One And Done, as defined under proposed paragraph (h)(3)(B), and join the SNAP Cycle in progress. This default handling addresses the scenario, among others, where two or more limit orders marked Start SNAP are received by the Matching System at nearly the same time. Additionally, an order sender may instruct that the limit order marked Start SNAP not be subject to this special handling even if eligible.

Proposed paragraph (h)(2) defines ''Cancel On SNAP,'' which is a limit order modifier that requires the order to be cancelled upon initiation of a SNAP Cycle or cancelled upon receipt if received during a SNAP Cycle. Thus, resting orders marked Cancel On SNAP will be cancelled immediately after acceptance of a valid limit order marked Start SNAP and incoming orders

[21] The Exchange believes it necessary and appropriate to establish a special minimum size requirement for BRK–A, due to its exceptionally high market value and special round lot size.

[22] *See* CHX Article 19, Rule 1.

[23] Moreover, a SNAP Cycle that was initiated may be aborted prior to order matching at the SNAP Price, if the CHX Routing Services are unavailable at the time the SNAP Price is to be determined. *See infra* Section 5.

marked Cancel On SNAP will be cancelled by the Matching System if received during a SNAP Cycle.[24] Thus, Cancel On SNAP is similar to the current Cancel On Halt modifier, defined under Article 1, Rule 2(b)(1)(B), which requires the order to be cancelled if a trading halt or suspension is declared in the security.

Proposed paragraph (h)(3) details the three proposed SNAP AOO modifiers. SNAP AOOs are limit orders marked by, or handled as, SNAP AOO—One And Done; SNAP AOO—Day; or SNAP AOO—Pegged.[25] As the name suggests, SNAP AOOs shall not be active during the Open Trading State. Also, SNAP AOOs shall only be accepted from the beginning of the early session to five minutes prior to the end of the regular trading session.[26] Upon receipt by the Exchange, all valid SNAP AOOs are either queued or immediately ranked, as described under proposed Article 20, Rule 8(b)(2)(A), as discussed in detail below.[27]

Moreover, all SNAP AOOs must meet the below minimum size requirement at the time of original receipt associated with its corresponding SNAP AOO Reference Price, provided, however, that certain issues specified below have special minimum size requirements.[28] If there is no special minimum size requirement noted for a security, the SNAP AOO Reference Price shall be the last sale in the subject security that was not permitted to trade-through the NBBO at the time the last sale was executed.[29] If a SNAP AOO Reference Price cannot be determined (*i.e.,* there is no last sale in the security), the SNAP AOO shall be cancelled. The following represents the SNAP AOO Reference Prices and the corresponding minimum size requirement:

SNAP AOO reference price		Minimum size
From	To	
0.0001	0.9999	10,000
1.00	4.99	5,000
5.00	24.99	2,500
25.00	49.99	2,000
50.00	99.99	1,000
100.00	499.99	500
500.00	.....	250

Special issues	Minimum size
Berkshire Hathaway, Inc. (BRK–A)[30]	10

By pegging the SNAP AOO Reference Price to the last reported sale in the subject security, as opposed to the limit price of the SNAP AOO, order senders are discouraged from submitting hypermarketable SNAP AOOs in order to qualify for a lower minimum size tier. Moreover, the requirement that the last reported sale in the subject security not have been permitted to trade-through the NBBO at the time it was executed, such as Benchmark,[31] would better reflect the actual market price of the subject security.

Thereunder, proposed subparagraph (A) defines ''SNAP AOO—Day'' as a limit order modifier that requires the order to only participate in the next SNAP Cycle for which it is eligible and every SNAP Cycle thereafter for the remainder of the trading session until fully-executed or cancelled. Mechanically, the unexecuted balance of a limit order marked SNAP AOO—Day will be re-queued based on its original time of receipt and would be re-ranked in the SNAP CHX book during the next SNAP Cycle, pursuant to proposed Article 20, Rule 8(b)(2)(A).[32]

Proposed subparagraph (B) defines ''SNAP AOO—One And Done'' as a limit order modifier that requires the order to only participate in the next SNAP Cycle for which it is eligible with any unexecuted remainder to be cancelled; provided, however, that if the SNAP Cycle in which the limit order marked SNAP AOO—One And Done was participating was aborted prior to the stage three Pricing and Satisfaction Period, the order shall be re-queued pursuant to proposed Article 20, Rule 8(b)(2)(A), and not cancelled. Thus, unlike limit orders marked SNAP AOO—Day, which may be re-queued for any reason if an unexecuted balance exists, limit orders marked SNAP AOO—One And Done are only eligible to participate in one SNAP Cycle and may only be re-queued if the SNAP Cycle in which it was participating was aborted prior to the stage three Pricing and Satisfaction Period.

Proposed subparagraph (C) defines ''SNAP AOO—Pegged'' as a limit order modifier only available for orders marked SNAP AOO—Day or SNAP AOO—One And Done, that requires the order to be priced at the less aggressive of an optional limit price or mandatory offset price from the NBBO ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E). An order sender that submits a limit order marked SNAP AOO—Pegged must specify one of the following proposed pricing options.

(i) Midpoint. Priced at the midpoint of the NBBO or the locking price if the NBBO is locked. If the NBBO is crossed, the order shall not participate in the instant SNAP Cycle, even if there is an optional limit price indicated.

(ii) Market. A buy (sell) order shall be priced at, or a specified offset below or above, the NBO (NBB).

(iii) Primary. A buy (sell) order shall be priced at, or a specified offset below or above, the NBB (NBO).

Unlike non-auction pegged orders, which the Exchange does not currently offer, limit orders marked SNAP AOO—Pegged do not continuously track changes to the NBBO, but rather, are priced once per SNAP Cycle based on an single market snapshot taken immediately prior to the stage three Pricing and Satisfaction Period, as discussed in detail below.[33]

Section 4: Proposed SNAP CHX Book and SNAP AOO Queue

The SNAP CHX book will be used to establish the SNAP Price and execution priority for participating SNAP Eligible Orders with Working Prices[34] at and more aggressive than the SNAP Price.[35]

[24] An order marked Cancel On SNAP that is cancelled upon initiation of a SNAP Cycle or upon receipt during a SNAP Cycle is not a voluntary cancellation for the purposes of the Order Cancellation Fee and are excluded from the Order Cancellation Fee computation. *See* CHX Fee Schedule Section E.8.

[25] As currently proposed, the only orders that would be handled as a SNAP AOO, even if it not marked with an SNAP AOO modifier, would be limit orders marked Start SNAP, pursuant to Article 1, Rule 2(h)(1)(C), as described above. A limit order marked by any of the SNAP AOO modifiers will always be handled as a SNAP AOO.

[26] CHX Article 20, Rule 1(b) provides that the ''early session—shall begin at 6:00 a.m. and shall end at 8:30 a.m.'' All times are in central time, unless noted otherwise. *See supra* note 3.

[27] Invalid SNAP AOOs (*e.g.,* received after the end of the regular trading session) would be rejected. *See infra* Sections 4 and 5.

[28] SNAP AOOs that are queued upon receipt may also be re-queued, as discussed below. Thus, re-queued SNAP AOOs may be smaller than the minimum size, due to partial executions. *See infra* Sections 4 and 5.

[29] *Compare* proposed Article 1, Rule 1(rr), which has an additional requirement that the last sale be from the same trading day.

[30] *See supra* note 21.

[31] *See* CHX Article 1, Rule 2(b)(2)(A).

[32] *See infra* Sections 4 and 5.

[33] *See infra* Section 5.

[34] Incidentally, the Exchange proposes to amend current Article 1, Rule 1(pp)) to expand and clarify the definition of ''Working Price.'' Specifically, amended Article 1, Rule 1(pp) provides that Working Price means the most aggressive price at which *a limit order,* as opposed to the current ''resting'' limit orders, can execute within the Matching System, in compliance with CHX Rules and relevant securities laws and regulations, including Rule 611 of Regulation NMS and Rule 201 of Regulation SHO, *and any applicable exemptive relief therefrom. See supra* note 7.

[35] As noted above, the Exchange only operates one book. The SNAP CHX book merely reflects the reprioritizing of orders for the purposes of the SNAP Cycle and is not an independent book of orders maintained in addition to the regular CHX book. *See supra* Section 1.

Thus, the Exchange proposes to amend Article 20, Rule 8(b) (Ranking and display of orders) to adopt a distinction between the current ranking of orders on the CHX book, the proposed ranking of orders on the SNAP CHX book and the proposed queuing of certain SNAP AOO orders on the SNAP AOO Queue that would not be ranked on receipt.

Current Article 20, Rule 8(b) provides that all orders accepted by the Matching System that will post to the CHX book shall be ranked at each price point up or down to its limit price by display status then sequence number. Thereunder, current Rule 8(b)(1)–(3) outline the three display status pools according to priority on the CHX book as follows:

- Fully-displayable orders and displayed portions of Reserve Size orders, under paragraph (b)(1); [36]
- Undisplayed portion of Reserve Size orders, under paragraph (b)(2); and
- Orders marked Do Not Display, under paragraph (b)(3).[37]

The Exchange now proposes to amend Article 20, Rule 8(b) to expand the scope of the rules thereunder and to clarify the execution priority of resting orders on the CHX book. Specifically, amended Article 20, Rule 8(b) provides that orders shall be ranked and displayed as follows. Thereunder, proposed Rule 8(b)(1) provides that otherwise than during a SNAP Cycle, as described under proposed Article 18, Rule 1(b), orders that may post to the CHX book shall be executable in Working Price/display status/sequence number priority [38] and shall be ranked on the CHX book as described under proposed subparagraphs (A)–(C), which mirrors current Article 20, Rule 8(b)(1)–(3), respectively, but for amendments to certain cross-references affected by the proposed rule change.

Proposed Rule 8(b)(2) provides that the following orders shall not be ranked on the CHX book upon receipt, but shall be queued until ranked as follows. Thereunder, proposed subparagraph (A) describes the SNAP AOO Queue, which provides that valid SNAP AOOs, as defined under proposed Article 1, Rule 2(h)(3), shall be queued in the order in which they were originally received; provided, however, that SNAP AOOs not marked SNAP AOO—Pegged received during a SNAP Order Acceptance Period shall be immediately ranked on the SNAP CHX book upon receipt and not queued.[39] All SNAP AOOs shall be ranked on the SNAP CHX book, pursuant to proposed paragraph (b)(3)(E). Also, SNAP AOOs that are re-queued shall be re-queued based on time of original receipt.

Proposed Rule 8(b)(3) provides that during a SNAP Cycle, as described under proposed Article 18, Rule 1(b), orders shall receive execution priority as described under proposed Article 18, Rule 1(b)(4)(A) [40] and be ranked on the SNAP CHX book, as provided under proposed subparagraphs (A)–(E). In sum, all SNAP Eligible Orders ranked on the CHX book at the time a SNAP Cycle is initiated (''precedent orders'') shall maintain their priority in the SNAP CHX book, pursuant proposed subparagraphs (A)—(C). Following such precedent orders, the limit order marked Start SNAP that initiated the instant SNAP Cycle would be ranked, pursuant to proposed subparagraph (D). Finally, after the precedent orders and the limit order marked Start SNAP, SNAP AOOs and other SNAP Eligible Orders received during the SNAP Order Acceptance Period would be ranked by sequence number.

Examples 2–5 illustrate the process of creating the SNAP CHX book.[41] A discussion concerning SNAP Cycle order execution priority may be found below.[42]

Section 5: Proposed SNAP Cycle

Stage One: Initiating the SNAP Cycle

Upon the acceptance of a valid limit order marked Start SNAP, the Matching System shall begin the SNAP Cycle in the subject security, pursuant to proposed Article 18, Rule 1(b)(1), and take the following actions:

- Suspend automatic execution of orders in the subject security.
- Remove the Exchange's Protected Quotation(s) in the subject security, if any.
- Notify the market that a SNAP Cycle in the subject security has begun.
- Disseminate messages through the CHX Book Feed indicating that precedent orders on the CHX book in the subject security are no longer automatically executable.[43]
- Suspend dissemination of any other order information concerning the subject security through the CHX Book Feed.

Proposed Article 18, Rule 1(b)(1) describes how a SNAP Cycle is initiated. Specifically, a SNAP Cycle may be initiated upon acceptance by the Matching System of a valid limit order marked Start SNAP, as defined under proposed Article 1, Rule 2(h)(1), discussed in detail above. That is, a SNAP will only be initiated if all of the requirements of proposed Article 1, Rule 2(h)(1) are met. If a valid Start SNAP order is accepted by the Matching System, the Exchange shall only then immediately suspend automated matching of orders in the subject security and initiate the SNAP Cycle.

Thereunder, proposed subparagraph (A) provides that the Exchange will remove its Protected Quotation(s) in the subject security, if any, and will notify the market that a SNAP is taking place in the subject security.[44] Aside from the identity of the security subject to the SNAP, the Exchange will not disseminate any other information concerning the SNAP, including, but not limited to, the size, price or side of the Start SNAP order.

Incidentally, the Exchange proposes to amend Article 20, Rule 8(b)(6) to provide that the displayed CHX best bid and offer protocol shall be suspended during a SNAP Cycle, pursuant to proposed Article 18, Rule 1(b), and amend a citation to current ''paragraph (b)(1)'' to ''paragraph (b)(1)(A),'' as the citation has changed pursuant to this rule filing.[45]

Proposed subparagraph (B) provides that the Exchange shall submit messages through the CHX Book Feed to reflect that precedent orders previously disseminated through the CHX Book Feed are no longer automatically executable and that the Exchange will suspend dissemination of any other order information concerning the subject security. Any executions and

[36] *See* CHX Article 1, Rule 2(c)(3) defining ''Reserve Size.''

[37] *See* CHX Article 1, Rule 2(c)(2) defining ''Do Not Display.''

[38] Orders are currently executable in Working Price/display status/sequence number priority. *See* Exchange Act Release No. 73150 (September 19, 2014), 79 FR 57603 (September 25, 2014) (SR–CHX–2014–15) (''Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Adopt the CHX Routing Services'').

[39] As discussed below, SNAP AOOs marked SNAP AOO—Pegged can only be priced based on the market snapshot taken immediately after the end of the SNAP Order Acceptance Period, pursuant to proposed Article 18, Rule 1(b)(2)(E), and thus, cannot be ranked upon original receipt. *See infra* Section 5.

[40] *See infra* Section 5.

[41] *See infra* Section 6.

[42] *See infra* Section 5.

[43] The CHX Book Feed is the Exchange's proprietary data feed, which allows subscribers to view all displayable orders in the Matching System, including the size and price associated with such orders and trade data for executions that occur within the Matching System. *See* CHX Article 4, Rule 1.

[44] As of the time of this filing, the Exchange anticipates that the SNAP Cycle notice will be achieved by a unique identifier that will be disseminated to the market through the relevant securities information processor at the time the Exchange removes its Protected Quotation(s) in the subject security and a message through the CHX Book Feed indicating that a SNAP Cycle is occurring in the subject security.

[45] *See supra* Section 4.

cancellations that occur during the SNAP Cycle will continue to be reported immediately to the relevant Participant order sender(s). Similarly, any executions that occur during the SNAP Cycle will continue to be reported immediately to the relevant securities information processor and to clearing. However, information concerning displayable orders received, and cancellations and executions effected, during the SNAP Cycle shall not disseminated through the CHX Book Feed for the remainder of the SNAP Cycle. Upon the restarting of the CHX Book Feed, pursuant to proposed Article 18, Rule 1(b)(5)(C), the Exchange shall only disseminate information concerning the displayable orders posted to the CHX book at the conclusion of the SNAP Cycle. Incidentally, the Exchange propose to amend current Article 4, Rule 1(a) to provide that the availability of the CHX Book Feed is subject to proposed Article 18, Rule 1(b).[46]

Example 2 below illustrates how the SNAP Cycle could be initiated.[47]

Stage Two: SNAP Order Acceptance Period

Upon the initiation of the SNAP Cycle, the Matching System shall take the following actions, pursuant to proposed Article 18, Rule 1(b)(2):

- Begin the SNAP Order Acceptance Period.
- Begin establishing the SNAP CHX book.
- Begin the First In—First Out (''FIFO'') Queue for certain messages and orders received during the SNAP Cycle.

Proposed paragraph (b)(2) starts by providing that the SNAP Order Acceptance Period shall begin upon initiation of a SNAP Cycle and last approximately 475 to 525 milliseconds, the actual length of which will be randomized by the Matching System. By randomizing the exact length of the SNAP Order Acceptance Period, market participants would not be able to pinpoint exactly when the SNAP Order Acceptance Period would end, thereby minimizing speed advantages, which is one of the goals of the SNAP functionality.[48]

Proposed subparagraph (A) details how precedent resting orders would be handled upon the initiation of a SNAP Cycle. Specifically, subparagraph (A)(i) provides that SNAP Eligible Orders, as defined under proposed Article 1, Rule 1(ss), not marked SNAP AOO—Pegged, as defined under proposed Article 1, Rule 2(h)(3)(C), resting on the CHX book or SNAP AOO Queue, as described under proposed Article 20, Rule 8(b)(2)(A), prior to the initiation of the current SNAP Cycle, shall be ranked on the SNAP CHX book, pursuant to proposed Article 20, Rule 8(b)(3)(A)—(C) and (E), as applicable.[49] In turn, precedent SNAP AOOs marked SNAP AOO—Pegged shall remain on the SNAP AOO Queue until ranked on the SNAP CHX book, pursuant to proposed paragraph (b)(3)(A).

SNAP AOO—Pegged orders are not ranked on the SNAP CHX book during the SNAP Order Acceptance Period because the limit price of SNAP AOO—Pegged orders can only be confirmed by the market snapshot immediately after the end of the SNAP Order Acceptance Period, pursuant to proposed Article 18, Rule 1(b)(2)(E).[50] In contrast, all other SNAP Eligible Orders, including SNAP AOOs not marked SNAP AOO—Pegged, have confirmed limit prices known at the time of original receipt, which enables such orders to be immediately ranked on the SNAP CHX book upon initiation of the SNAP Cycle or upon receipt if received during a SNAP Order Acceptance Period.

Proposed subparagraph (A)(ii) provides that the limit order marked Start SNAP that initiated the current SNAP Cycle shall be ranked on the SNAP CHX book, pursuant to proposed Article 20, Rule 8(b)(3)(D). Proposed subparagraph (A)(iii) provides that precedent non-SNAP Eligible Orders resting on the CHX book (*i.e.,* limit orders marked Cancel On SNAP) shall be cancelled.

Proposed subparagraph (B) details how incoming orders received during the SNAP Cycle would be handled. Specifically, subparagraph (B)(i) provides that incoming SNAP Eligible Orders received during the SNAP Order Acceptance Period shall be immediately ranked on the SNAP CHX book, pursuant to proposed Article 20, Rule 8(b)(3)(E); provided, however, that SNAP AOOs marked SNAP AOO—Pegged shall be placed in the SNAP AOO Queue upon receipt and shall only be ranked on the SNAP CHX book, pursuant to paragraph (b)(3)(A).[51] Incoming SNAP Eligible Orders received after the SNAP Order Acceptance Period has expired, but during a SNAP Cycle, shall not be eligible to participate in the current SNAP Cycle and shall be queued in the FIFO Queue, pursuant to proposed subparagraph (C). To the extent an order on the FIFO Queue is a SNAP AOO, upon processing of the SNAP AOO during the stage five Transition to the Open Trading State, the SNAP AOO will be placed in the SNAP AOO Queue, for activation in the next SNAP Cycle for which it is eligible to participate. Also, proposed subparagraph (B)(ii) provides that incoming non-SNAP Eligible Orders received during the SNAP Cycle shall be cancelled upon receipt, except for cross orders, which shall be placed in the FIFO Queue.

Currently, cross orders are always handled Immediate Or Cancel, pursuant to Article 1, Rule 2(a)(2). In light of SNAP, the Exchange now proposes to amend the definition of cross orders, under Article 1, Rule 2(a)(2), to provide that cross orders received during a SNAP Cycle shall be placed in the FIFO Queue for later processing and not immediately cancelled. This special handling of cross orders is necessary because, for example, the Exchange receives a significant number of cross orders marked Qualified Contingent Trade (''QCT''),[52] the execution of which is required, among other things, to be contingent upon the execution of all other components at or near the same time. Thus, the Exchange believes it preferable to momentarily delay processing of QCTs to give such orders the opportunity to clear the CHX book, whereas an immediate cancellation could result in the QCT being out-of-hedge with the other component trades. Moreover, in light of the manual nature of QCT order packaging process, the Exchange submits that the approximate one second delay in processing a QCT on the FIFO Queue is immaterial with respect to the execution ''at or near the same time'' requirement for QCTs.[53]

Proposed subparagraph (C) lists the following messages received during a SNAP Cycle that would be placed in the FIFO Queue for later processing, pursuant to proposed paragraph (b)(5)(B):

(i) Cancel and cancel/replace messages for resting or queued orders.

(ii) Cancel messages from away markets for routed orders received after the SNAP Order Acceptance Period.[54]

(iii) SNAP Eligible Orders received after the SNAP Order Acceptance Period.

[46] *See supra* note 43.

[47] *See infra* Section 6.

[48] *See infra* Statutory Basis.

[49] *See supra* Section 4.

[50] *See supra* note 39.

[51] *See id.*

[52] *See* CHX Article 1, Rule 2(b)(2)(E).

[53] *See infra* Statutory Basis.

[54] Cancel messages from away markets for routed orders received during the SNAP Order Acceptance Period would result in the corresponding order being immediately released as unexecuted. The released order will then either join the SNAP Cycle in progress or be cancelled, if marked Cancel On SNAP.

(iv) Cross orders.

The FIFO Queue is necessary because the immediate processing of most messages are suspended during the SNAP Cycle. The Exchange submits that the momentary delay of processing such messages is reasonable because the delay will be no longer than the approximate one second that it would take for the SNAP Cycle to be completed. In addition, market liquidity in the subject security would be enhanced by preserving such orders and reducing unnecessary order cancellations.

Proposed subparagraph (D) provides that prior to being ranked on the SNAP CHX book, the following modifiers shall be deactivated for the subject security only:

(i) CHX Only, as defined under Article 1, Rule 2(b)(1)(C).

(ii) Post Only, as defined under Article 1, Rule 2(b)(1)(D).

(iii) Do Not Route, as defined under Article 1, Rule 2(b)(3)(A).

(iv) Match Trade Prevention, as defined under Article 1, Rule 2(b)(3)(F).

(v) Always Quote, as defined under Article 1, Rule 2(c)(1).

(vi) Reserve Size, as defined under Article 1, Rule 2(c)(3).

Deactivating each of these modifiers is necessary so that SNAP Eligible Orders subject to a SNAP Cycle are handled in a manner which do not violate the terms of the specified order modifiers, as the SNAP Cycle requires all participating orders to be routable, undisplayed in whole and executable, without restriction.

Specifically, the CHX Only, Post Only and Do Not Route modifiers [55] must be deactivated because each of these modifiers, among other things, requires the order to be unroutable and, as discussed in detail below, the SNAP Price may require the routing of one or more orders to prevent improper trade-through(s) of Protected Quotations of external markets. In addition, the Always Quote and Reserve Size modifiers must be deactivated because each of these modifiers requires all or a portion of the order to be displayed, whereas all SNAP Eligible Orders must be fully-hidden during a SNAP Cycle.[56] Also, the Match Trade Prevention (''MTP'') modifier must be deactivated because the MTP modifier will prevent the execution of certain orders that originate from the same MTP Trading Group or subgroup, whereas all participating SNAP Eligible Orders must be executable without condition.[57] Incidentally, the Exchange proposes to amend Article 1, Rule 2 to provide that order modifiers listed under proposed Article 18, Rule 1(b)(2)(D) shall not be active for a security that is subject to a SNAP Cycle, as described under proposed Article 18, Rule 1.

Proposed subparagraph (E) provides that upon conclusion of the SNAP Order Acceptance Period, the Matching System shall take a snapshot of the Protected Quotation(s) of external market(s) in the subject security and determine whether or not the CHX Routing Services are available. If the snapshot of the Protected Quotation(s) of external market(s) in the subject security shows that a two-sided NBBO exists and the CHX Routing Services are available, the SNAP Cycle shall continue to the stage three Pricing and Satisfaction Period. This proposed subparagraph (E) market snapshot will serve as the basis for the stage three Pricing and Satisfaction Period, as described below.

Alternatively, proposed subparagraph (F) provides that if the market snapshot taken pursuant to proposed subparagraph (E) above shows that a two-sided NBBO does not exist or the CHX Routing Services are unavailable, the SNAP Cycle shall be aborted without any executions and the Matching System shall take another market snapshot of the Protected Quotation(s) of external market(s) in the subject security and immediately begin the stage five Transition to the Open Trading State, as described below.

In sum, one or two market snapshots may be taken during the stage two Order Acceptance Period, depending on whether or not the SNAP Cycle was aborted during the stage two Order Acceptance Period. Specifically, if the market snapshot taken pursuant to proposed subparagraph (E) shows that a two-sided NBBO exists and the CHX Routing Services are available, the Matching System would not take any additional market snapshots during the stage two Order Acceptance Period, as the SNAP Cycle would immediately continue to the stage three Pricing and Satisfaction Period. In such a case, a third market snapshot would be taken during either the stage three Pricing and Satisfaction Period or the stage four Order Matching Period, as applicable, as discussed below. However, if the market snapshot taken pursuant to proposed subparagraph (E) shows that a two-sided NBBO does not exist or the CHX Routing Services are unavailable, the Matching System would immediately take a final market snapshot, pursuant to proposed subparagraph (F), abort the SNAP Cycle, skip stages three and four and enter the stage five Transition to the Open Trading State. Thus, there would always be a total of three market snapshots taken during the course of any given SNAP Cycle.[58]

Examples 3–4 below illustrate the various processes of the stage two SNAP Order Acceptance Period.[59]

Stage Three: Pricing and Satisfaction Period

Upon the conclusion of the stage two SNAP Order Acceptance Period, the Matching System shall take the following actions, pursuant to proposed Article 18, Rule 1(b)(3):

- Process the remaining orders on the SNAP AOO Queue and finalize the SNAP CHX book.
- Determine the SNAP Price.
- Route orders away to satisfy Protected Quotations of external markets, if necessary.

Proposed Article 18, Rule 1(b)(3) provides that, if permitted, pursuant to proposed paragraph (b)(2)(E), the Matching System will utilize the market snapshot taken pursuant to proposed paragraph (b)(2)(E) to initiate the Pricing and Satisfaction Period by taking the actions described under proposed subparagraphs (A)–(C).

Thereunder, proposed subparagraph (A) provides that the Matching System shall price all SNAP AOOs marked SNAP AOO—Pegged remaining on the SNAP AOO Queue, then rank such orders on the SNAP CHX book, pursuant to proposed Article 20, Rule 8(b)(3)(E). SNAP AOO—Pegged orders will be priced based on the market snapshot taken pursuant to proposed paragraph (b)(2)(E). Upon the completion of processing the remaining orders on the SNAP AOO Queue, the SNAP CHX book will be complete.

Proposed subparagraph (B) provides that once the process described under proposed subparagraph (A) has been completed, the Matching System shall determine the SNAP Price, as defined under Article 1, Rule 1(rr).[60] If the SNAP Price cannot be determined, the

[55] CHX Only and Post Only orders are always handled ''Do Not Route,'' even if not marked Do Not Route. *See* CHX Article 1, Rule 2(b)(1)(C) and (D).

[56] While precedent Reserve Size orders will not have a displayed portion during the SNAP Cycle, as all orders participating in a SNAP Cycle are fully-hidden, the Matching System will maintain the distinction between the displayed and reserved portions of Reserve Size orders for the purposes of ranking on the SNAP CHX book. *See supra* Section 4.

[57] The Exchange notes that the deactivation of the MTP modifier during the SNAP Cycle does not extinguish Participants' obligations regarding self-trades, pursuant to CHX Rules and securities laws and regulations. *See e.g.,* CHX Article 9, Rule 9 (Fictitious Transactions).

[58] *See infra* note 79.

[59] *See supra* Section 6.

[60] *See supra* Section 2.

Matching System shall take a snapshot of the Protected Quotation(s) of external market(s) in the subject security and the SNAP Cycle shall continue to the stage five Transition to the Open Trading State, as described below. The most obvious reason that a SNAP Price could not be determined is that there are no orders that could matched. Another reason why the SNAP Price could not be determined is if the limit order marked Start SNAP noted a SNAP minimum size condition, pursuant to proposed Article 1, Rule 2(h)(1)(B), and the minimum size condition was not met. In such a case, the SNAP Price would not be in compliance with ''CHX Rules,'' per the proposed definition. However, if the SNAP Price could be determined and one or more orders must be routed away, pursuant to proposed Article 19, Rule 3(a)(4) and/or (5), the SNAP Cycle would continue to the Satisfaction Period, pursuant to proposed subparagraph (C). If no order routing is necessary, the SNAP Cycle shall continue to the stage four Order Matching Period.

By definition, the SNAP Price will always be at a price that is in compliance with Rule 611 of Regulation NMS, LULD price bands and Rule 201 of Regulation SHO or applicable exemptive relief.[61] Specifically, the SNAP Price will be in compliance with Rule 611 of Regulation NMS through the routing of one or more Intermarket Sweep Orders (''ISOs'') to satisfy Protected Quotations of external markets, as necessary, pursuant to proposed subparagraph (C). Moreover, the SNAP Price will never be outside the LULD Price Bands.

The SNAP Price would also be in compliance with Rule 201 of Regulation SHO or applicable exemptive relief by ensuring that SNAP Eligible Orders marked Sell Short, as defined under Article 1, Rule 2(b)(3)(D), in a covered security subject to the short sale price test restriction, would never participate in a SNAP execution if the SNAP Price were determined to be at or below the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E).[62] Specifically, such SNAP Eligible Orders marked Sell Short ranked on the SNAP CHX book will never have an executable price lower than one minimum price increment above the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E) because such SNAP Eligible Orders marked Sell Short with limit prices at or below that NBB would be repriced to one minimum price increment above that NBB, whereas such SNAP Eligible Orders marked Sell Short with limit prices at one minimum price increment above that NBB or higher would be ranked on the SNAP CHX book at their limit prices without being repriced.[63] Thus, if the SNAP Price were ultimately determined to be at or below the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E), such participating SNAP Eligible Orders marked Sell Short would not be able to execute at the SNAP Price. However, if the SNAP Price were determined to be at one price increment above the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E) or higher, such SNAP Eligible Orders marked Sell Short may execute at the SNAP Price, depending on their respective executable prices and rank on the SNAP CHX book.

In order to clarify how SNAP is designed to comply with Rule 201 of Regulation SHO or applicable exemptive relief, the Exchange proposes to amend Article 20, Rule 8(d)(4) (Rule 201 of Regulation SHO).[64] Initially, the Exchange proposes to reorganize current Rule 8(d)(4) by creating subparagraphs (A) and (B). Proposed subparagraph (A) would contain the current rules concerning Rule 201 of Regulation SHO compliance during the Open Trading State, as well as the stage five Transition to the Open Trading State, as described under proposed Article 18, Rule 1(b)(5), whereas proposed subparagraph (B) would apply to Rule 201 of Regulation SHO compliance (or compliance with applicable exemptive relief) during the stage four Order Matching Period, as described under proposed Article 18, Rule 1(b)(4).[65]

Specifically, proposed subparagraph (A) provides that during the Open Trading State, as defined under proposed Article 1, Rule 1(qq), and the stage five Transition to the Open Trading State, as described under proposed Article 18, Rule 1(b)(5), orders marked Sell Short in a covered security subject to the short sale price test restriction shall be handled as described thereunder. The contents of proposed subparagraphs (A)(i)—(iv) mirror current Article 20, Rule 8(d)(4).

Proposed subparagraph (B) provides that during the stage four Order Matching Period of a SNAP Cycle, as described under proposed Article 18, Rule 1(b)(4), in a covered security subject to the short sale price test restriction, participating SNAP Eligible Orders, as defined under Article 1, Rule 1(ss), marked Sell Short shall not be permitted to execute at prices at or below the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E) and shall be handled as described thereunder.

Proposed subparagraph (B)(i) provides that a SNAP Eligible Order marked Sell Short in a covered security subject to the short sale price test restriction, with a limit price at or below the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E), shall be repriced to one minimum price increment above that NBB for ranking purposes on the SNAP CHX book. A SNAP Eligible Order marked Sell Short in a covered security subject to the short sale price test restriction, with a limit price at one minimum price increment above the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E) or higher, shall be ranked on the SNAP CHX book at its limit price, without repricing. A SNAP Eligible Order marked Short Exempt, as defined under current Article 1, Rule 2(b)(3)(E), in a covered security subject to the short sale price test restriction, shall be handled like a SNAP Eligible Order not marked Sell Short, as described under proposed Article 18, Rule 1(b). Also, a SNAP Eligible Orders marked Sell Short in a covered security subject to the short sale

[61] *See supra* note 7.

[62] *Id.* Rule 201(b)(1) of Regulation SHO provides as follows: ''A trading center shall establish, maintain, and enforce written policies and procedures reasonably designed to: (i) Prevent the execution or display of a short sale order of a covered security at a price that is less than or equal to the current national best bid if the price of that covered security decreases by 10% or more from the covered security's closing price as determined by the listing market for the covered security as of the end of regular trading hours on the prior day; and (ii) Impose the requirements of paragraph (b)(1)(i) of this section for the remainder of the day and the following day when a national best bid for the covered security is calculated and disseminated on a current and continuing basis by a plan processor pursuant to an effective national market system plan. (iii) Provided, however, that the policies and procedures must be reasonably designed to permit: (A) The execution of a displayed short sale order of a covered security by a trading center if, at the time of initial display of the short sale order, the order was at a price above the current national best bid; and (B) The execution or display of a short sale order of a covered security marked 'short exempt' without regard to whether the order is at a price that is less than or equal to the current national best bid.'' *See* ''Division of Trading and Markets: Responses to Frequency Asked Questions Concerning Rule 201 of Regulation SHO.'' U.S. Securities and Exchange Commission, 20 Jan. 2011. Web. 16 June 2014. <*http://www.sec.gov/divisions/marketreg/rule201faq.htm*>; *see also* Securities Exchange Act Release No. 50103 (July 28, 2004), 69 FR 48008 (August 6, 2004) (''Short Sales'').

[63] *See infra* Section 6, Examples referring to ''Sell Order E.''

[64] *See supra* note 7.

[65] *Id.*

price test restriction will never be permitted to execute at prices at or below the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E).

Proposed subparagraph (B)(ii) provides that the Rule 201(b)(1)(iii)(A) of Regulation SHO exception shall not apply to a SNAP Eligible Order marked Sell Short that is being transitioned to the SNAP CHX book and such an order shall be repriced, if necessary, pursuant to subparagraph (B)(i) above. This language clarifies that the Rule 201(b)(1)(iii)(A) of Regulation SHO exception would not apply to a resting Sell Short order that had been transitioned to the SNAP CHX book because the order would no longer be displayed.

Proposed subparagraph (B)(iii) provides that a limit order marked Start SNAP and Sell Short for a covered security subject to the short sale price test restriction shall not initiate a SNAP Cycle and shall be cancelled. This language mirrors the last sentence of proposed Article 1, Rule 2(h)(1)(A)(ii), which sets forth the pricing requirements for a limit order marked Start SNAP.[66]

Proposed Article 18, Rule 1(b)(3)(C) provides that if the SNAP Price requires the routing of one or more orders, pursuant to proposed Article 19, Rule 3(a)(4) and/or (5), the Exchange's routing systems shall route away the necessary SNAP Eligible Orders, or portions thereof, based on their execution priority, pursuant to proposed paragraph (b)(4)(A). The Matching System shall then delay proceeding to the stage four Order Matching Period for 200 milliseconds or until all the confirmations for routed orders have been received from away market(s), whichever occurs first. Moreover, the unexecuted remainders of orders routed away pursuant to proposed Article 19, Rule 3(a)(4) and/or (5) returned to the Matching System *prior* to the expiration of the Satisfaction Period during which the orders were routed away shall maintain their respective original execution priority within the SNAP CHX book,[67] whereas such unexecuted remainders returned to the Matching System *after* the expiration of the Satisfaction Period during which the orders were routed away shall be handled pursuant to amended Article 20, Rule 8(b)(7), as discussed below.

The purpose of the Satisfaction Period, which includes the period of time during which orders are routed away pursuant to proposed Article 19, Rule 3(a)(4) and/or (5) (''SNAP routed orders'') and the subsequent delay of up to 200 milliseconds, is to give away markets sufficient time to respond to the SNAP routed orders, so that any unexecuted SNAP routed orders would be included in the SNAP execution within the Matching System. If the Exchange receives confirmations concerning all SNAP routed orders prior to the expiration of the 200-millisecond period, the SNAP Cycle will immediately move on to the stage four Order Matching Period. At the expiration of the 200-millisecond time period, the SNAP Cycle will continue to the stage four Order Matching Period, even if the Exchange had not received confirmations for all SNAP routed orders. To the extent that the Exchange does not receive confirmation(s) for routed order(s) prior to the expiration of the 200 millisecond time period, the corresponding SNAP Eligible Order(s) would not participate in the instant SNAP Cycle. In such a case, upon the eventual receipt of the away execution or cancellation confirmation by the Matching System, the corresponding order(s) would be handled pursuant to amended Article 20, Rule 8(b)(7).

While current Article 20, Rule 8(b)(7) addresses the priority of unexecuted remainders of routed orders returned to the Matching System, it does not address such priority in the context of the SNAP Cycle. Thus, the Exchange proposes to expand Article 20, Rule 8(b)(7) to provide that an unexecuted remainder of a routed order returned to the Matching System in one or more parts shall be added to the existing balance of the related Routable Order already posted to the CHX book, *the SNAP CHX book or the SNAP AOO Queue,*[68] *as applicable*. Moreover, if no balance exists at the time a part of an unexecuted remainder of a routed order is returned to the Matching System, it shall be treated as a new incoming order, *subject to proposed Article 18, Rule 1(b)(3)(C).* As discussed above, proposed Article 18, Rule 1(b)(3)(C) provides, in pertinent part, that the unexecuted remainders of orders routed away pursuant to proposed Article 19, Rule 3(a)(4) and/or (5) returned to the Matching System prior to the expiration of the Satisfaction Period during which the orders were routed away would maintain their respective original execution priority within the SNAP CHX book and, thus, would not be treated as new incoming orders.

The Exchange also proposes to adopt two new Routing Events, as proposed Article 19, Rule 3(a)(4) and (5). In sum, proposed Article 19, Rule 3(a)(4) is designed to prevent improper trade-through(s) in compliance with Regulation NMS, whereas proposed Article 19, Rule 3(a)(5) is designed to increase the execution of participating SNAP Eligible Orders at the SNAP Price if they cannot be executed within the Matching System due to an order imbalance at the SNAP Price.[69]

Specifically, proposed paragraph (a)(4) provides that Routable Orders, or portions thereof, shall be routed away to permit SNAP Eligible Orders to be executed within the Matching System at the SNAP Price (''Routing Event #4'') in compliance with Regulation NMS.[70] Orders routed away pursuant to this Routing Event #4 shall be priced at the SNAP Price, as opposed to the contra-side Protected Quotation price, so that the routed order would maximize the chance of executions at multiple price points. Moreover, where the SNAP Price is priced at a price increment smaller than the relevant minimum price increment (*e.g.,* $10.005), the routed order shall be priced at the minimum price increment less aggressive than the SNAP Price.

Proposed paragraph (a)(5) provides that Routable Orders, or portions thereof, shall be routed away so as to execute SNAP Eligible Orders at the SNAP Price against Protected Quotations of external markets priced at the SNAP Price that could not be matched within the Matching System during a SNAP Cycle (''Routing Events #5). Routing Event #5 addresses order imbalances on the SNAP CHX book at the SNAP Price by routing away orders, or portions thereof, that could not be executed within the Matching System, only if the contra-side Protected Quotation(s) of external market(s) are priced at the SNAP Price.

Mechanically, similar to how routed orders are currently handled during the Open Trading State, SNAP Eligible Orders or portions thereof that have been routed away are placed in a pending state by the Exchange's routing systems. Away execution confirmations will result in the corresponding SNAP

[66] *See supra* Section 3.

[67] *See infra* Section 6, Examples 7 and 9 regarding ''Buy Order F.''

[68] For example, an unexecuted remainder of a partially routed SNAP AOO—Day returned to the Matching System after the conclusion of the SNAP Cycle during which the order was partially routed would be added to any existing unrouted and unexecuted balance of the same SNAP AOO—Day that was re-queued during the stage five transition the Open Trading State.

[69] Currently, Routable Orders may be routed away from the Exchange if a Routing Event, listed under Article 19, Rule 3(a) is triggered.

[70] Incidentally, the Exchange proposes to amend Article 1, Rule 1(oo) defining ''Routable Order'' to add that during a SNAP Cycle, participating SNAP Eligible Orders are always Routable Orders.

Eligible Order being released from the pending state as executed. Away cancellation confirmations, however, will be handled differently depending on when the confirmation was received. If the away cancellation confirmation is received during the Satisfaction Period, the corresponding SNAP Eligible Order would be released as cancelled and placed back in the SNAP CHX book at its original rank. If the away cancellation confirmation is received after the Satisfaction Period, but during the SNAP Cycle, or during a subsequent SNAP Cycle, the cancellation confirmation would be placed in the FIFO Queue for processing during the stage five Transition to the Open Trading State. If the away cancellation confirmation is received otherwise than during a SNAP Cycle, it shall be processed immediately upon receipt, as they are currently.

Examples 5–8 illustrate the various processes of the stage three Pricing and Satisfaction Period.[71]

Stage Four: Order Matching Period

Upon the conclusion of the stage three Pricing and Satisfaction Period, proposed paragraph (b)(4) provides that orders remaining on the SNAP CHX book, if any, shall be matched at the SNAP Price.

Proposed subparagraph (A) provides the execution priority of orders at the SNAP Price. Specifically, SNAP Eligible Orders with a Working Price at or more aggressive than the SNAP Price shall be executed in Working Price priority and if more than one such order shares the same Working Price, then as described under proposed Article 20, Rule 8(b)(3).[72] That is, orders will be executed according to their rank at the SNAP Price, except that orders with a more aggressive Working Price shall be executed first.

The Exchange utilizes the term ''Working Price,'' as opposed to ''limit price'' or ''price,'' in discussing execution priority, so as to be clear that orders with a limit price through the LULD Price Bands or marked Sell Short with a limit price at or below the NBB during a short sale price test restriction, shall only receive execution priority based on the most aggressive price at which such orders could execute (*i.e.,* Working Price) and not based on a limit price that could not be executable. For example, a SNAP Eligible buy order priced through the Upper Price Band would receive priority based on its Working Price, which is at the Upper Price Band, and a SNAP Eligible Order marked Sell Short with a limit price at or below the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E), during a short sale price test restriction of Rule 201 of Regulation SHO, would be repriced, pursuant to proposed Article 20, Rule 8(d)(4)(B)(i), and would receive priority based on its new price.[73]

It is important to note that during the Open Trading State, orders always execute at the Working Price of the resting order, pursuant to current Article 20, Rule 8(d)(1). However, as noted above, during a SNAP Cycle, participating SNAP Eligible Orders may execute at prices less aggressive than its Working Price. Thus, as an exception to current Article 20, Rule 8(d)(1), the Exchange proposes to amend Article 20, Rule 8(e)(2) to provide that during a SNAP Cycle, participating SNAP Eligible Orders shall be executed within the Matching System at the SNAP Price, pursuant to proposed Article 18, Rule 1(b)(4)(A). Incidentally, the Exchange proposes to amend the header to current Article 20, Rule 8(e) to provide that the amended rule addresses execution of certain orders, order types and auctions.

Proposed subparagraph (B) provides that upon conclusion of the matching of orders at the SNAP Price, the Matching System shall then take a snapshot of the Protected Quotation(s) of external market(s) in the subject security. Similar to the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E), this snapshot will be utilized for regulatory compliance purposes in transitioning to the Open Trading State.

Example 9 illustrates the execution priority of the stage four Order Matching Period.[74]

Stage Five: Transition to the Open Trading State

Upon conclusion of the stage two SNAP Order Acceptance Period or stage four Order Matching Period, as applicable, the Exchange shall take the following actions, pursuant to proposed Article 18, Rule 1(b)(5):

- Route away or cancel resting orders on the SNAP CHX book or transfer such resting orders to the CHX book or SNAP AOO Queue, as applicable, in preparation for the Open Trading State.
- Process the FIFO Queue.
- Notify the market that the SNAP has concluded and begin the normal dissemination of relevant market data in the subject security.

Proposed Article 18, Rule 1(b)(5) provides that upon conclusion of stages two, three or four of the SNAP Cycle, the Matching System shall utilize the relevant market snapshot taken pursuant to proposed paragraph (b)(2)(E) or (F), (b)(3)(B) or (b)(4)(B), as applicable, to transition trading in the subject security to the Open Trading State by taking the actions described under proposed subparagraphs (A)—(C).

Proposed subparagraph (A) provides that orders resting on the SNAP CHX book shall be transitioned to the CHX book and shall be ranked, pursuant to proposed Article 20, Rule 8(b)(1); routed away, pursuant to Article 19, Rule 3(a); placed in the proposed SNAP AOO Queue, pursuant to proposed Article 20, Rule 8(b)(2)(A), if the order is a SNAP AOO that may participate in a subsequent SNAP Cycle; or otherwise cancelled. All order modifiers attached to the SNAP Eligible Orders being transitioned to the CHX book that were deactivated shall be reactivated prior to transition to the CHX book.

Proposed subparagraph (B) provides that once the process under subparagraph (A) has been completed, all messages queued under the FIFO Queue, as described under proposed paragraph (b)(2)(C), shall be processed as incoming messages in the order in which they were received.[75] Thus, new orders that have been queued in the FIFO Queue may be ranked, cancelled, deactivated or routed, depending on the attached order modifiers and the relevant market snapshot.

Proposed subparagraph (C) provides that once the processes under proposed subparagraphs (A) and (B) have been completed, the Exchange will notify the market that the SNAP Cycle has concluded; publish CHX's Protected Quotation(s) in the subject security, if any; and begin the dissemination of relevant order information concerning orders resting on the CHX book, pursuant to current Article 4, Rule 1.[76]

Example 10 illustrates the various processes of the stage five Transition to the Open Trading State.[77]

Halt and Pause during a SNAP Cycle

Proposed Article 18, Rule 1(c) outlines the interplay between the SNAP Cycle and trading halts or pauses that require the Exchange to suspend trading in the subject security (''material

[71] *See infra* Section 6.

[72] *Compare e.g.,* BATS Exchange Rule 11.23(b)(2)(C).

[73] *See supra* note 7.

[74] *See infra* Section 6.

[75] Messages queued in the FIFO Queue are not considered to have been received by the Matching System.

[76] *See supra* note 43.

[77] *See infra* Section 6.

halt or pause'').[78] Currently, the Exchange suspends trading in a subject security upon receipt of a material halt or pause messages from the securities information processor (''SIP''). Since the SNAP Cycle is a sub-second process and the Matching System only draws upon the SIP data at three different points in the SNAP Cycle,[79] the Exchange proposes to require the SNAP Cycle to be aborted at those points if a material halt or pause is declared in the subject security and to unwind the SNAP Cycle in a manner consistent with current CHX Rules.[80]

Proposed paragraph (c) provides that if a material halt or pause is in effect for a subject security at the time a limit order marked Start SNAP is received, a SNAP Cycle shall not be initiated. In the event a material halt or pause has been declared for the subject security during a SNAP Cycle, the Exchange shall take the actions as described thereunder, as applicable.

Proposed paragraph (c)(1) provides that during either -1- a LULD Trading Pause or -2- a material halt or pause other than a LULD Trading Pause, the Exchange shall take the steps as described under subparagraphs (A)—(C), as applicable.

Subparagraph (A) (During stages one or two) provides that if the market snapshot taken pursuant to proposed paragraph (b)(2)(E) or (F) indicates that a material halt or pause is in effect, the SNAP Cycle shall be aborted and not proceed to stage three or stage five, as applicable. The Exchange shall then either:

(i) Cancel all orders resting on the SNAP CHX book, subject to proposed paragraph (c)(2) below, for a LULD Trading Pause; or

(ii) cancel all resting orders received during the SNAP Order Acceptance Period that have been ranked on the SNAP CHX book, but otherwise maintain all other resting orders not marked Cancel On Halt, as defined under Article 1, Rule 2(b)(1)(B), subject to proposed paragraph (c)(2) below and Article 20, Rule 12(a),[81] for a material halt or pause other than an LULD Trading Pause.

Proposed subparagraph (A)(i) is consistent with the current LULD Trading Pause rules, which requires the Exchange to cancel all orders resting on the CHX book during a LULD Trading Pause.[82]

Proposed subparagraph (A)(ii) is consistent with the current rules for a material halt or pause other than an LULD Trading Pause, which permits the Exchange to maintain all orders within the Matching System during a material halt or pause other than a LULD Trading Pause.[83] Since the SNAP CHX book could be locked and/or crossed after the conclusion of the stage two SNAP Order Acceptance Period, the Exchange proposes to unlock or uncross the SNAP CHX book by cancelling all orders received during the SNAP Order Acceptance Period, subject to proposed paragraph (c)(2) and Article 20, Rule 12(a). Thus, an uncrossed book would be achieved by essentially reverting to the state of the CHX book at the time the SNAP Cycle was initiated because the CHX book is never locked or crossed during the Open Trading State.

Subparagraph (B) (During stages three or four) provides that if the market snapshot taken pursuant to proposed paragraph (b)(3)(B) or paragraph (b)(4)(B) indicates that a material halt or pause is in effect for the subject security, the SNAP Cycle shall be aborted and will not proceed to stage five. The Exchange shall then either:

(i) Cancel the unexecuted remainders of all orders resting on the SNAP CHX book, subject to paragraph (c)(2) below, for a LULD Trading Pause; or

(ii) maintain all unexecuted resting orders not marked Cancel On Halt, subject to paragraph (c)(2) below and Article 20, Rule 12(a),[84] for a material halt or pause other than an LULD Trading Pause; provided, however, that if the SNAP Price could not be determined, pursuant to proposed paragraph (b)(3)(B) above, resting orders will be handled pursuant to proposed subparagraph (A)(ii) above.

Proposed subparagraph (B)(i) is consistent with the current LULD Trading Pause rules, which requires the Exchange to cancel all orders resting on the CHX book during a LULD Trading Pause.[85]

Proposed subparagraph (B)(ii) is consistent with the current rules for a material halt or pause other than an LULD Trading Pause, which permits the Exchange to maintain all orders within the Matching System during a material halt or pause other than a LULD Trading Pause.[86] While a SNAP Cycle that was completed through the stage four Order Matching Period would always result in an unlocked and uncrossed SNAP CHX book, a SNAP Cycle that was aborted due to an inability to determine a SNAP Price, pursuant to proposed paragraph (b)(3)(B), could result in a locked or crossed SNAP CHX book (*e.g.,* the SNAP Price did not meet the SNAP minimum execution size condition). Thus, in such a case, the Exchange proposes to handle order cancellations pursuant to proposed subparagraph (A)(ii), as discussed above.

Proposed subparagraph (C) provides that any subsequent material halt or pause shall be handled pursuant to the relevant CHX Rules.[87]

Proposed paragraph (c)(2) (SNAP AOOs) provides an exception for SNAP AOOs from the order cancellation requirements of proposed paragraph (c)(1). It provides that upon initiation of a material halt or pause, all SNAP AOOs not marked Cancel On Halt or otherwise cancelled by the order sender that are -1- on the SNAP AOO Queue or -2- resting on the SNAP CHX book and may be re-queued on the SNAP AOO Queue,[88] shall remain or be re-queued on the SNAP AOO Queue, as applicable, and not cancelled.

Proposed paragraph (c)(3) (FIFO Queue) provides that upon the initiation of a material halt or pause, the FIFO Queue shall be processed until exhausted. The FIFO Queue must be processed because messages on the FIFO Queue are not considered to have been received by the Matching System

[78] Certain trading halts initiated by away markets would be considered immaterial for the purposes of proposed CHX Article 18, Rule 1(c), because such a halt would not require the Exchange to cease trading in the subject security (*e.g.,* technical problems at an away exchange which causes other exchanges to declare self-help).

[79] As discussed above, the Matching System will take three market snapshots during the SNAP Cycle based on SIP data of away markets. The first snapshot will be taken in validating the pricing requirement of a limit order marked Start SNAP, pursuant to proposed CHX Article 1, Rule 2(h)(1)(A)(ii). The second snapshot will be taken to establish the SNAP Price and route orders, pursuant to proposed CHX Article 18, Rule 1(b)(2)(E). The third snapshot will be taken to transition orders to the Open Trading State at one of three points during a SNAP Cycle, as applicable: -1- during the stage two Order Acceptance Period, pursuant to proposed CHX Article 18, Rule 1(b)(2)(F), if a two-sided NBBO does not exist or the CHX Routing Services are unavailable; -2- during the stage three Pricing and Satisfaction Period, pursuant to proposed CHX Article 18, Rule 1(b)(3)(B), if a SNAP Price could not be determined; or during the stage four Order Matching Period, pursuant to proposed CHX Article 18, Rule 1(b)(4)(B), after the matching of orders at the SNAP Price.

[80] The Exchange has two different processes for addressing material halts or pauses. LULD trading pauses are addressed pursuant to CHX Article 20, Rule 2A(c), whereas all other material halts or pauses are addressed pursuant to paragraph .02 of CHX Article 20, Rule 1. The Exchange also has the authority to cancel orders within the Matching System, pursuant to CHX Article 20, Rule 12(a).

[81] CHX Article 20, Rule 12(a) permits the Exchange to cancel orders as it deems to be necessary to maintain fair and orderly markets if, among other places, a technical or systems issue occurs at the Exchange.

[82] *See* CHX Article 20, Rule 2A(c)(3)(A).

[83] *See* paragraph .02 of CHX Article 20, Rule 1.

[84] *See supra* note 81.

[85] *See supra* note 80.

[86] *See* paragraph .02 of CHX Article 20, Rule 1.

[87] *See supra* note 80.

[88] *See* proposed CHX Article 1, Rule 2(h)(3)(A) and (B).

until they are sent to the Matching System. Thus, the FIFO Queue messages will be handled as incoming messages and processed pursuant to proposed paragraphs (c)(4) and (c)(5).

Proposed paragraph (c)(4) (Incoming orders) provides that upon initiation of a material halt or pause and for the remainder of the material halt or pause, all incoming orders shall be rejected; provided, however, that incoming SNAP AOOs shall be placed on the SNAP AOO Queue, if the material halt or pause is not the result of a systems issue at the Exchange. That is, if the material halt or pause is the result of a systems issue at the Exchange, all incoming orders shall be rejected, without exception.

Proposed paragraph (c)(5) (Incoming cancel messages) provides that incoming cancel messages and the cancel component of cancel/replace messages shall be immediately processed during a material halt or pause. The replace component of a cancel/replace message, which is a new incoming order, would be ignored, pursuant to proposed paragraph (c)(4).

In light of the proposed paragraph (c), the Exchange proposes to amend paragraph .02 of Article 20, Rule 1 and Article 20, Rule 2A(c)(3) to provide that the actions described thereunder are subject to proposed Article 18, Rule 1(c), as the current rules do not contemplate special treatment for SNAP AOOs or the SNAP AOO Queue. The Exchange also proposes to clarify that the provisions of paragraph .02 of Article 20, Rule 1 only apply to halts or pauses, ''which requires the Exchange to suspend trading in the issue, other than a LULD Trading Pause.'' [89]

Example 5 illustrates how a trading halt or pause may abort a SNAP Cycle in progress.

SECTION SIX: Examples

The following Examples are illustrative of the SNAP Cycle, but do not exhaustively depict every possible scenario during a SNAP Cycle. Moreover, the charts used herein are illustrative and do not necessarily depict the actual technical processes involved in sorting orders.

Example 1: Precedent Orders. Assume that the NBBO for security XYZ is $10.00 × $10.01 and the short sale price test restriction is in effect. Assume that the CHX book is empty. Assume also that the Protected Quotations of external markets in security XYZ is as follows:

- *Protected Bid A* at Exchange 1 displaying 500 shares at $10.00.
- *Protected Offer A* at Exchange 2 displaying 500 shares at $10.01.
- *Protected Offer B* at Exchange 3 displaying 500 shares at $10.02.

Assume then that the Exchange receives orders in security XYZ at 10:59 a.m. during the Open Trading State in the following sequence:

- *Buy Order A* for 5000 shares priced at $10.00/share marked Reserve Size, with 1000 displayed and 4000 reserved.
- *Buy Order B* for 100 shares priced at $10.04/share marked CHX Only,[90] price slid to a Working Price of $10.01 and displayed at $10.00.
- *Buy Order C* for 100 shares priced at $9.99/share marked Cancel On SNAP.
- *Sell Order A* for 200 shares priced at $10.03/share.
- *Sell Order B* for 3,000 shares priced at $10.00/share marked SNAP AOO–Day and SNAP AOO–Pegged–Midpoint.

Under this Example 1, Buy Orders A through C and Sell Order A would be immediately posted to the CHX book and ranked in the CHX book pursuant to proposed Article 20, Rule 8(b)(1)(A)–(C) (*i.e.,* current Article 20, Rule 8(b)(1)–(3)). However, Sell Order B would be placed in the SNAP AOO Queue, pursuant to proposed Article 20, Rule 8(b)(2)(A), and not immediately ranked, as SNAP AOOs are never active during the Open Trading State.

Example 2: Initiating the SNAP Cycle. Assume the same as Example 1. Assume that at 11:00 a.m., the Matching System receives the following order:

- *Buy Order D* for 25,000 shares of security XYZ priced at $10.02/share marked Start SNAP with a minimum SNAP execution size condition noted.

Assume also that the CHX Routing Services are available and operational. Under this Example 2, Buy Order D would initiate a SNAP Cycle in security XYZ because Buy Order D meets the size, price, time and routing availability requirements of proposed Article 1, Rule 2(h)(1)(A). Thus, the Matching System would validate Buy Order D. The Exchange would then take the actions as described under proposed Article 18, Rule 1(b)(1).

The Matching System would then begin the stage two SNAP Order Acceptance Period, pursuant to Article 18, Rule 1(b)(2), as follows:

- All order modifiers listed under proposed subparagraph (D) would be deactivated.
- *Buy Order A* would be ranked on the SNAP CHX book. The 1000 displayed shares would be ranked at each price point up to its limit price of $10.00, pursuant to proposed Article 20, Rule 8(b)(3)(A), while the remaining undisplayed 4000 reserved shares would be ranked at each price point up to its limit price of $10.00, pursuant to proposed Article 20, Rule 8(b)(3)(B).
- *Buy Order B* would be ranked on the SNAP CHX book at each price point up to its limit price of $10.04, pursuant to proposed Article 20, Rule 8(b)(3)(A). In doing so, Buy Order B would be unslid from its previous Working Price of $10.00 because the CHX Only modifier would be deactivated prior to the order being ranked on the SNAP CHX book.
- *Buy Order C* would be cancelled because it is ineligible for SNAP.
- *Sell Order A* would be ranked on the SNAP CHX book at each price point down to its limit price of $10.03, pursuant to proposed Article 20, Rule 8(b)(3)(A).
- *Sell Order B* would remain on the SNAP AOO Queue, as SNAP AOOs marked SNAP AOO–Pegged are only ranked on the SNAP CHX book during the stage three Pricing and Satisfaction Period, pursuant to proposed Article 18, Rule 1(b)(3)(A).
- *Buy Order D* would be ranked on the SNAP CHX book at each price point up to its limit price of $10.02, pursuant to proposed Article 20, Rule 8(b)(3)(D).

Thus, the SNAP CHX book for security XYZ is now as follows:

SNAP CHX Book and Away Protected Quotes—Example 2

Buy orders					Sell orders			
Total *away* buy size *at* price point	Total *CHX* buy size *at* price point	Total buy size *better* than price point	Total buy size *at and better* than price point	Price point	Total sell size *at and better* than price point	Total sell size *better* than price point	Total *CHX* sell size *at* price point	Total *away* sell size *at* price point
0	0	0	0	10.05	1,200	1,200	0	0

[89] *See supra* note 78.

[90] *See* CHX Article 1, Rule 2(b)(3)(C).

SNAP CHX BOOK AND AWAY PROTECTED QUOTES—EXAMPLE 2—Continued

Buy orders				Price point	Sell orders			
Total *away* buy size *at* price point	Total *CHX* buy size *at* price point	Total buy size *better* than price point	Total buy size *at and better* than price point		Total sell size *at and better* than price point	Total sell size *better* than price point	Total *CHX* sell size *at* price point	Total *away* sell size *at* price point
0	100	0	100	10.04	1,200	1,200	0	0
0	0	100	100	10.03	1,200	1,000	200	0
0	25,000	100	25,100	10.02	1,000	500	0	500
0	0	25,100	25,100	10.01	500	0	0	500
500	5,000	25,100	30,600	10.00	0	0	0	0
0	0	30,600	30,600	9.99	0	0	0	0

Example 3: SNAP Order Acceptance Period. Assume the same as Example 2 and the eligible same day last sale in security XYZ was priced at $10.01. Assume then that during the SNAP Order Acceptance Period, the Exchange receives the following orders in security XYZ:

- *Buy Order E* for 5,000 shares of security XYZ priced at $10.03/share marked SNAP AOO–Day.
- *Sell Order C* for 25,000 shares of security XYZ at $10.00/share marked Start SNAP.
- *Sell Order D* for 100 shares of security XYZ at market.
- *Sell Order E* for 100 shares of security XYZ priced at $10.00/share marked Sell Short and Do Not Display.
- *Buy Order F* for 2,500 shares of security XYZ marked SNAP AOO—One And Done and SNAP AOO—Pegged—Market (+ three minimum price increments more aggressive).

The Exchange would handle the orders as follows:

- *Buy Order E* would be ranked on the SNAP CHX book at each price point up to its limit price of $10.03, pursuant to Article 20, Rule 8(b)(3)(E).
- *Sell Order C* would not trigger a SNAP Cycle because it was received during an ongoing SNAP Cycle, pursuant to proposed Article 1, Rule 2(h)(1)(A)(iii). However, Sell Order C would nevertheless join the SNAP Cycle in progress, pursuant to proposed Article 1, Rule 2(h)(1)(C), because it meets the minimum size requirement for SNAP AOOs, pursuant to proposed Article 1, Rule 2(h)(3). Thus, Sell Order C would be handled as SNAP AOO—One And Done and would be ranked on the SNAP CHX book at each price point down to its limit price of $10.00.
- *Sell Order D* would be immediately cancelled by the Matching System because it is a market order and, thus, not a SNAP Eligible Order.
- *Sell Order E* would be ranked on the SNAP CHX book, pursuant to Article 20, Rule 8(b)(3)(E), at each price point down to its Working Price of $10.01 and not its limit price of $10.00, pursuant to proposed Article 20, Rule 8(d)(4)(B)(i), because it is a Sell Short order priced at the NBB during a short sale price test restriction in a covered security. This would be achieved by repricing Sell Order E from $10.00 to $10.01.
- *Buy Order F* would be placed on the SNAP AOO Queue, pursuant to proposed Article 20, Rule 8(b)(2)(A), as SNAP AOOs marked SNAP AOO—Pegged are only ranked on the SNAP CHX book during the stage three Pricing and Satisfaction Period, pursuant to proposed Article 18, Rule 1(b)(3)(A).

Thus, the SNAP AOO Queue for security XYZ is as follows:

SNAP AOO QUEUE—Example 3	
1	Sell Order B.
2	Buy Order F.

Example 4: FIFO Queue. Assume the same as Example 3. Assume then that during the SNAP Order Acceptance Period, the Exchange receives the following messages in order:

- *Cancel Buy Order B.*
- *Cross Order A* for 100,000 shares of security XYZ priced at $10.01/share.

Under this Example 4, the Exchange will place Cancel Buy Order B and Cross Order A in the FIFO Queue, pursuant to proposed Article 18, Rule 1(b)(2)(C), in the order in which they were received.

Thus, the FIFO Queue for security XYZ is as follows:

FIFO QUEUE—Example 4	
1	Cancel Buy Order B.
2	Cross Order A.

Example 5: SNAP AOO Queue Processing. Assume the same as Example 4 and that the SNAP Order Acceptance Period ends without any additional orders received. Assume also that the market snapshot taken of security XYZ, pursuant to proposed Article 18, Rule 1(b)(2)(E), remains unchanged from Example 1.

Assuming that the market snapshot does not indicate that a material halt or pause has been issued in the security and that the CHX Routing Services are available, the SNAP Cycle would continue to the stage three Pricing and Satisfaction Period.

Thus, pursuant to proposed Article 18, Rule 1(b)(3)(A), the Matching System would utilize that single market snapshot and process the SNAP AOO Queue and rank such orders on the SNAP CHX book as follows:

- *Sell Order B* would be processed first and since Sell Order B is marked SNAP AOO—Midpoint, the Matching System will utilize the latest market snapshot to determine the NBBO midpoint price of $10.005. Since $10.005 is less aggressive than the stated limit price of Sell Order B of $10.00, pursuant to proposed Article 1, Rule 2(h)(3)(C), the Matching System will rank all 3,000 shares of Sell Order B at each price point down to $10.005.
- *Buy Order F* would then be processed and since Buy Order F is marked SNAP AOO—Market (+ three minimum price increments more aggressive) and does not have an optional limit price noted, the Matching System will rank all 2,500 shares of Buy Order F at each price point up to three minimum price increments more aggressive than the NBO, which is $10.04.

Thus, the SNAP CHX book for security XYZ is now as follows:

SNAP CHX BOOK AND AWAY PROTECTED QUOTES—EXAMPLE 5

Buy orders				Price point	Sell orders			
Total *away* buy size *at* price point	Total *CHX* buy size *at* price point	Total buy size *better* than price point	Total buy size *at and better* than price point		Total sell size *at and better* than price point	Total sell size *better* than price point	Total *CHX* sell size *at* price point	Total *away* sell size *at* price point
0	0	0	0	10.05	29,300	29,300	0	0
0	2,600	0	2,600	10.04	29,300	29,300	0	0
0	5,000	2,600	7,600	10.03	29,300	29,100	200	0
0	25,000	7,600	32,600	10.02	29,100	28,600	0	500
0	0	32,600	32,600	10.01	28,600	28,000	100	500
0	0	32,600	32,600	10.005	28,000	25,000	3,000	0
500	5,000	32,600	38,100	10.00	25,000	0	25,000	0
0	0	38,100	38,100	9.99	0	0	0	0

If, however, the market snapshot indicated that a relevant trading halt or pause was issued in the subject security, the SNAP Cycle would not continue to the stage three Pricing and Satisfaction Period and the SNAP would be unwound pursuant to proposed Article 18, Rule 1(c). Similarly, if the CHX Routing Services were not available at the conclusion of the stage two SNAP Order Acceptance Period, the SNAP Cycle would immediately proceed to the stage five Transition to the Open Trading State.

Example 6: SNAP Price and Minimum Size Condition. Assume the same as Example 5. The Matching System will now attempt to establish the SNAP Price, pursuant to proposed Article 18, Rule 1(b)(3)(B). Pursuant to proposed Article 1, Rule 1(rr), the SNAP Price is a single price at which the greatest number of shares may be executed during a SNAP Cycle, which would not trade-through any more aggressively priced orders on either side of the market. The size requirement is inclusive of all executions that may result during the SNAP Cycle, which would include executions within and without the Matching System.

Under this Example 6, the SNAP Price is determined by ascertaining the price point with the greatest number of shares that may be executed. Pursuant to the Example 5 chart, that price point would be $10.02, with 29,100 executable shares (*i.e.,* 1,000 executable shares away and 28,100 executable shares within the Matching System).

The next step would be to ensure that no orders priced more aggressively than $10.02 on the SNAP CHX book would be traded-through by verifying that -1- the total buy size at and better than $10.02, minus away size, is equal to or greater than the total sell size better than $10.02 (*i.e.,* 32,600 ≥ 28,600) *and* -2- the total sell size at and better than $10.02, minus away size, is equal to or greater than the total buy size better than $10.02 (*i.e.,* 28,100 ≥ 7,600). Thus, the total executable size within the Matching System on one side of the market will cover all orders that *must* be executed within the Matching System on the other side of the market to avoid an impermissible trade-through of the CHX book and Protected Quotations of external markets. This requirement is satisfied at $10.02. Since Buy Order D noted a minimum SNAP execution size condition, the SNAP Price will only be $10.02, if the size requirement, as described under proposed Article 1, Rule 2(h)(1)(B), is met.

Under this Example 6, the sum of the minimum number of shares that could be executed within the Matching System (*i.e.,* 28,100), plus all shares that are to be routed away (*i.e.,* 1,000 shares), equals 29,100 shares, which is greater than the minimum size requirement that was necessary to trigger the instant SNAP Cycle (*i.e.,* 25,000 shares). Thus, the minimum size condition is met and the SNAP Price will be $10.02.

Example 7: Satisfaction Period. Assume the same as Example 6. Since execution at the SNAP Price of $10.02 would result in one or more orders, or portions thereof, to be routed away (*i.e.,* to satisfy Protected Offers A and B), the SNAP Cycle will enter the Satisfaction Period prior to matching orders within the Matching System at the SNAP Price.

Pursuant to proposed Article 18, Rule 1(b)(3)(C), orders to be routed away would be selected based on their execution priority, in a manner consistent with proposed Article 19, Rule 3(a)(4). After routing orders away, the Matching System will delay executing the 28,100 shares within the Matching System for 200 milliseconds or until all confirmations are received from away markets, whichever is sooner.

Under this Example 7, execution priority on the buy side is as follows:

- *Buy Order B* for 100 shares, with a Working Price of $10.04.
- *Buy Order F* for 2,500 shares, with a Working Price of $10.04.
- *Buy Order E* for 5,000 shares with a Working Price of $10.03.
- *Buy Order D* for 25,000 shares, with a Working Price of $10.02. Whereas, execution priority on the sell side is as follows:
- *Sell Order C* for 25,000 shares, with a Working Price of $10.00.
- *Sell Order B* for 3,000 shares, with a Working Price of $10.005.
- *Sell Order E* for 100 shares, with a Working Price of $10.01.

Pursuant to proposed Article 19, Rule 3(a)(4), the Exchange's routing systems would route away one corresponding routing buy order for 500 shares of security XYZ priced at $10.02/share to execute against the 500 displayed shares of Protected Offer A at $10.01, representing 100 shares of Buy Order B and 400 shares of Buy Order F (''Routed Order A''). In addition, pursuant to proposed Article 19, Rule 3(a)(5), the Exchange's routing systems would route away one corresponding routing buy order for 500 shares of security XYZ priced at $10.02/share to execute against the 500 displayed shares of Protected Offer B at $10.02, representing the next 500 shares of Buy Order F (''Routed Order B''). During the Satisfaction Period, the routed portions of Buy Orders B and F will enter a pending state on the Exchange's routing systems. The routed portions of Buy Orders B and F will be released as either executed or cancelled, depending on the confirmation returned from the away market.

Assume then that within the Satisfaction Period, the Matching System receives an order execution confirmation for Routed Order A and a cancellation confirmation for Routed Order B. In this case, -1- all 100 shares of Buy Order B and -2- 400 shares of Buy Order F represented by Routed

Order A would be released as executed. However, the 500 shares of Buy Order F represented by Routed Order B would be released as unexecuted and would join the existing balance of Buy Order F at its original rank on the SNAP CHX book.

Example 8: SNAP Eligible Order received after SNAP Order Acceptance Period. Assume the same as Example 7 and that during the Satisfaction Period, the Exchange receives the following orders:

- *Buy Order G* for 100 shares of security XYZ priced at $10.03/share.
- *Sell Order F* for 100 shares of security XYZ priced at $10.02/share marked Post Only.
- *Buy Order H* for 5,000 shares of security XYZ priced at $10.02/share marked SNAP AOO—One And Done.
- *Buy Order I* for 100 shares of security XYZ priced at $10.03/share.
- *Buy Order J* for 100 shares of security XYZ priced at $10.02/share marked IOC. Pursuant to proposed Article 18, Rule 1(b)(2)(B)(i), incoming SNAP Eligible Orders that are received after the SNAP Order Acceptance Period, but during a SNAP Cycle, will be placed in the FIFO Queue, pursuant to proposed subparagraph (C). Pursuant to proposed Article 18, Rule 1(b)(2)(B)(ii), incoming non-SNAP Eligible Orders will be immediately cancelled.

Since Buy Orders G—I and Sell Order F are SNAP Eligible Orders, they will all be placed in the FIFO Queue, which is now as follows:

FIFO QUEUE—Example 8	
1	Cancel Buy Order B.
2	Cross Order A.
3	Buy Order G.
4	Sell Order F.
5	Buy Order H.
6	Buy Order I.

Buy Order J will be immediately cancelled because it is non-SNAP Eligible Order by virtue of its IOC designation.

Example 9: Order Matching. Assume the same as Example 8.

Upon conclusion of the Satisfaction Period, the SNAP Cycle would continue to the stage four Order Matching Period and execute 28,100 shares within the Matching System at the SNAP Price of $10.02, in the following priority, pursuant to proposed Article 18, Rule 1(b)(4)(A):

Under this Example 9, execution priority on the buy side is as follows:

- *Buy Order F* for the remaining 2,100 shares.
- *Buy Order E* for all 5,000 shares.
- *Buy Order D* for 21,000 shares, with 4,000 shares remaining unexecuted.[91]

Whereas, execution priority on the sell side is as follows:

- *Sell Order C* for 25,000 shares.
- *Sell Order B* for 3,000 shares.
- *Sell Order E* for 100 shares.

These orders are matched by the Matching System and each trade is reported first to the appropriate SIP and then to the parties of each side of the trade as follows:

Buy order	Sell order	Number of shares	Trade price
F	C	2,100	10.02
E	C	5,000	10.02
D	C	17,900	10.02
D	E	100	10.02
D	B	3,000	10.02

Thus, the SNAP CHX book after execution at the SNAP Price would be as follows:

SNAP CHX Book and Away Protected Quotes—Example 9

Buy Orders				Price point	Sell Orders			
Total *away* buy size *at* price point	Total *CHX* buy size *at* price point	Total buy size *better* than price point	Total buy size *at and better* than price point		Total sell size *at and better* than price point	Total sell size *better* than price point	Total *CHX* sell size *at* price point	Total *away* sell size *at* price point
0	0	0	0	10.05	200	200	0	0
0	0	0	0	10.04	200	200	0	0
0	0	0	0	10.03	200	0	200 (A)	0
0	4,000 (D)	0	4,000	10.02	0	0	0	0
0	0	4,000	4,000	10.01	0	0	0	0
0	0	4,000	4,000	10.005	0	0	0	0
0	5,000 (A)	4,000	9,000	10.00	0	0	0	0
0	0	9,000	9,000	9.99	0	0	0	0

The only remaining orders are the unexecuted balance of Buy Order D, Buy Order A and Sell Order A.

Example 10: Transition to Open Trading State. Assume the same as Example 9. Assume also that after executing the orders within the Matching System at the SNAP Price, the Matching System takes another market snapshot of security XYZ, pursuant to proposed Article 18, Rule 1(b)(4)(B),

[91] Note that while the minimum execution size condition of 25,000 shares was met, Buy Order D received an execution size less than the minimum. This may result if there are orders on the SNAP CHX book, on the same side of the market as a Start SNAP order, that have more aggressive Working Prices.

which shows that the NBBO for security XYZ is now $10.02 x. $10.03. Assume also that the Protected Quotations of away markets in security XYZ is as follows:

- *Protected Bid B* on Exchange 4 displaying 100 shares at $10.02.
- *Protected Offer C* on Exchange 5 displaying 100 shares at $10.03.

Under this Example 10, the Matching System will utilize the above market snapshot in security XYZ to transition the remaining unexecuted resting orders on the SNAP CHX book to the CHX book, pursuant to proposed Article 18, Rule 1(b)(5)(A), as follows:

- *Buy Order A* would post to the CHX book at $10.00, with the 1,000 displayed shares ranked, pursuant to proposed Article 20, Rule 8(b)(1)(A), and the 4,000 undisplayed reserved shares ranked, pursuant to proposed Article 20, Rule 8(b)(1)(B).
- *Sell Order A* would post to the CHX book at $10.03 and ranked, pursuant to proposed Article 20, Rule 8(b)(1)(A).
- *Buy Order D* would be cancelled as limit orders marked Start SNAP are never eligible for the Open Trading State.

The Matching System will then process the FIFO Queue, pursuant to proposed Article 18, Rule 1(b)(5)(B), as follows:

- *Cancel Buy Order B* message would have no effect because Buy Order B was fully executed during the stage three Satisfaction Period.[92]
- *Cross Order A* would be cancelled because execution at the crossing price of $10.01 would result in an impermissible trade-through of Protected Bid B at $10.02, in violation of Rule 611 of Regulation NMS.
- *Buy Order G* would execute against 100 shares of Sell Order A at $10.03, leaving Sell Order A with 100 shares at $10.03.
- *Sell Order F* would be cancelled pursuant to its Post Only designation because it would impermissible lock the NBO at $10.02 and it is not routable.
- *Buy Order H* would be placed in the SNAP AOO Queue, since it was received after the SNAP Order Acceptance Period and is, thus, eligible for the next SNAP Cycle that is initiated.
- *Buy Order I* would execute against the remaining 100 shares of Sell Order A at $10.03.

Thus, the only remaining order on the CHX book is Buy Order A for 5,000 shares (*i.e.,* 1,000 displayed and 4,000 undisplayed) at $10.00.

Immediately after the FIFO Queue has been processed, pursuant to proposed Article 18, Rule 1(b)(5)(C), the Exchange will notify the market that the SNAP has concluded; publish its Protected Bid at $10.00 for 1,000 shares; and begin dissemination of information through the CHX Book Feed, including information regarding the displayable portions of all orders posted to the CHX book (*i.e.,* 1,000 displayed shares of Buy Order A).

Section Seven: Market Maker Requirements

The Exchange does not propose to include any market making requirements with regards to SNAP. Pursuant to current Article 16, Rule 8, Participant Market Makers in a security are required to maintain two-sided quotes in the security and to meet certain pricing obligations concerning such quotes, during the regular trading session. As such, the current requirements would only be applicable during the Open Trading State, which is the only time during the regular trading session when quotes would be displayed and automatically executable. Thus, the current requirements are inapplicable to SNAP Cycles because quotes are never displayed and never automatically executable during a SNAP Cycle. Moreover, in light of the substantial size and aggressive pricing requirements to initiate a SNAP Cycle, the Exchange does not believe it appropriate, at this time, to propose additional requirements for Participant Market Makers with regards to SNAP.

Thus, the Exchange proposes to amend Article 16, Rule 8(a) to provide that the current two-sided quote and pricing obligations for Participant Market Makers only apply during the Open Trading State. Incidentally, the Exchange proposes to amend an obsolete reference to ''member'' with the more accurate ''Participant,'' under paragraph (a)(1).

Section Eight: Operative Date

In the event the proposed rule change is approved by the SEC, the Exchange proposes to make the proposed rule change operative pursuant to two weeks' notice by the Exchange to its Participants via Regulatory Notice. Prior to the operative date, the Exchange will ensure that policies and procedures are in place to allow Exchange operations personnel to effectively monitor the use of the SNAP functionality. The Exchange will also ensure that any special notices required pursuant to the proposed rule change will be made to Participants, including notices regarding securities that will not be eligible for SNAP.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act in general,[93] and furthers the objectives of Section 6(b)(5) in particular,[94] in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments and perfect the mechanisms of a free and open market, and, in general, to protect investors and the public interest.

The Exchange believes that SNAP will further the objectives of Section 6(b)(5) of the Act precisely because it will address a market need, as noted by Chair White, for a trading service that deemphasizes speed as a key to trading success in order to further serve the interests of investors,[95] which will operate in compliance with Regulation NMS and Rule 201 of Regulation SHO or applicable exemptive relief.[96]

In recent years, market participants seeking to trade securities in bulk have largely avoided exchanges due to a lack of trading services that sufficiently minimize the downside of exposing large orders to the market, which may include unfavorable market activity in response to the posting of a large displayed order and insufficient displayed liquidity, both of which result in inadequate price discovery for bulk orders. It is a vicious cycle: market participants seeking to execute bulk orders in whole at marketable or even hypermarketable prices are frequently unable to find sufficient liquidity on exchanges, whereas market participants wishing to provide bulk liquidity to the market are unwilling to display such orders on an exchange due to the inevitable and unfavorable market activity to follow.

The Exchange believes that the key to bulk trading success on an exchange is a functionality that momentarily consolidates trading interest in a security in one place, while automated trading in the security continues elsewhere in the national market system, and to permit such orders to interact on a fully-hidden book based on a set of carefully-designed rules that minimize the downside of exposing large orders to the market. The Exchange submits that SNAP is precisely such a functionality because it would enhance market liquidity and the price discovery process, while

[92] *See supra* Example 7.

[93] 15 U.S.C. 78f(b).

[94] 15 U.S.C. 78f(b)(5).

[95] *See supra* note 4.

[96] *See supra* note 7.

minimizing information leakage and speed advantages.

The Exchange believes that incentivizing market participants to initiate and respond to SNAPs would remove impediments and perfect the mechanisms of a free and open market because it would enhance market liquidity. In order to incentivize market participants to initiate SNAP Cycles, upon initiation of a SNAP Cycle, the Exchange will notify the market that a SNAP Cycle has been initiated, which gives the Start SNAP order sender the benefit of notifying the market of its bulk trading interest, without giving away crucial details, such as exact price, size or side of the Start SNAP order, that could disadvantage the Start SNAP order sender.[97] In turn, market participants will be incentivized to respond to SNAP Cycles knowing that a SNAP Cycle will only be initiated by a valid marketable or hypermarketable Start SNAP order that meets a substantial minimum size requirement.[98] Also, market participants will also know that SNAP AOOs that could participate in a SNAP Cycle will also be ranked on the SNAP CHX book, all of which must meet a substantial minimum size requirement, thereby potentially increasing the size of interest on the SNAP CHX book.[99] Moreover, SNAP will further incentivize market participants to participate in SNAP Cycles by prohibiting order cancellations during a SNAP Cycle, which will assure potential order senders that the Start SNAP order that initiated the SNAP Cycle, as well as any other orders participating in the instant SNAP Cycle, will not be cancelled, and has the additional effect of encouraging order senders to submit *bona fide* SNAP Eligible Orders.[100] In light of all of these characteristics, the market will be on notice that aggressively priced interest of a substantial size is guaranteed to exist at CHX.

Similarly, the Exchange believes that incentivizing market participants to initiate and respond to SNAPs would remove impediments and perfect the mechanisms of a free and open market because it would enhance the price discovery process. That is, SNAP would enhance the price discovery process through enhanced market liquidity. Specifically, the concentration of liquidity at CHX combined with the aggressive pricing requirement of the Start SNAP order will maximize the probability of overlap of orders at one or more price points. If overlap exists, a SNAP Price will be determined pursuant to a ruled-based algorithm that balances maximum execution size with an execution price that accurately reflects market demand.[101] As such, SNAP Eligible Order senders can submit aggressively priced orders knowing that the SNAP Price will be equitable, which enhances the price discovery process.

The Exchange further believes that certain aspects of SNAP designed to minimize information leakage concerning orders participating in a SNAP Cycle would promote just and equitable principles of trade and remove impediments and perfect the mechanisms of a free and open market because such measures would minimize the probability of unfavorable market activity in response to a SNAP that could disadvantage orders participating in a SNAP Cycle and, in particular, the Start SNAP order. Specifically, this would be achieved by requiring the SNAP CHX book to be fully-hidden and market data dissemination to be suspended during the SNAP Cycle (except for SNAP execution reports to the relevant SIP and order senders).[102] Also, since orders are only executed within the Matching System during the stage four Order Matching Period, market participants will be prevented from ''pinging'' the SNAP CHX book in an attempt to glean the contents of the book.[103] Moreover, a Start SNAP order sender has the option to place a minimum SNAP execution size condition equal to the minimum size requirement to initiate a SNAP Cycle, which prevents the market from being able to deduce crucial information concerning the Start SNAP order without maximizing the probability of substantial executions.[104]

The Exchange also believes that the fact that SNAP would never be scheduled and that the length of the SNAP Order Acceptance Period would be randomized would promote just and equitable principles of trade and remove impediments and perfect the mechanisms of a free and open market because such aspects deemphasize speed as a key for trading success. For example, by randomizing key aspects of the SNAP Cycle, market participants will not be able to utilize speed advantages to ascertain precisely when a SNAP Cycle will be initiated and when certain events during a SNAP Cycle will begin or end. That is, since SNAP Cycles are never scheduled, market participants, other than the Start SNAP order sender, will never know precisely when a SNAP Cycle will be initiated.[105] Similarly, since the stage two SNAP Order Acceptance Period is randomized, within a time frame of 475 to 525 milliseconds, market participants will never be able to know exactly when the SNAP Order Acceptance Period will end.[106] At the same time, the Exchange believes that 475 to 525 milliseconds is sufficient time for virtually all order senders to submit SNAP Eligible Orders in response to a SNAP Cycle notification.

The Exchange further believes that the special order ranking plan and new order modifiers for SNAP promote just and equitable principles of trade and remove impediments and perfect the mechanisms of a free and open market because such aspects also deemphasize speed as a key for trading success. Specifically, SNAP Eligible Orders received in response to a SNAP Cycle notification will be subordinated in rank on the SNAP CHX book to all precedent SNAP Eligible Orders.[107] Thus, market participants submitting orders in response to a notice of a SNAP Cycle will never be able to utilize speed advantages to achieve priority over precedent resting SNAP Eligible Orders. Moreover, SNAP AOOs further minimize speed advantages by permitting order senders to submit SNAP AOOs from as early as the beginning of the early session,[108] well before a SNAP Cycle could be initiated.[109] Thus, an order sender could submit a SNAP AOO before a SNAP Cycle is initiated knowing that that order will never lose priority to orders received during a subsequent SNAP Order Acceptance Period. Similarly, SNAP AOO—Pegged further minimize speed advantages by obviating the need to directly consume and process market data at the crucial moment when the order is submitted because such orders will be priced at the last possible moment, after the end of the SNAP Order Acceptance Period, by the Exchange's systems, which will utilize the most recent market data.[110]

In adopting Regulation NMS, the SEC highlighted the importance of maintaining an appropriate balance between competition among markets

[97] *See* proposed CHX Article 18, Rule 1(b)(1)(A).

[98] *See* proposed CHX Article 1, Rule 2(h)(1)(A).

[99] *See* proposed CHX Article 1, Rule 2(h)(3).

[100] *See* proposed CHX Article 18, Rule 1(b)(2)(C)(i).

[101] *See* proposed CHX Article 1, Rule 1(rr); *see also supra* Section 6, Example 6.

[102] *See* proposed CHX Article 18, Rule 1(a) and (b)(1).

[103] *See* proposed CHX Article 18, Rule 1(b)(4).

[104] *See* proposed CHX Article 1, Rule 2(h)(1)(B).

[105] *See* proposed CHX Article 18, Rule 1(a).

[106] *See* proposed CHX Article 18, Rule 1(b)(2).

[107] *See* proposed CHX Article 20, Rule 8(b)(3).

[108] *See supra* note 26.

[109] *See* proposed CHX Article 1, Rule 2(h)(3).

[110] *See* proposed CHX Article 1, Rule 2(h)(3)(C).

and competition among orders.[111] Specifically, the SEC stated, ''vigorous competition among markets promotes more efficient and innovative trading services, while integrated competition among orders promotes more efficient pricing of individual stocks for all types of orders, large and small.'' [112] The SEC noted, however, the difficulty in striking that balance in that ''competition among multiple markets trading the same stock can detract from the most vigorous competition among orders in an individual stock, thereby impeding efficient price discovery for orders of all sizes.'' [113] The Exchange believes that SNAP is consistent with these concepts because it is an innovative functionality that promotes competition among markets by enhancing the price discovery process for orders of all sizes, thereby also promoting competition among orders. As such, the Exchange believes that SNAP would further the objectives of Section 6(b)(5) the Act precisely because it would operate consistently with Regulation NMS [114] and Rule 201 of Regulation SHO or applicable exemptive relief.[115]

Specifically, SNAP will be compliant with the Order Protection Rule of Rule 611 of Regulation NMS.[116] SNAP executions during the stage four Order Matching Period will only occur after the routing of one or more ISOs to execute against the Protected Quotations of external markets priced better than the SNAP Price.[117] In addition, where there are additional orders resting on the SNAP CHX book at the SNAP Price that could not be executed within the Matching System during the stage four Order Matching Period, but could be executed against Protected Quotations of external markets at the SNAP Price, the Exchange will route those orders to execute against such Protected Quotations, even though such routing is not required by Rule 611 of Regulation NMS.[118] Thus, SNAP routing is compliant with Rule 611 of Regulation NMS because executions at the SNAP Price will never impermissibly trade-through better priced Protected Quotations of external markets.

With respect to the proposed queuing of cross orders on the FIFO Queue received during a SNAP Cycle for later processing during the stage five Transition to the Open Trading State,[119] the Exchange believes that the queuing of cross orders marked Qualified Contingent Transaction (''QCT'') during a SNAP Cycle will have no material impact on its ability to meet all of the requirements for the QCT exemption.[120]

The SEC defines ''QCT'' as a transaction consisting of two or more component orders, executed as agent or principal, where:

(1) At least one component order is in an NMS stock;

(2) all components are effected with a product or price contingency that either has been agreed to by the respective counterparties or arranged for by a broker-dealer as principal or agent;

(3) the execution of one component is contingent upon the execution of all other components at or near the same time;

(4) the specific relationship between the component orders (*e.g.,* the spread between the prices of the component orders) is determined at the time the contingent order is placed;

(5) the component orders bear a derivative relationship to one another, represent different classes of shares of the same issuer, or involve the securities of participants in mergers or with intentions to merge that have been announced or since cancelled; and

(6) the Exempted NMS Stock Transaction is fully hedged (without regard to any prior existing position) as a result of the other components of the contingent trade.[121]

The proposed queuing of QCTs on the FIFO Queue only implicates the QCT timing requirement because the proposed queuing would only impact the timing of the QCT execution. However, the Exchange believes that the momentary delay resulting from the proposed queuing would be immaterial because of the fact that the execution of the different components that comprise QCTs usually take many seconds, if not minutes, to accomplish. This is because the packaging of QCTs is inherently a manual process that frequently involves numerous broker-dealers representing several counter-parties with two or more component orders to be executed on two or more venues. In fact, this reality is recognized by the QCT exemption itself through the timing requirement of ''at or *near* the same time,'' which does not note a specific time requirement.[122]

SNAP is also consistent with Rule 201 of Regulation SHO or applicable exemptive relief.[123] Specifically, SNAP Eligible Orders marked Sell Short in a covered security subject to the short sale price test restriction will never be permitted to execute at prices at or below the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E). For SNAP Eligible Orders marked Sell Short with a limit price at one minimum price increment above the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E) or higher, such orders would simply be ranked on the SNAP CHX book at its limit price. However, for SNAP Eligible Orders marked Sell Short with a limit price at or below the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E), the Matching System would reprice such orders to one minimum price increment above that NBB and rank such orders on the SNAP CHX book at the new higher price.[124] Thus, if the SNAP Price is ultimately determined to be at or below the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E), during a short sale price test restriction, this ranking methodology would ensure that SNAP Eligible Orders marked Sell Short would not participate in the SNAP execution, as such orders would never have an executable price lower than one minimum price increment above the NBB ascertained from the market snapshot taken pursuant to proposed Article 18, Rule 1(b)(2)(E).[125]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that any burden on competition is necessary and

[111] *See* Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005) (''NMS Release'').

[112] *Id.*

[113] *Id.*

[114] 17 CFR 242.611.

[115] *See supra* note 7; 17 CFR 242.201.

[116] Since the Exchange will remove its Protected Quotations in the subject security, if any, upon the initiation of a SNAP Cycle and will not disseminate Protected Quotations in the subject security until the end of the SNAP Cycle, SNAP does not implicate any Rule 610 of Regulation NMS issues.

[117] *See* proposed CHX Article 19, Rule 3(a)(4).

[118] *See* proposed CHX Article 19, Rule 3(a)(5).

[119] *See* proposed CHX Article 18, Rule 1(b)(2)(C)(iv).

[120] *See* Securities Exchange Act Release No. 54389 (August 31, 2006), 71 FR 52829 (September 7, 2006) (''Order Granting an Exemption for Qualified Contingent Trades From Rule 611(a) of Regulation NMS Under the Securities Exchange Act of 1934''); *see also* Securities Exchange Act Release No. 57620 (April 4, 2008), 73 FR 19271 (April 4, 2008) [sic] (''Order Modifying the Exemption for Qualified Contingent Trades From Rule 611(a) of Regulation NMS Under the Securities Exchange Act of 1934''); *see also* Article 1, Rule 2(b)(2)(E).

[121] *See id.*

[122] *See id* (emphasis added).

[123] *See supra* note 7.

[124] *See* proposed CHX Article 20, Rule 8(d)(4)(B)(i).

[125] *See* proposed CHX Article 18, Rule 1(b)(4)(A).

appropriate in furtherance of the purposes of Section 6(b)(5) of the Act because SNAP is an initiative that seeks to deemphasize speed as a key to trading success in order to further serve the interests of investors, as recently noted by Chair White, and thereby removes impediments and perfects the mechanisms of a free and open market.[126]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

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–CHX–2015–03 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–CHX–2015–03. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CHX–2015–03, and should be submitted on or before July 29, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[127]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–16651 Filed 7–7–15; 8:45 am]

BILLING CODE 8011–01–P

[126] *See supra* note 4; *see also supra* Statutory Basis.

[127] 17 CFR 200.30–3(a)(12).

SUSQUEHANNA RIVER BASIN COMMISSION

Public Hearing

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: The Susquehanna River Basin Commission will hold a public hearing on August 6, 2015, in Grantville, Pennsylvania. At this public hearing, the Commission will hear testimony on the projects listed in the Supplementary Information section of this notice. Such projects are intended to be scheduled for Commission action at its next business meeting, tentatively scheduled for September 10, 2015, which will be noticed separately. The Commission will also hear testimony on amending the *Comprehensive Plan for the Water Resources of the Susquehanna River Basin*. The public should take note that this public hearing will be the only opportunity to offer oral comment to the Commission for the listed projects and other items. The deadline for the submission of written comments is August 17, 2015.

DATES: The public hearing will convene on August 6, 2015, at 7:00 p.m. The public hearing will end at 9:00 p.m. or at the conclusion of public testimony, whichever is sooner. The deadline for the submission of written comments is August 17, 2015.

ADDRESSES: The public hearing will be conducted at the East Hanover Township Municipal Building, Main Hall, 8848 Jonestown Road, Grantville, PA 17028 (parking lot entry off of Manada Gap Road; see *http://easthanovertwpdcpa.org/index.php/about-contact*).

FOR FURTHER INFORMATION CONTACT: Jason Oyler, General Counsel, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436. Information concerning the applications for these projects is available at the SRBC Water Resource Portal at *www.srbc.net/wrp.* Additional supporting documents are available to inspect and copy in accordance with the Commission's Access to Records Policy at *www.srbc.net/pubinfo/docs/2009-02_Access_to_Records_Policy_20140115.pdf.*

SUPPLEMENTARY INFORMATION: The public hearing will cover amendments to the *Comprehensive Plan for the Water Resources of the Susquehanna River Basin.* The public hearing will also cover the following projects:

Projects Scheduled for Action

1. Project Sponsor and Facility: Caernarvon Township Authority, Caernarvon Township, Berks County, Pa. Application for groundwater withdrawal of up to 0.763 mgd (30-day average) from Well 7.

2. Project Sponsor and Facility: Chetremon Golf Course, LLC, Burnside Township, Clearfield County, Pa. Application for consumptive water use of up to 0.200 mgd (peak day).

3. Project Sponsor and Facility: Chetremon Golf Course, LLC (Irrigation Storage Pond), Burnside Township, Clearfield County, Pa. Application for surface water withdrawal of up to 0.200 mgd (peak day).

4. Project Sponsor and Facility: Chief Oil & Gas LLC (Loyalsock Creek), Forksville Borough, Sullivan County, Pa. Application for surface water withdrawal of up to 2.000 mgd (peak day).

5. Project Sponsor and Facility: Furman Foods, Inc., Point Township, Northumberland County, Pa.

Application for renewal of groundwater withdrawal of up to 0.320 mgd (30-day average) from Well 1 (Docket No. 19850901).

6. Project Sponsor and Facility: Furman Foods, Inc., Point Township, Northumberland County, Pa. Application for renewal of groundwater withdrawal of up to 0.190 mgd (30-day average) from Well 4 (Docket No. 19850901).

7. Project Sponsor and Facility: Furman Foods, Inc., Point Township, Northumberland County, Pa. Application for renewal of groundwater withdrawal of up to 0.090 mgd (30-day average) from Well 7 (Docket No. 19850901).

8. Project Sponsor and Facility: JELD–WEN, inc. Fiber Division—PA, Wysox Township, Bradford County, Pa. Application for groundwater withdrawal of up to 0.252 mgd (30-day average) from Well 1.

9. Project Sponsor and Facility: JELD–WEN, inc. Fiber Division—PA, Wysox Township, Bradford County, Pa. Application for groundwater withdrawal of up to 0.252 mgd (30-day average) from Well 4.

10. Project Sponsor and Facility: JELD–WEN, inc. Fiber Division—PA, Wysox Township, Bradford County, Pa. Application for groundwater withdrawal of up to 0.323 mgd (30-day average) from Well 5.

11. Project Sponsor and Facility: JELD–WEN, inc. Fiber Division—PA, Wysox Township, Bradford County, Pa. Application for groundwater withdrawal of up to 0.323 mgd (30-day average) from Well 6.

12. Project Sponsor and Facility: JELD–WEN, inc. Fiber Division—PA, Wysox Township, Bradford County, Pa. Application for groundwater withdrawal of up to 0.345 mgd (30-day average) from Well 7.

13. Project Sponsor and Facility: JELD–WEN, inc. Fiber Division—PA, Wysox Township, Bradford County, Pa. Application for consumptive water use of up to 0.424 mgd (peak day).

14. Project Sponsor and Facility: Keister Miller Investments, LLC (West Branch Susquehanna River), Mahaffey Borough, Clearfield County, Pa. Application for surface water withdrawal of up to 2.000 mgd (peak day).

15. Project Sponsor and Facility: Lycoming County Water and Sewer Authority, Fairfield Township, Lycoming County, Pa. Application for groundwater withdrawal of up to 0.180 mgd (30-day average) from Production Well 3.

16. Project Sponsor and Facility: Moxie Freedom LLC, Salem Township, Luzerne County, Pa. Application for consumptive water use of up to 0.092 mgd (peak day).

17. Project Sponsor and Facility: Moxie Freedom LLC, Salem Township, Luzerne County, Pa. Application for groundwater withdrawal of up to 0.062 mgd (30-day average) from Production Well 1.

18. Project Sponsor: Pennsylvania Department of Environmental Protection, Bureau of Conservation and Restoration. Project Facility: Cresson Mine Drainage Treatment Plant, Cresson Borough, Cambria County, Pa. Application for groundwater withdrawal from Argyle Stone Bridge Well for inclusion in treatment of up to 6.300 mgd (30-day average) from four sources.

19. Project Sponsor: Pennsylvania Department of Environmental Protection, Bureau of Conservation and Restoration. Project Facility: Cresson Mine Drainage Treatment Plant, Cresson Township, Cambria County, Pa. Application for groundwater withdrawal from Cresson No. 9 Well for inclusion in treatment of up to 6.300 mgd (30-day average) from four sources.

20. Project Sponsor: Pennsylvania Department of Environmental Protection, Bureau of Conservation and Restoration. Project Facility: Cresson Mine Drainage Treatment Plant, Gallitzin Township, Cambria County, Pa. Application for groundwater withdrawal from Gallitzin Shaft Well 2A (Gallitzin Shaft #2) for inclusion in treatment of up to 6.300 mgd (30-day average) from four sources.

21. Project Sponsor: Pennsylvania Department of Environmental Protection, Bureau of Conservation and Restoration. Project Facility: Cresson Mine Drainage Treatment Plant, Gallitzin Township, Cambria County, Pa. Application for groundwater withdrawal from Gallitzin Shaft Well 2B (Gallitzin Shaft #1) for inclusion in treatment of up to 6.300 mgd (30-day average) from four sources.

22. Project Sponsor and Facility: Seneca Resources Corporation (Marsh Creek), Delmar Township, Tioga County, Pa. Application for renewal of surface water withdrawal of up to 0.499 mgd (peak day) (Docket No. 20110907).

23. Project Sponsor and Facility: Shrewsbury Borough, York County, Pa. Application for renewal and modification to increase groundwater withdrawal by an additional 0.024 mgd (30-day average), for a total of up to 0.089 mgd (30-day average) from the Blouse Well (Docket No. 19820103).

24. Project Sponsor and Facility: Shrewsbury Borough, York County, Pa. Application for renewal of groundwater withdrawal of up to 0.099 mgd (30-day average) from the Smith Well (Docket No. 19811203).

25. Project Sponsor and Facility: SWN Production Company, LLC (Tioga River), Hamilton Township, Tioga County, Pa. Application for surface water withdrawal of up to 2.000 mgd (peak day).

26. Project Sponsor and Facility: Talisman Energy USA Inc. (Wappasening Creek), Windham Township, Bradford County, Pa. Application for renewal of surface water withdrawal of up to 1.000 mgd (peak day) (Docket No. 20110621).

27. Project Sponsor: UGI Development Company. Project Facility: Hunlock Creek Energy Center, Hunlock Township, Luzerne County, Pa. Modification to increase consumptive water use by an additional 1.526 mgd (peak day), for a total of up to 2.396 mgd (peak day) (Docket No. 20090916).

28. Project Sponsor and Facility: XTO Energy, Inc. (West Branch Susquehanna River), Chapman Township, Clinton County, Pa. Application for renewal of surface water withdrawal of up to 2.000 mgd (peak day) (Docket No. 20110911).

Request for Conditional Transfer

1. Panda Power Funds request for transfer of ownership of Hummel Station LLC (Docket Nos. 20081222 and 20081222–2). Transferred dockets will include modification of conditions requiring mitigation of all consumptively used water.

Opportunity To Appear and Comment

Interested parties may appear at the hearing to offer comments to the Commission on any project or other item listed above. The presiding officer reserves the right to limit oral statements in the interest of time and to otherwise control the course of the hearing. Ground rules will be posted on the Commission's Web site, *www.srbc.net,* prior to the hearing for review. The presiding officer reserves the right to modify or supplement such rules at the hearing. Written comments on any project or other item listed above may also be mailed to Mr. Jason Oyler, General Counsel, Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, Pa. 17110–1788, or submitted electronically through *www.srbc.net/pubinfo/publicparticipation.htm.* Comments mailed or electronically submitted must be received by the Commission on or before August 17, 2015, to be considered.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: July 2, 2015.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2015–16712 Filed 7–7–15; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Change in Use of Aeronautical Property at Louisville International Airport, Louisville, Kentucky

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for Public Comment.

SUMMARY: The Federal Aviation Administration (FAA) is requesting public comment on a request by the Louisville Regional Airport Authority of Louisville, Kentucky, owner of the Louisville International Airport, to change a portion of airport property from aeronautical to non-aeronautical use at the Louisville International Airport. The request consists of approximately 0.91 acres to the Commonwealth of Kentucky for use as right-of-way for the relocated portion of Grade Lane. This action is taken under the provisions of Section 125 of the Wendell H. Ford Aviation Investment Reform Act for the 21st Century (AIR 21).

DATES: Comments must be received on or before *August 7, 2015*.

ADDRESSES: Documents are available for review at the Louisville Regional Airport Authority, 700 Administration Drive, Louisville, KY 40209; and the FAA Memphis Airports District Office, 2600 Thousand Oaks Boulevard, Suite 2250, Memphis, TN 38118–2482. Written comments on the Sponsor's request must be delivered or mailed to: Mr. Tommy L. Dupree, Assistant Manager, Memphis Airports District Office, 2600 Thousand Oaks Boulevard, Suite 2250, Memphis, TN 38118–2482.

In addition, a copy of any comments submitted to the FAA must be mailed or delivered to Mr. Charles T. Miller, Executive Director, Louisville Regional Airport Authority, P.O. Box 9129, Louisville, KY 40209.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Wilson, Community Planner, Federal Aviation Administration, Memphis Airports District Office, 2600 Thousand Oaks Boulevard, Suite 2250, Memphis, TN 38118–2482. The application may be reviewed in person at this same location, by appointment.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the request to release property for non-aeronautical purposes at Louisville International Airport, Louisville, KY 40209 under the provisions of AIR 21 (49 U.S.C. 47107(h)(2)).

On July 1, 2015, the FAA determined that the request to release property for non-aeronautical purposes at Louisville International Airport meets the procedural requirements of the agency. The FAA may approve the request, in whole or in part, no later than *August 7, 2015.*

The following is a brief overview of the request:

The Louisville Regional Airport Authority is proposing the release of approximately 0.91 acres to the Commonwealth of Kentucky for use as right-of-way for the relocated portion of Grade Lane. In turn, allowing U.S. Department of Homeland Security to enhance security for the KYANG base at the airport. This property is located along the existing airport eastern property line extending approximately 1,400 feet along I–65.

Any person may inspect, by appointment, the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

Issued in Memphis, TN, on July 1, 2015.

Tommy L. Dupree,

Assistant Manager, Memphis Airports District Office, Southern Region.

[FR Doc. 2015–16716 Filed 7–7–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2015–0030; Notice 2]

Continental Tire the Americas, LLC, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of Petition.

SUMMARY: Continental Tire the Americas, LLC, (CTA), has determined that certain Continental brand TKC80 diagonal (bias) motorcycle replacement tires do not fully comply with paragraph S6.5(c) of Federal Motor Vehicle Safety Standard (FMVSS) No. 119, *New Pneumatic Radial Tires for motor vehicles with a GVWR of more than 4,536 Kilograms (10,000 pounds) and Motorcycles.* CTA has filed an appropriate report dated February 18, 2015, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.*

ADDRESSES: For further information on this decision contact Abraham Diaz, Office of Vehicles Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–5310, facsimile (202) 366–5930.

SUPPLEMENTARY INFORMATION:

I. CTA's Petition

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), CTA submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

Notice of receipt of the CTA's petition was published, with a 30-day public comment period, on May 4, 2015 in the **Federal Register** (80 FR 25355). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: *http://www.regulations.gov/*. Then follow the online search instructions to locate docket number ''NHTSA–2015–0030.''

II. Tires Involved

Affected are approximately 1,062 Continental brand TKC80 size 120/70–19 M/C 60Q diagonal (bias) motorcycle replacement tires manufactured between April 8, 2012 and January 31, 2015.

III. Noncompliance

CTA explains that the noncompliance is that the tire size designation marking on the sidewalls of the subject tires does not contain the correct construction code designator symbol from The Tire and Rim Association yearbook. Therefore, the tires do not fully comply with paragraph S6.5(c) of FMVSS No. 119 because the tire size designation is not as listed in the documents and publications designated in S5.1. Specifically, the tires were marked with the construction code designator ''B'' indicating bias-belted construction and should have been marked with the designator ''-'' indicating diagonal (bias) construction.

IV. Rule Text

Paragraph S6.5 of FMVSS No. 119 requires in pertinent part:

S6.5 Tire Markings. Except as specified in paragraphs, each tire shall be marked on each sidewall with the information specified in paragraphs (a) through (j) of this section . . .

(c) The tire size designation as listed in the documents and publications designated in S5.1.

V. Summary of CTA's Analyses

CTA stated its belief that the subject noncompliance is inconsequential to motor vehicle safety for the following reasons:

(A) CTA notes that the only improper marking on the sidewall of the subject tires is the use of the letter character ''B'' in the tire size designation instead of a hyphen character ''-,'' and that from its experience it believes that most motorcycle tire consumers do not understand the differences in tire construction and therefore do not base tire purchases on the tire construction type.

(B) CTA stated that the subject tires were built as designed and that the performance requirements and testing requirements specified in FMVSS No. 119 are exactly the same for both bias-belted and diagonal (bias) tires.

(C) CTA believes that the subject noncompliance has no impact on the safety of vehicles on which the subject tires are mounted and that the subject tires meet or exceed all the performance requirement of FMVSS No. 119.

(D) CTA also stated that it is not aware of any crashes, injuries, customer complaints, or field reports associated with the subject noncompliance.

CTA additionally informed NHTSA that the molds at the manufacturing plant have been corrected so that no additional tires will be manufactured or sold with the noncompliance.

In summation, CTA believes that the described noncompliance of the subject tires is inconsequential to motor vehicle safety, and that its petition, to exempt CTA from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

NHTSA's Decision

NHTSA's Analysis of CTA's Arguments: CTA acknowledges that the subject tires were wrongly stamped with the size marking ''120/70B19 M/C 60Q,'' which includes the construction code designator ''B'' that incorrectly indicates bias-belted ply construction. The tires should have been marked ''120/70-19M/C 60Q,'' which includes the hyphen ''-'' indicating diagonal (bias) ply construction.

Because bias-belted motorcycle tires and diagonal (bias) motorcycle tires require the same rim specification, there is no additional possibility of confusion when mounting a bias-belted or a diagonal bias tire due to the noncompliance.

Furthermore, there is no additional safety risk of overloading or over pressurization due to the subject noncompliance because the maximum permissible pressures and maximum permissible loads for the subject tires as listed in the Tire and Rim Association Yearbook are the same for all three types of motorcycle tire ply construction; radial, diagonal (bias), and bias-belted.

Because mislabeling has no impact on the operational performance or durability of these tires, or on the safety of vehicles on which these tires are mounted, NHTSA agrees with CTA that the noncompliance is inconsequential to motor vehicle safety.

NHTSA's Decision: In consideration of the foregoing, NHTSA has decided that CTA has met its burden of persuasion that the noncompliance described is inconsequential to motor vehicle safety. Accordingly, CTA's petition is hereby granted and CTA is exempted from the obligation of providing notification of, and remedy for the subject noncompliance.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject tires that CTA no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve tire distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after CTA notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120: Delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey Giuseppe,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2015–16640 Filed 7–7–15; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

[Docket ID Number DOT–OST–2014–0031]

Agency Information Collection; Activity Under OMB Review; Submission of Audit Reports—Part 248

AGENCY: Office of the Assistant Secretary for Research and Technology (OST–R), Bureau of Transportation Statistics (BTS), Department of Transportation.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for extension of currently approved collections. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on April 21, 2015 (80 FR 22264). No comments were received.

DATES: Written comments should be submitted by August 7, 2015.

FOR FURTHER INFORMATION CONTACT: Jeff Gorham, Office of Airline Information, RTS–42, Room E34, OST–R, BTS, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, Telephone Number (202) 366–4406, Fax Number (202) 366–3383 or E–MAIL *jeff.gorham@dot.gov.*

Comments: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street NW., Washington, DC 20503, Attention: OST Desk Officer.

SUPPLEMENTARY INFORMATION:

OMB Approval No. 2138–0004.

Title: Submission of Audit Reports—Part 248.

Form No.: None.

Type Of Review: Extension of a currently approved collection.

Respondents: Large certificated air carriers.

Number of Respondents: 63.

Number of Responses: 63.

Total Annual Burden: 20 hours.

Needs and Uses: BTS collects independent audited financial reports from U.S. certificated air carriers. Carriers not having an annual audit must file a statement that no such audit has been performed. In lieu of the audit report, BTS will accept the annual report submitted to the stockholders. The audited reports are needed by the

Department of Transportation as: (1) A means to monitor an air carrier's continuing fitness to operate; (2) reference material used by analysts in examining foreign route cases; (3) reference material used by analyst in examining proposed mergers, acquisitions and consolidations; (4) a means whereby BTS sends a copy of the report to the International Civil Aviation Organization (ICAO) in fulfillment of a United States treaty obligation; and, (5) corroboration of a carrier's Form 41 filings.

The Confidential Information Protection and Statistical Efficiency Act of 2002 (44 U.S.C. 3501), requires a statistical agency to clearly identify information it collects for non-statistical purposes. BTS hereby notifies the respondents and the public that BTS uses the information it collects under this OMB approval for non-statistical purposes including, but not limited to, publication of both Respondent's identity and its data, and submission of the information to agencies outside BTS for review, analysis and possible use in regulatory and other administrative matters.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department concerning consumer protection. Comments should address whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on June 26, 2015.

William Chadwick, Jr.,

Director, Office of Airline Information, Bureau of Transportation Statistics.

[FR Doc. 2015–16691 Filed 7–7–15; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

[Docket ID Number: DOT–OST–2014–0031]

Agency Information Collection; Activity Under OMB Review; Reporting Required for International Civil Aviation Organization

AGENCY: Office of the Assistant Secretary for Research and Technology (OST–R), Bureau of Transportation Statistics (BTS), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for extension of currently approved collections. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on April 21, 2015 (80 FR 22265). No comments were received.

DATES: Written comments should be submitted by August 7, 2015.

FOR FURTHER INFORMATION CONTACT: Jeff Gorham, Office of Airline Information, RTS–42, Room E34, OST–R, BTS, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, Telephone Number (202) 366–4406, Fax Number (202) 366–3383 or E–MAIL *jeff.gorham@dot.gov*.

Comments: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street NW., Washington, DC 20503, Attention: OST Desk Officer.

SUPPLEMENTARY INFORMATION:

OMB Approval No. 2138–0039.

Title: Reporting Required for International Civil Aviation Organization (ICAO).

Form No.: BTS Form EF.

Type Of Review: Extension of a currently approved collection.

Respondents: Large certificated air carriers.

Number of Respondents: 38.

Number of Responses: 38.

Total Annual Burden: 26 hours.

Needs and Uses: As a party to the Convention on International Civil Aviation (Treaty), the United States is obligated to provide ICAO with financial and statistical data on operations of U.S. air carriers. Over 99% of the data filed with ICAO is extracted from the air carriers' Form 41 submissions to BTS. BTS Form EF is the means by which BTS supplies the remaining 1% of the air carrier data to ICAO.

The Confidential Information Protection and Statistical Efficiency Act of 2002 (44 U.S.C. 3501), requires a statistical agency to clearly identify information it collects for non-statistical purposes. BTS hereby notifies the respondents and the public that BTS uses the information it collects under this OMB approval for non-statistical purposes including, but not limited to, publication of both Respondent's identity and its data, and submission of the information to agencies outside BTS for review, analysis and possible use in regulatory and other administrative matters.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department concerning consumer protection. Comments should address whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on June 26, 2015.

William Chadwick, Jr.,

Director, Office of Airline Information, Bureau of Transportation Statistics.

[FR Doc. 2015–16693 Filed 7–7–15; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

[Docket: DOT–OST–2014–0031 BTS Paperwork Reduction Notice]

Agency Information Collection; Activity Under OMB Review; Report of Extension of Credit to Political Candidates

AGENCY: Office of the Assistant Secretary for Research and Technology (OST–R), Bureau of Transportation Statistics (BTS), Department of Transportation.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request, abstracted below, is being forwarded to the Office of Management and Budget for extension of currently approved reporting requirement. Earlier, a **Federal Register** Notice with a 60-day comment period was published on April 21, 2015 (80 FR 22265).

The agency did not receive any comments to its previous notice.

DATES: Written comments should be submitted by August 7, 2015.

FOR FURTHER INFORMATION CONTACT: Jeff Gorham, Office of Airline Information, RTS–42, Room E34, OST–R, BTS, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, Telephone Number (202) 366–4406, Fax Number (202) 366–3383 or EMAIL *jeff.gorham@dot.gov.*

Comments: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 715 17th Street NW., Washington, DC 20503, Attention: OST Desk Officer.

SUPPLEMENTARY INFORMATION:

OMB Approval No. 2138–0016.

Title: Report of Extension of Credit to Political Candidates.

Form No.: 183.

Type of Review: Extension of a currently approved reporting requirement.

Respondents: Certificated air carriers.

Number of Respondents: 2 (Monthly Average).

Number of Responses: 24.

Estimated Time per Response: 1 hour.

Total Annual Burden: 24 hours.

Needs and Uses: The Department uses this form as the means to fulfill its obligation under the Federal Election Campaign Act of 1971 (the Act). The Act's legislative history indicates that one of its statutory goals is to prevent candidates for Federal political office from incurring large amounts of unsecured debt with regulated transportation companies (*e.g.,* airlines). This information collection allows the Department to monitor and disclose the amount of unsecured credit extended by airlines to candidates for Federal office. All certificated air carriers are required to submit this information.

The Confidential Information Protection and Statistical Efficiency Act of 2002 (44 U.S.C. 3501 note), requires a statistical agency to clearly identify information it collects for non-statistical purposes. BTS hereby notifies the respondents and the public that BTS uses the information it collects under this OMB approval for non-statistical purposes including, but not limited to, publication of both Respondent's identity and its data, and submission of the information to agencies outside BTS for review, analysis and possible use in regulatory and other administrative matters.

Comments are invited on whether the proposed retention of records is necessary for the proper performance of the functions of the Department of Transportation.

Issued in Washington, DC, on June 26, 2015.

William Chadwick, Jr.,

Director, Office of Airline Information, Bureau of Transportation Statistics.

[FR Doc. 2015–16690 Filed 7–7–15; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[OCC Charter Number 702353]

Liberty Savings Bank, FSB, Whiting, Indiana; Approval of Voluntary Supervisory Conversion Application

Notice is hereby given that on June 10, 2015, the Office of the Comptroller of the Currency (OCC) approved the application of Liberty Savings Bank, FSB, Whiting, Indiana, to convert from a Federally chartered mutual savings association to a Federally chartered stock savings association. Copies of the application are available for inspection on the OCC Web site at the FOIA Electronic Reading Room *https://foia-pal.occ.gov/palMain.aspx.* If you have any questions, please call OCC Licensing Activities at (202) 649–6260.

Dated: July 1, 2015.

By the Office of the Comptroller of the Currency.

Stephen A. Lybarger,

Deputy Comptroller for Licensing.

[FR Doc. 2015–16654 Filed 7–7–15; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Guidance on Stress Testing for Banking Organizations With More Than $10 Billion in Total Consolidated Assets

AGENCY: Office of the Comptroller of the Currency, Treasury (OCC).

ACTION: Notice and request for comment.

SUMMARY: The OCC, 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 a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning renewal of its information collection titled, ''Guidance on Stress Testing for Banking Organizations with more than $10 Billion in Total Consolidated Assets.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted on or before August 7, 2015.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0312, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0312, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by email to: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, (202) 649–5490, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to extend OMB approval of the following information collection:

Title: Recordkeeping and Disclosure Provisions Associated with Stress Testing Guidance.

OMB Control No.: 1557–0312.

Description: Each banking organization should have the capacity to understand its risks and the potential impact of stressful events and circumstances on its financial condition.[1] On May 17, 2012, the OCC, along with the Federal Deposit Insurance Corporation (FDIC) and Board of Governors of the Federal Reserve (FRB), published guidance on the use of stress testing as a means to better understand the range of a banking organization's potential risk exposures.[2] The OCC is now seeking to renew the information collection associated with that guidance.

The guidance provides an overview of how a banking organization should structure its stress testing activities to ensure they fit into the banking organization's overall risk management program. The purpose of the guidance is to outline broad principles for a satisfactory stress testing framework and to describe the manner in which stress testing should be used, that is as an integral component of risk management applicable at various levels of aggregation within a banking organization, as well as a tool for capital and liquidity planning. While the guidance is not intended to provide detailed instructions for conducting stress testing for any particular risk or business area, it does describe several types of stress testing activities and how they may be most appropriately used by banking organizations. The guidance also does not explicitly address the stress testing requirements imposed upon certain companies by section 165(i) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act).[3]

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 62.

Estimated annual burden: 16,120 hours.

On April 15, 2015, the OCC issued a 60-day **Federal Register** notice regarding the collection (80 FR 20290). No comments were received. However, the burden estimates in the 60-day **Federal Register** notice were inaccurate and have been corrected. They have increased by 12 respondents and 3,120 hours. Comments continue to be invited on:

(a) Whether the collections of information are necessary for the proper performance of the OCC's functions, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the information collections, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: July 1, 2015.

Mary H. Gottlieb,

Regulatory Specialist, Legislative and Regulatory Activities Division.

[FR Doc. 2015–16655 Filed 7–7–15; 8:45 am]

BILLING CODE 4810–33–P

[1] For purposes of this guidance, the term ''banking organization'' means national banks and Federal branches and agencies supervised by the OCC; state member banks, bank holding companies, and all other institutions for which the FRB is the primary Federal supervisor; and state nonmember insured banks and other institutions supervised by the FDIC.

[2] 77 FR 29458 (May 17, 2012).

[3] Public Law 111–203, 124 Stat. 1376. Section 165(i) of the Dodd-Frank Act is codified at 12 U.S.C. 5365(i)(2).

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Registration of Mortgage Loan Originators

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, 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 a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning the renewal of its information collection titled, ''Registration of Mortgage Loan Originators.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: You should submit written comments by August 7, 2015.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0243, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 400 7th Street, SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0243, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by email to: oira *submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, (202) 649–5490, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is requesting extension of OMB approval for this collection. There have been no changes to the requirements of the regulations.

Title: Registration of Mortgage Loan Originators.

OMB Number: 1557–0243.

Description: Among other things, the Secure and Fair Enforcement for Mortgage Licensing Act (S.A.F.E. Act), *codified at* 12 U.S.C. 5101- 5116, requires an employee of a bank, savings association, or credit union or a

subsidiary thereof regulated by a Federal banking agency or an employee of an institution regulated by the Farm Credit Administration (FCA) (collectively, Agency-Regulated Institutions), who engages in the business of a residential mortgage loan originator (MLO), to register with the Nationwide Mortgage Licensing System and Registry (Registry) and obtain a unique identifier. Pursuant to implementing regulations set forth at 12 CFR part 1007, Agency-Regulated Institutions must require their employees who act as residential MLOs to comply with the requirements to register and obtain a unique identifier under the S.A.F.E. Act and must adopt and follow written policies and procedures to assure compliance with these requirements. In order to register, an MLO must provide to the Registry identifying information, including: (1) Fingerprints for submission to the Federal Bureau of Investigation and any other relevant governmental agency for a State and national criminal background check; and (2) personal history and experience, including authorization for the Registry to obtain information related to any administrative, civil, or criminal findings by any governmental jurisdiction. The S.A.F.E. Act originally required the Federal banking agencies and the FCA to develop and maintain the Registry; however, the Dodd-Frank Act subsequently transferred that responsibility to the Consumer Financial Protection Bureau.

The Registry is intended to aggregate and improve the flow of information to and between regulators; provide increased accountability and tracking of mortgage loan originators; enhance consumer protections; reduce fraud in the residential mortgage loan origination process; and provide consumers with easily accessible information at no charge regarding the employment history of, and the publicly adjudicated disciplinary and enforcement actions against, MLOs.

MLO Reporting Requirements

Twelve CFR 1007.103(a) generally requires an MLO of an Agency-Regulated Institution to register with the Registry, maintain such registration, and obtain a unique identifier. Under § 1007.103(b), an Agency-Regulated Institution must require each such registration to be renewed annually and updated within 30 days of the occurrence of specified events. Section 1007.103(d) sets forth the categories of information that an employee, or the employing institution on the employee's behalf, must submit to the Registry, along with the employee's attestation as to the correctness of the information supplied and an authorization to obtain further information.

MLO Disclosure Requirement

Section 1007.105(b) requires an MLO to provide the unique identifier to a consumer upon request.

Financial Institution Reporting Requirements

Section 1007.103(e) specifies the institution and employee information that an institution must submit to the Registry in connection with the initial registration of one or more MLOs and thereafter update.

Financial Institution Disclosure Requirements

Section 1007.105(a) requires the institution to make the unique identifier of MLOs available to consumers in a manner and method practicable to the institution.

Financial Institution Recordkeeping Requirements

- Section 1007.103(d)(1)(xii) requires the collection of MLO fingerprints.
- Section 1007.104 requires an institution employing MLOs to:
  - Adopt and follow written policies and procedures, at a minimum addressing certain specified areas, but otherwise appropriate to the nature, size, and complexity of their mortgage lending activities;
  - Establish reasonable procedures and tracking systems for monitoring registration compliance; and
  - Establish a process for, and maintain records related to, employee criminal history background reports and actions taken with respect thereto.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals; Businesses or other for-profit.

Estimated Number of Respondents: 65,027.

Estimated Total Annual Burden: 44,899 hours.

The OCC issued a 60-day **Federal Register** notice regarding the collection on February 26, 2015, (80 FR 10566). No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC'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 on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: July 1, 2015.

Mary H. Gottlieb,

Regulatory Specialist, Legislative and Regulatory Activities Division.

[FR Doc. 2015–16695 Filed 7–7–15; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of the Secretary

List of Countries Requiring Cooperation With an International Boycott

In accordance with section 999(a)(3) of the Internal Revenue Code of 1986, the Department of the Treasury is publishing a current list of countries which require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

On the basis of the best information currently available to the Department of the Treasury, the following countries require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

Iraq
Kuwait
Lebanon
Libya
Qatar
Saudi Arabia
Syria
United Arab Emirates
Yemen

Dated: July 1, 2015.

Danielle Rolfes,

International Tax Counsel. (Tax Policy).

[FR Doc. 2015–16681 Filed 7–7–15; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF VETERANS AFFAIRS

Solicitation of Nominations for Appointment to the Advisory Committee on Disability Compensation

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA), Veterans Benefits

Administration (VBA), is seeking nominations of qualified candidates to be considered for appointment as a member of the Advisory Committee on Disability Compensation (''the Committee''). In accordance with 38 U.S.C. 546, the Committee advises the Secretary on the maintenance and periodic readjustment of the VA Schedule for Rating Disabilities. In providing advice to the Secretary, the Committee assembles and reviews relevant information relating to the needs of Veterans with disabilities; provides information relating to the nature and character of the disabilities arising from service in the Armed Forces; provides an ongoing assessment of the effectiveness of VA's Schedule for Rating Disabilities; and provides ongoing advice on the most appropriate means of responding to the needs of Veterans relating to disability compensation in the future. In carrying out its duties, the Committee takes into special account the needs of Veterans who have served in a theater of combat operations. Nominations of qualified candidates are being sought to fill upcoming vacancies on the Committee.

Authority: The Committee is authorized by 38 U.S.C. 546 and operates under the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. 2.

DATES: Nominations for membership on the Committee must be received no later than 5:00 p.m. EST on August 20, 2015. Packages received after this time will not be considered for the current membership cycle. All nomination packages should be sent to the Advisory Committee Management Office by email (recommended) or mail. Please see contact information below.

Advisory Committee Management Office (00AC), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, *VA.Advisory.Cmte@va.gov*.

SUPPLEMENTARY INFORMATION: The Committee was established pursuant to 38 U.S.C. 546. The Committee responsibilities include:

(1) Advising the Secretary and Congress on the maintenance and periodic readjustment of the VA Schedule for Rating Disabilities.

(2) Providing a biennial report to Congress assessing the needs of Veterans with respect to disability compensation and outlining recommendations, concerns, and observations on the maintenance and periodic readjustment of the VA Schedule for Rating Disabilities.

(3) Meeting with VA officials, Veterans Service Organizations, and other stakeholders to assess the Department's efforts on the maintenance and periodic readjustment of the VA Schedule for Rating Disabilities.

Management and support services for the Committee are provided by VBA.

Membership Criteria: VBA is requesting nominations for upcoming vacancies on the Committee. The Committee is currently composed of 12 members. As required by statute, the members of the Committee are appointed by the Secretary from the general public, including:

(1) Individuals with experience with the provision of disability compensation by VA;

(2) Individuals who are leading medical and scientific experts in relevant fields.

In accordance with § 546, the Secretary determines the number, terms of service, and pay and allowances of members of the Committee, except that a term of service of any such member may not exceed four years. The Secretary may reappoint any member for additional terms of service.

Professional Qualifications: In addition to the criteria above, VA seeks:

(1) Diversity in professional and personal qualifications;

(2) Experience in military service and military deployments (please identify branch of service and rank);

(3) Current work with Veterans;

(4) Disability compensation subject matter expertise;

(5) Experience working in large and complex organizations.

Requirements for Nomination Submission: Nominations should be typewritten (one nomination per nominator). The nomination package should include: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes that qualify the nominee for service in this capacity), and a statement from the nominee indicating a willingness to serve as a member of the Committee; (2) the nominee's contact information, including name, mailing address, telephone numbers, and email address; (3) the nominee's curriculum vitae, and (4) a summary of the nominee's experience and qualifications relative to the *membership criteria* and *professional qualifications* listed above.

Individuals selected for appointment to the Committee shall be invited to serve a two-year term. Committee members will receive a stipend for attending Committee meetings, including per diem and reimbursement for travel expenses incurred.

The Department makes every effort to ensure that the membership of its Federal advisory committees is fairly balanced in terms of points of view represented. Every effort is made to ensure that a broad representation of geographic areas, gender, and racial and ethnic minority groups, and that the disabled are given consideration for membership. Appointment to this Committee shall be made without discrimination because of a person's race, color, religion, sex (including gender identity, transgender status, sexual orientation, and pregnancy), national origin, age, disability, or genetic information. Nominations must state that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude membership. An ethics review is conducted for each selected nominee.

Dated: July 2, 2015.

Jelessa Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2015–16676 Filed 7–7–15; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 80 Wednesday,
No. 130 July 8, 2015

Part II

Department of Health and Human Services

Center for Medicare & Medicaid Services

42 CFR Parts 410, 412, 416
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; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 412, 416, and 419

[CMS–1633–P]

RIN 0938–AS42

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise 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 proposed rule, we describe the proposed 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 proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Further, this proposed rule includes certain proposals relating to the hospital inpatient prospective payment system: proposed changes to the 2-midnight rule under the short inpatient hospital stay policy, as well as a discussion of the related −0.2 percent payment adjustment; and a proposed transition for Medicare-dependent, small rural hospitals located in all-urban States.

DATES: *Comment Period:* To be assured consideration, comments on all sections of this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on August 31, 2015.

ADDRESSES: In commenting, please refer to file code CMS–1633–P. 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–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1633–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call 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 Erick Chuang at (410) 786–1816.

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) Data 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) Services, contact Twi Jackson at (410) 786–1159.

CPT and Level II Alphanumeric HCPCS Codes, 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 Elisabeth Daniel at (410) 786–0237.

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 and Data Issues, 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.

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 Two 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 Medicare-Dependent, Small Rural Hospitals in All-Urban States, 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, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 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, Public Law 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
E/M Evaluation and management
ESRD End-stage renal disease
ESRD QIP End-Stage Renal Disease Quality Improvement Program
FACA Federal Advisory Committee Act, Public Law 92–463
FDA Food and Drug Administration
FFS [Medicare] Fee-for-service
FY Fiscal year
GAO Government Accountability Office
GI Gastrointestinal
HAI Healthcare-associated infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCERA Health Care and Education Reconciliation Act of 2010, Public Law 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, Public Law 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
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, Public Law 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, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MLR Medical loss ratio
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 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
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, Public Law 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, Public Law 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, Public Law 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
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

Table of Contents

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we are proposing to update 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 proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Further, we are proposing certain changes relating to the hospital inpatient prospective payment system (IPPS): Proposed changes to the 2-midnight rule under the short inpatient hospital stay policy and a discussion of the related −0.2 percent payment adjustment; and a proposed transition for Medicare-dependent, small rural hospitals (MDHs) in all-urban States.

2. Summary of the Major Provisions

• *OPPS Update:* For CY 2016, we are proposing to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.9 percent. This proposed increase is based on the proposed hospital inpatient market basket percentage increase of 2.7 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.6 percentage point, and minus a 0.2 percentage point adjustment required by the Affordable Care Act. In addition, we are proposing to apply 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 proposed rule. Under this proposed rule, we estimate that total payments for CY 2016, including beneficiary cost-sharing, to the approximate 3,800 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)), would decrease by approximately $43 million compared to CY 2015 payments, excluding our

estimated changes in enrollment, utilization, and case-mix.

We are proposing to continue 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 proposing to continue the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This proposed adjustment would 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 proposing to continue 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 proposed target PCR of 0.90 would be used to determine the CY 2016 cancer hospital payment adjustment to be paid at cost report settlement. That is, the proposed payment adjustments would be the additional payments needed to result in a PCR equal to 0.90 for each cancer hospital.
- *Payment of Drugs, Biologicals, and Radiopharmaceuticals:* For CY 2016, proposed 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 Biosimilar Biological Products:* For CY 2016, we are proposing to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act. We also are proposing to extend 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 proposing to expand the set of conditionally packaged ancillary services to include three new APCs.
- *Conditionally Packaged Outpatient Laboratory Tests:* For CY 2016, we are proposing to conditionally package 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 proposing to establish 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 would be made. The ''L1'' modifier would 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 proposing extensive changes to the already established methodology used for C–APCs. However, we are proposing to create 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 proposing to restructure 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 proposing to add a rulemaking component to the current quarterly device pass-through payment application process. Specifically, we are proposing 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 change would help achieve the goals of increased transparency and stakeholder input. In addition, the proposal would 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 proposing 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 applicable FDA premarket approval, clearance, or investigational device exemption.
- *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 proposed rule, we are proposing to modify our existing ''rare and unusual'' exceptions policy under which the only exceptions to the 2-midnight benchmark were cases involving services designated by CMS as inpatient only, and those rare and unusual circumstances published on the CMS Web site or other subregulatory guidance, 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 are revising our medical review strategy and announcing that no later than October 1, 2015, we are changing the medical review strategy and have Quality Improvement Organization (QIO) contractors conduct reviews of short inpatient stays rather than the Medicare administrative contractors (MACs).
- *Chronic Care Management (CCM):* For CY 2016, we are proposing 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 proposing to establish a new modifier that would 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 would 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 in time for inclusion to this CY 2016 OPPS/ASC proposed rule. The new and revised CY 2016 Category I and III CPT codes can be found in OPPS Addendum B and assigned to new comment indicator ''NP'' to indicate that the code is a new code 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 the current calendar year with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator.

• *Ambulatory Surgical Center Payment Update:* For CY 2016, we are proposing to increase payment rates under the ASC payment system by 1.1 percent. This proposed increase is based on a projected CPI–U update of 1.7 percent minus a multifactor productivity adjustment required by the Affordable Care Act that is projected to be 0.6 percentage point. Based on this proposed update, we estimate that proposed total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2016 would be approximately $4.293 billion, an increase of approximately $186 million compared to estimated CY 2015 Medicare payments. In addition, we are proposing 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 proposing to include 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.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are making proposals for the CY 2017 payment determination and subsequent years, the CY 2018 payment determination and subsequent years, and the CY 2019 payment determination and subsequent years. For CY 2017 and subsequent years, we are proposing 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 from November 1 to August 31; (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) from July 1 through November 1 to January 1 through May 15; (5) rename our extension and exception policy to extension and exemption policy; (6) change the deadline for submitting a reconsideration request 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; 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.''

For CY 2018 and subsequent years, we are proposing a new measure: OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF # 1822). For CY 2019 and subsequent years, we also are proposing a new measure: OP–34: Emergency Department Transfer Communication (EDTC) (NQF # 0291). In addition, 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 electronically beginning with the CY 2019 payment determination.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are proposing to align data submission end dates for data submitted using a Web-based tool, to align policies regarding paid claims to be included in the calculation for all claims-based measures, to modify the submission date for reconsideration requests, to modify our policy for the facility identifier for public reporting of ASCQR Program data, and to not consider IHS hospital outpatient departments that bill as ASCs to be ASCs for purposes of the ASCQR Program. We also are proposing to codify a number of existing and proposed policies and are soliciting public comments on the possible inclusion of two measures in the ASCQR Program measure set in the future.

3. Summary of Costs and Benefits

In sections XX. and XXI. of this proposed rule, we set forth a detailed analysis of the regulatory and federalism impacts that the proposed changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of the Proposed OPPS Update

(1) Impacts of All OPPS Proposed Changes

Table 65 in section XX. of this proposed rule displays the distributional impact of all the proposed 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 proposed policies in this proposed rule would result in a 0.2 percent overall decrease in OPPS payments to providers. We estimate that proposed

total OPPS payments for CY 2016, including beneficiary cost-sharing, to the approximate 3,800 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would decrease by approximately $43 million compared to CY 2015 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our proposed 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 14.8 percent increase in CY 2016 payments to CMHCs relative to their CY 2015 payments.

(2) Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY 2016 IPPS proposed rule wage indexes results in a 0.1 percent increase 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 Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our proposed CY 2016 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make 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 Proposed OPD Fee Schedule Increase Factor

As a result of the proposed OPD fee schedule increase factor, the proposed 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 proposed budget neutrality adjustments, we estimate that urban and rural hospitals would experience decreases of approximately 0.1 percent for urban hospitals and 0.3 percent for rural hospitals. Classifying hospitals by teaching status or type of ownership suggests that these hospitals would receive similar decreases.

b. Impacts of the Proposed 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 proposed percentage change in estimated total payments by specialty groups under the proposed 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 proposed 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 proposed 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 proposed rule. 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 Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 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 March 9, 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 placement 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 March 9, 2015 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the March 9, 2015 Panel meeting are included in the sections of this proposed rule 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 will be set forth in the CY 2016 OPPS/ASC final rule with comment period under the appropriate subject-matter headings.

II. Proposed Updates Affecting OPPS Payments

A. Proposed 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.

For this CY 2016 OPPS/ASC proposed rule, we are proposing 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 are proposing 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 hospital outpatient department services furnished on or after January 1, 2014, and before January 1, 2015. For exact counts of claims used, we refer readers to the claims accounting narrative under supporting documentation for this CY 2016 OPPS/ASC proposed rule on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Of the approximately151 million final action claims for services provided in hospital outpatient settings used to calculate the CY 2016 OPPS payment rates for this proposed rule, approximately 117 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 117 million claims, approximately 4 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 113 million claims, we created approximately 88 million single records, of which approximately 38 million were ''pseudo'' single or ''single session'' claims (created from approximately 16 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 85 million single bills for ratesetting. As described in section II.A.2. of this proposed rule, 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 proposed rule. 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 proposed APC relative weights and payments for CY 2016 in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site) were calculated using

claims from CY 2014 that were processed through December 31, 2014. 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, we are proposing to use 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. Proposed Use of Single and Multiple Procedure Claims

For CY 2016, in general, we are proposing 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 are proposing to continue 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 enables 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 are proposing 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 are proposing to establish additional packaging policies for the CY 2016 OPPS, as discussed in section II.A.3. of this proposed rule.

We are proposing 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 this 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 this proposed rule for further discussion), to add to the approximately 49 million ''natural'' single procedure claims.

In addition, we are proposing 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 proposed restructuring of APCs are discussed in the applicable sections of this proposed rule. In conjunction with this initiative, we are proposing 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 proposed rule. We are providing a crosswalk from the existing APC numbers to the proposed new APC renumber in Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site).

For CY 2016, we are proposing to bypass 178 HCPCS codes that are identified in Addendum N to this 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 bills that contained packaging for each HCPCS code and the amount of packaging on each ''natural'' single bill 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 March 9, 2015 meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) from CY 2014 claims processed through September 30, 2014) to determine whether it would be appropriate to add additional codes to the previous year's bypass list. For CY 2016, we are proposing to continue to bypass all of the HCPCS codes on the CY 2015 OPPS bypass list, with the exception of HCPCS codes that we are proposing to delete for CY 2016, which are listed in Table 1 of this 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 are proposing 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 are proposing to remove from the CY 2016 bypass list are affected by the CY 2016 proposed packaging policy, discussed in section II.A.3. of this proposed rule. Some of the codes we are proposing 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 are proposing to add to the bypass list for CY 2016 HCPCS codes that are not on the CY 2015 bypass list that, using the March 9, 2015 Panel data (first 9 months of 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 are proposing that the packaged cost criterion 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) is open to public comment in this 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 are:

- 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 are proposing 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 are proposing 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 are proposing 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 are proposing to set the geometric mean packaged cost threshold on the CY 2014 claims 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 are proposing 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 are proposing 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'' bills, 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 this proposed rule for further discussion of the treatment of ''overlap bypass codes.'') This process also created multiple imaging composite ''single session'' bills that could be used for calculating composite APC costs. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site).

Addendum N to this proposed rule includes 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 are retaining 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 allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we are proposing to add for CY 2016 are identified by asterisks (*) in the fourth column of Addendum N.

Table 1 below contains the list of codes that we are proposing to remove from the CY 2016 bypass list.

TABLE 1—HCPCS CODES PROPOSED TO BE 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. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2016, we are proposing 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 are 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, are 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 this proposed rule.

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 this 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 are proposing 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 are proposing 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 December 2014 HCRIS update to estimate costs in the proposed CY 2016 OPPS ratesetting process, we were able to calculate a valid implantable device CCR for 2,940 hospitals, a valid MRI CCR for 1,978 hospitals, a valid CT scan CCR for 2,069 hospitals, and a valid Cardiac Catheterization CCR for 1,429 hospitals.

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 are proposing 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 this proposed rule includes the impacts of calculating the proposed 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 STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost allocation method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0451	0.0589	0.0890	0.1124
Square Feet Only	0.0364	0.0493	0.0787	0.1019
Direct Assign	0.0641	0.0732	0.1078	0.1286
Dollar Value	0.0536	0.0692	0.1001	0.1235
Direct Assign and Dollar Value	0.0534	0.0690	0.1004	0.1237

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—PERCENTAGE CHANGE IN ESTIMATED COST FOR CT AND MRI APCS WHEN EXCLUDING CLAIMS FROM PROVIDERS USING ''SQUARE FEET'' AS THE COST ALLOCATION METHOD

Proposed CY 2016 APC	Proposed CY 2016 APC descriptor	Percent change
5570*	Computed Tomography without Contrast	13.2
5571*	Level 1 Computed Tomography with Contrast and Computed Tomography Angiography	9.3
5581*	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	7.6
5582*	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	6.2
8005	CT & CTA without Contrast Composite	12.1
8006	CT & CTA with Contrast Composite	9.0
8007	MRI & MRA without Contrast Composite	7.1
8008	MRI & MRA with Contrast Composite	6.8

*Proposed renumbered APC. We refer readers to Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a crosswalk of the existing APCs to the proposed renumbered APCs.

In summary, we are proposing 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 this proposed rule, we are proposing to continue our policy of removing claims from cost modeling for those providers using ''square feet'' as the cost allocation statistic for CY 2016.

2. Proposed Data Development Process and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the proposed OPPS payment rates for CY 2016. The Hospital OPPS page on the CMS Web site on which this proposed rule 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 proposed 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 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 are proposing to continue to use geometric mean costs to calculate the relative weights on which the proposed 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 proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the proposed OPPS payment rates for CY 2016 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

a. Claims Preparation

For this 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. To begin the calculation of the proposed relative payment weights for CY 2016, we pulled 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 are claims that providers submitted to Medicare knowing that no payment would be made. For example, providers submit claims with a condition code 21 to elicit an official denial notice from Medicare and document that a service is not covered. 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 117 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.

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 proposed rule. 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 we are proposing to continue this payment policy for CY 2016. We refer readers to section V.B.3. of this proposed rule for a complete discussion of our CY 2016 proposed 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 are proposing 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 to continue packaging of clinical diagnostic laboratory tests, we also are proposing to apply 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.

b. Splitting Claims and Creation of ''Pseudo'' Single Procedure Claims

(1) Splitting Claims

For the CY 2016 OPPS, we 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 are proposing to define major procedures as any HCPCS code having a status indicator of ''J1,'' ''J2,'' ''S,'' ''T,'' or ''V,'' to define minor procedures as any code having a status indicator of ''F,'' ''G,'' ''H,'' ''K,'' ''L,'' ''R,'' ''U,'' or ''N,'' and to classify ''other'' procedures as any code having a status indicator other than one that we have classified as major or minor. For CY 2016, we are proposing to continue to assign status indicator ''R'' to blood and blood products; status indicator ''U'' to brachytherapy sources; status indicator ''Q1'' to all ''STV-packaged codes;'' status indicator ''Q2'' to all ''T-packaged codes;'' and status indicator ''Q3'' to all 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.

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 are proposing to treat these codes in the same manner for data purposes for CY 2016 as we have treated them since CY 2008. Specifically, we are continuing to evaluate whether the criteria for separate payment of codes with status indicator ''Q1'' or ''Q2'' are met in determining whether they are treated as major or minor codes. Codes with status indicator ''Q1'' or ''Q2'' are carried through the data either with status indicator ''N'' as packaged or, if they meet the criteria for separate payment, they are given the status indicator of the APC to which they are assigned and are considered as ''pseudo'' single procedure claims for major codes. Codes 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 carry 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 proposed rule.

Specifically, we are proposing 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 proposed rule; 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 proposed rule, depending on the specific composite calculation.

In this CY 2016 proposed rule, we are proposing 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 believe that this proposed adjustment more accurately sorts claims that have a bilateral modifier.

(2) Creation of ''Pseudo'' Single Procedure Claims

To develop ''pseudo'' single procedure claims for this 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 are proposing to use the bypass codes listed in Addendum N to this proposed rule (which is available via the Internet on the CMS Web site) and discussed in section II.A.1.b. of this proposed rule 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 ignore the ''overlap bypass codes,'' that is, those HCPCS codes that are 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'' are listed in Addendum N to this 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 proposed criteria for the multiple imaging composite APCs, discussed in section II.A.2.f.(3) of this proposed rule, 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 would not be a separately payable procedure, we considered it to be unavailable for use in setting the composite APC costs on which the proposed 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 are proposing to examine 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, 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 proposed 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 proposed rule.

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 are proposing to continue to apply the methodology described above for the purpose of creating ''pseudo'' single procedure claims for the CY 2016 OPPS.

c. Completion of Claim Records and Geometric Mean Cost Calculations

(1) General Process

We then packaged the costs of packaged HCPCS codes (codes with status indicator ''N'' listed in Addendum B to this 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 below 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 proposed CY 2016 OPPS packaging policy, we refer readers to section II.A.3. of this proposed rule.

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 proposing to continue 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 would propose to package for CY 2016. We believe that the charges reported under the revenue codes listed in Table 4 below continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, for CY 2016, we are proposing to continue to package the costs that we derive from the charges reported without HCPCS codes under the revenue codes displayed in Table 4 below for purposes of calculating the geometric mean costs on which the proposed CY 2016 OPPS/ASC payment rates are based.

TABLE 4—PROPOSED 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
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

TABLE 4—PROPOSED CY 2016 PACKAGED REVENUE CODES—Continued

Revenue code	Description
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 are proposing 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 proposing to continue these processes for the CY 2016 OPPS.

For the remaining claims, we are proposing to then standardize 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 are proposing to use 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 are proposing to use these pre-reclassified wage indices for standardization using the new OMB labor market area delineations described in section II.C. of this proposed rule.

In accordance with our longstanding practice, we also are proposing to exclude 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 113 million claims were left. Using these approximately 113 million claims, we created approximately 105 million single and ''pseudo'' single procedure claims, of which we used approximately 88 million single bills (after trimming out approximately 17 million claims as discussed in section II.A.1.a. of this proposed rule) 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 proposing to continue 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 proposed policy to calculate relative payment weights based on geometric means, we refer readers to section II.A.2.c. of this proposed rule.

We are proposing to use these claims to calculate the CY 2016 geometric mean costs for each separately payable 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, we are proposing to continue 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 88 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 bills 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 proposed 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 are proposing to pay separately under this proposed rule, and we reassigned HCPCS codes to different APCs where it was necessary to ensure clinical and resource homogeneity within the APCs. The proposed 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 proposed rule, in some cases, APC geometric mean costs are calculated using variations of the process outlined above. Specifically, section II.A.2.d. of this proposed rule addresses the proposed calculation of single APC criteria-based geometric mean costs. Section II.A.2.f. of this proposed rule discusses the proposed calculation of composite APC criteria-based geometric mean costs. Section VIII.B. of this proposed rule addresses the methodology for calculating the proposed geometric mean costs for partial hospitalization services.

(2) Recommendations of the Panel Regarding Data Development

At the March 9, 2015 meeting of the Panel, we discussed our standard analysis of APCs, and specifically, those APCs for which geometric mean costs in the Panel 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 claims accounting process for the CY 2015 OPPS/ASC final rule with comment period.

At the March 9, 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.

d. Proposed Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

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.

For CY 2016, we are proposing 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 are proposing 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 are proposing 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 are proposing to calculate the costs upon which the proposed 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 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 would 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 note that, as discussed in section II.A.2.e. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66798 through 66810), we defined a comprehensive APC (C–APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C–APCs. We are proposing to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C–APCs (79 FR 66796). Because the costs of blood and blood products will be reflected in the overall costs of the C–APCs (and, as a result, in the final payment rates of the C–APCs), we are proposing to not make separate payments for blood and blood products when they appear on the same claims as services assigned to the C–APCs (79 FR 66796).

We are inviting public comments on these proposals. We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed CY 2016 payment rates for blood and blood products (which are identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

(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 payment 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 prospective payment 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 this proposed rule, for CY 2016, we are proposing to use the costs derived from CY 2014 claims data to set the proposed CY 2016 payment rates for brachytherapy sources, as we are proposing 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 this proposed rule. We also are proposing 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 are proposing 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 are proposing 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 are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) and are identified with status indicator ''U.''

We are inviting public comments on this proposed policy. We also are requesting recommendations for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new 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. Proposed 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. 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 5, 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 5 below, we list the services that are excluded from the C–APC payment policy.

TABLE 5—COMPREHENSIVE APC PAYMENT POLICY EXCLUSIONS FOR CY 2016

Ambulance services;
Brachytherapy;
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 CFR410.2:
- 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 is identified as Addendum J to this proposed rule (which is available via the Internet on the CMS Web site). For CY 2016, we are not proposing 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 proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the Internet on the CMS Web site).

We are providing in Addendum J to this proposed rule a breakdown of cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the code combinations that describe a complex code combination that would qualify for a complexity adjustment and are proposed to be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed 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 proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3208A, which is assigned to proposed renumbered C–APC 5223 (Level 3 Pacemaker and Similar Procedures) (existing APC 0089), includes all code combinations that are proposed to be reassigned to proposed renumbered C–APC 5223 when CPT code 33208 is the primary code. Providing the information contained in Addendum J in this proposed rule allows stakeholders the opportunity to better assess the impact associated with the proposed reassignment of each of the code combinations eligible for a complexity adjustment.

(2) Proposed C–APCs to be Paid under the C–APC Payment Policy for CY 2016

(a) Proposed CY 2016 C–APCs

For CY 2016, we are proposing to continue to implement the C–APC payment policy methodology made effective in CY 2015, as described in detail below. We are proposing 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 are proposing to continue 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.

After our annual review of the OPPS, we are proposing 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, are displayed in Table 6 below with the proposed new C–APCs denoted with an asterisk. Addendum J to this proposed rule (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 proposed complexity adjustments.

TABLE 6—PROPOSED CY 2016 C–APCS

Proposed CY 2016 C–APC+	Proposed CY 2016 APC descriptor	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	

TABLE 6—PROPOSED CY 2016 C–APCS—Continued

Proposed CY 2016 C–APC+	Proposed CY 2016 APC descriptor	Clinical family	New C–APC
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	
5471	Implantation of Drug Infusion Device	PUMPS	
5631	Single Session Cranial Stereotactic Radiosurgery	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 proposed rule for a discussion of the proposed overall restructuring and renumbering of APCs and to Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a complete crosswalk of the existing APC numbers to the proposed new APC numbers.

* Proposed 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) Proposed Observation Comprehensive APC

As part of our proposed 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, for CY 2016, we are proposing 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 HCPCS code G0463; a Level 4 or 5 Type A ED visit (CPT code 99284 or 99285); a Level 5 Type B ED visit (HCPCS code G0384); a direct referral for observation (G0379), or critical care (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 are proposing 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 are proposing 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 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 HCPCS code G0378;

- The claims contain 8 or more units of services described by HCPCS code G0378 (Observation services, per hour);
- The claims contain 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 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 HCPCS code G0378;
- The claims do not contain a HCPCS code to which we have assigned status indicator ''J1.''

We are proposing to utilize all 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 is 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, we are correspondingly proposing to delete APC 8009, as it would be replaced with proposed new C–APC 8011 (Comprehensive Observation Services).

As stated earlier, we are proposing 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 ''Comprehensive Observation Services'' C–APC 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 being present 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 as claims containing status indicator ''T'' procedures 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 status indicator ''T'' procedures from qualifying for payment.

For claims reporting services qualifying for payment through a C–APC assigned to status indicator ''J1'' and qualifying for payment through a C–APC with a status indicator of ''J2,'' we are proposing that payment would be made through the C–APC with status indicator ''J1'' and all the OPPS payable services 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 with a status indicator of ''J2.'' We are proposing 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 it 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.

(3) Proposed 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, billed 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 encounter payment are furnished prior to a primary service and billed separately. That is, our analysis of billing patterns associated with certain procedures assigned status indicator ''J1'' indicates providers are reporting planning services, imaging tests, and other ''planning and preparation'' services that are integrally associated with the direct provision of the ''J1'' procedure on a separate claim. The physician practice patterns associated with 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 (proposed to be renumbered to C–APC 5631 for CY 2016) for single-session cranial stereotactic radiosurgery (SRS). 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 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).

Based on our analysis of CY 2014 claims data (the data used to develop the proposed CY 2016 payment rates), we identified differences in billing patterns between SRS procedures delivered using Cobalt-60 based and LINAC based technologies. In particular,

our claims data analysis results revealed that 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 SRS treatment on the same date of service and reported on the same claim. In contrast, claims data analysis results revealed that 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 and reported on different dates of services and billed on claims separate from the actual SRS treatment. Because Cobalt-60 based and LINAC based technologies are assigned to proposed renumbered C–APC 5631, the costs of both technologies are reflected in the 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 should be paid through the C–APC. For clean payment, we would make a single payment through the C–APC that would include these essential planning and preparation services, and we would not pay separately for C–APC services when furnished prior to delivery of the ''J1'' procedure and reported on separate claims. SRS services are just one example of where this may be occurring under our C–APC policy.

As a result of our SRS claims data findings, for CY 2016, we are proposing to change payment for SRS treatment under proposed renumbered C–APC 5631 by identifying any services that are differentially billed for HCPCS codes 77371 and 77372 on the same claim and on claims 1 month prior to delivery of SRS services in proposed renumbered C–APC 5631, including planning and preparation services, and removing them from our C–APC geometric mean calculation for CY 2016 and CY 2017 while we collect data using a modifier, which is discussed in greater detail below. For any codes that we remove from the C–APC bundle, we are proposing that those codes would receive separate payment even when appearing with a ''J1'' procedure code (HCPCS code 77371 or 77372) on the same claim for both CY 2016 and CY 2017. Specifically, we are proposing 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 are inviting public comments on our proposal to remove planning and preparation service from our calculation of 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 encounter payment for C–APC services by packaging all planning and preparation services that occur prior to the primary ''J1'' procedure.

(b) Proposed 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 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 associated primary service so that payments under the encounter-based C–APC will be more accurate.

To meet this objective, for CY 2016, we are proposing to establish a HCPCS modifier to be reported with every code that is adjunctive to a comprehensive service, but is billed on a different claim. 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 HCPCS code with status indicator ''J1'' and that are billed 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 the primary ''J1'' services that reflects resources of all the primary services. Further, we also would discontinue separate payment for any of these packaged adjunctive services, even when furnished prior to delivery of the primary service. As noted above, we are proposing to use the modifier to identify planning and preparation services for SRS primary procedures with this goal in mind. We are seeking additional public comment 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.

(c) Proposed Policy Regarding Payment for Claims Reporting Inpatient Only Services Performed on a Patient Who Dies Before Admission

Currently, composite APC 0375 packages payment for all services provided on the same date as an inpatient only procedure that is performed emergently on an outpatient who dies before admission represented by the presence of modifier ''–CA'' on the claim. We are proposing to renumber APC 0375 to APC 5881 for CY 2016. For CY 2016, we are proposing to provide comprehensive payment through proposed renumbered C–APC 5881 for all services reported on the same claim as an inpatient only procedure billed with modifier ''–CA.'' This proposal provides for all services provided on the same claim as an inpatient only procedure billed with modifier ''–CA'' to be paid through a single prospective payment for the comprehensive service.

f. Proposed 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 this CY 2016 OPPS/ASC proposed rule, for CY 2016, we are proposing 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 are proposing 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 this proposed rule. As a result, we are proposing to delete APC 8009 for CY 2016.

We note 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 are proposing to continue to pay for cardiac electrophysiologic evaluation and ablation services through existing C–APC 0086 (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 are not proposing to change the existing number for composite APC 8001 as part of our overall APC restructuring and renumbering discussed in section III.D. of this proposed rule.)

In this proposed rule, for CY 2016, we are proposing 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 are proposing 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 this proposed rule, we are proposing not to 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) (proposed to be renumbered APC 5375 in this proposed rule) and APC 0651 (Complex Interstitial Radiation Source Application) (proposed to be renumber APC 5641 in this proposed rule), the APCs to which CPT codes 55875 and 77778 are assigned, respectively. We are proposing 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 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 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 this 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 is based.

(2) Mental Health Services Composite APC

In this proposed rule, for CY 2016, we are proposing 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 are proposing 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 APC 8010 (Mental Health Services Composite) (existing APC 0034). We also are proposing to continue to set the payment rate for proposed renumbered APC 8010 (existing APC 0034) at the same payment rate that we are proposing 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 one unit of proposed renumbered 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 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.

(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 bills 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 in 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 are not proposing to renumber these composite APCs as part of our overall restructuring and renumbering of APCs as discussed in section III.D. of this 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 for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for composite APC payment, as well as 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 this proposed rule, for CY 2016, we are proposing 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 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) are based on proposed geometric mean costs calculated from a partial year of CY 2014 claims available for this proposed rule that qualified for composite payment under the current policy (that is, those claims with 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), are identified by asterisks in Addendum N to this CY 2016 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 this proposed rule.

For this CY 2016 proposed rule, we were able to identify approximately 584,194 ''single session'' claims out of an estimated 1.5 million potential composite APC cases from our ratesetting claims data, 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 this proposed rule lists 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.

TABLE 7—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1—Ultrasound	
CY 2016 APC 8004 (Ultrasound Composite)	CY 2016 Approximate Proposed 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.

TABLE 7—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

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 Proposed 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.
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 Proposed 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 would assign 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 Proposed 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.

TABLE 7—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

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.
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 Proposed 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 would assign APC 8008 rather than APC 8007.

3. Proposed 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 profitable 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. 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), including the two packaging policies that were added in CY 2015 (79 FR 66819 through 66823). 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 this proposed rule, for CY 2016, we are proposing 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 are proposing to package beginning in CY 2016. 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).

b. Proposed 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, for CY 2016, we are proposing to not limit our examination to ancillary service APCs with a geometric mean cost of $100 or less. 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 are proposing 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, and we did not apply the $100 geometric mean cost threshold that we applied for CY 2015. Specifically, for CY 2016, we are proposing to expand the set of conditionally packaged ancillary services to include services in the three APCs listed in Table 8 below. Ancillary services in the APCs in Table 8 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 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 are proposing 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. For the Level 3 and 4 pathology APCs listed below, we are proposing that the assigned status indicator would be ''Q2'' (''T packaging'').

The HCPCS codes that we are proposing to conditionally package as ancillary services for CY 2016 are displayed in Addendum B to this 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*.

TABLE 8—PROPOSED APCS FOR CONDITIONALLY PACKAGED ANCILLARY SERVICES FOR CY 2016

Proposed renumbered CY 2016 APC*	Proposed CY 2016 APC title	Proposed CY 2016 OPPS status indicator	Proposed 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

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed APC renumbers for CY 2016.

In addition, we are proposing 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 are listed in Table 9 below.

TABLE 9—PROPOSED PREVENTIVE SERVICES EXEMPTED FROM THE ANCILLARY SERVICES PACKAGING POLICY

HCPCS code	Short descriptor	Proposed renumbered CY 2016 APC*
76977	Us bone density measure.	5732
77078	Ct bone density axial.	5521
77080	Dxa bone density axial.	5522

TABLE 9—PROPOSED PREVENTIVE SERVICES EXEMPTED FROM THE ANCILLARY SERVICES PACKAGING POLICY—Continued

HCPCS code	Short descriptor	Proposed renumbered CY 2016 APC*
77081	Dxa bone density/peripheral.	5521
G0117	Glaucoma scrn hgh risk direc.	5732
G0118	Glaucoma scrn hgh risk direc.	5732
G0130	Single energy x-ray study.	5521
G0389	Ultrasound exam aaa screen.	5531
G0404	Ekg tracing for initial prev.	5731

TABLE 9—PROPOSED PREVENTIVE SERVICES EXEMPTED FROM THE ANCILLARY SERVICES PACKAGING POLICY—Continued

HCPCS code	Short descriptor	Proposed renumbered CY 2016 APC*
Q0091	Obtaining screen pap smear.	5731

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed APC renumbers.

(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 our 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 that exceeds 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, for CY 2016, we are proposing to package payment for the four drugs that are listed in Table 10 below based on their primary function as a supply in a surgical procedure, which typically means that the drug or biological is integral to, dependent on, or supportive of a surgical procedure. We note that one drug, described by HCPCS code C9447, that would otherwise be packaged in CY 2016 currently has pass-through payment status. Therefore, we are not proposing to package HCPCS code C9447 for CY 2016. Instead, we are proposing to package this drug for CY 2018, after its drug pass-through payment status has expired.

TABLE 10—SEPARATELY PAYABLE DRUGS PROPOSED FOR UNCONDITIONAL PACKAGING

HCPCS code	Descriptor	CY 2015 status indicator	Primary use in surgical procedure	Proposed first calendar year to be 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 certain 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 purpose than the primary service ordered by a practitioner different than the practitioner who ordered the other OPPS 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 proposed rule (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 unrelated laboratory tests excluded from the packaging proposal (except molecular pathology tests, which would still be reported on the 13X bill type), including both: (1) Those laboratory tests that are the only service provided on a date of service, and (2) laboratory tests provided on the same date of service as another OPPS service but ordered for a different purpose than the primary service and by a different practitioner than the practitioner who ordered the primary 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

For CY 2016 and subsequent years, we are proposing a few revisions to our

current laboratory packaging policy. First, with regard to the particular molecular pathology tests in the code range expressly excluded from the current policy, we are proposing 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. We believe that this rationale remains applicable and may be appropriately extended to any new molecular pathology tests. Therefore, for CY 2016, we are proposing to assign all laboratory tests that describe molecular pathology tests status indicator ''A'' in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site), which means that they are separately paid at the CLFS rates outside of the OPPS.

Second, we are proposing for CY 2016 to make separate payment for preventive laboratory tests and assign them a status indicator ''A'' in Addendum B to this proposed rule. Laboratory tests that are considered preventive appear 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). 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 are proposing 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 purpose and by the same practitioner as the practitioner who ordered the primary service. Specifically, we are proposing to expand our current conditional packaging policy and 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 purpose and by a different practitioner than the practitioner who ordered the other OPPS 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 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, 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 an OPPS service. We conclude 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 are proposing to package laboratory tests that are reported on the same claim with a primary service, regardless of the date of service.

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 purpose than another OPPS service by a practitioner different than the practitioner who ordered the primary service (78 FR 74942). 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 purpose than the primary OPPS services. However, as we discuss below, for ease of administration, we also are proposing 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.

Proposed 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 observe 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. Assigning a ''QX'' modifier generally indicates conditional packaging, where services are packaged, except in certain circumstances where separate payment can occur. Proposing a distinct ''Q4'' modifier allows for more precise categorization of the payment status of laboratory services. With the assignment of the proposed ''Q4'' modifier to laboratory tests, we are proposing that modifier ''L1'' would only be used to identify ''unrelated'' laboratory tests that are ordered for a different purpose and by a different practitioner than the other OPPS services on the claim.

We are inviting public comments on these proposals.

4. Proposed Calculation of OPPS Scaled Payment Weights

In this CY 2016 proposed rule, we are proposing to calculate the relative payment weights for each APC shown in Addenda A and B to this 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 this 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 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. We are

proposing 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 this proposed rule, for CY 2016, we are proposing to delete APC 0634 and to move the outpatient clinic visit HCPCS code G0463 to APC 0632 (Level 2 Examinations and Related Services). Accordingly, for CY 2016 and subsequent years, we are proposing to standardize all of the relative payment weights to APC 0632. 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 are proposing to renumber APC 0632 as APC 5012 (Level 2 Examination and Related Services). For CY 2016, we are proposing 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 are proposing 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.

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 are proposing to apply the same process using the estimated CY 2016 unscaled relative payment weights rather than scaled relative payment weights. We are proposing to calculate the weight scaler by dividing the CY 2015 estimated aggregate weight by the unscaled CY 2016 estimated aggregate weight.

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 proposed rule link and open the claims accounting document link at the bottom of the page.

In this CY 2016 proposed rule, we are proposing 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 are proposing to adjust the calculated CY 2016 unscaled relative payment weights for purposes of budget neutrality. We are proposing 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 this proposed rule (which are available via the Internet on the CMS Web site) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this 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 proposed rule) is included in the budget neutrality calculations for the CY 2016 OPPS.

B. Proposed 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 proposed rule (80 FR 24477), consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2015 forecast of the FY 2016 market basket increase, the proposed FY 2016 IPPS market basket update is 2.7 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 proposed rule (80 FR 24478), we discussed the calculation of the proposed MFP adjustment for FY 2016, which is −0.6 percentage point reduction.

We are proposing that if more recent data become subsequently available after the publication of this CY 2016 OPPS/ASC 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.

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, we are proposing 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 proposing to apply an OPD fee schedule increase factor of 1.9 percent for the CY 2016 OPPS (which is 2.7 percent, the proposed estimate of the hospital inpatient market basket percentage increase, less the proposed 0.6 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 proposed rule.

In this CY 2016 OPPS/ASC proposed rule, we are proposing 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.

To set the OPPS conversion factor for CY 2016, we are proposing to increase the CY 2015 conversion factor of $74.173 by 1.9 percent. In accordance with section 1833(t)(9)(B) of the Act, we are proposing to further adjust the conversion factor for CY 2016 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We are proposing to calculate an overall proposed budget neutrality factor of 0.9993 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed 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 CY 2016, we are proposing to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment would be 1.0000.

For CY 2016, we are proposing 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 proposed rule. We are proposing to calculate 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 proposed 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 proposed estimated payments applying the proposed CY 2016 cancer hospital payment adjustment are identical to estimated payments applying the CY 2015 final cancer hospital payment adjustment. Therefore, we are proposing to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment.

For this proposed rule, we estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2016 would equal approximately $136.8 million, which represents 0.25 percent of total projected CY 2016 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.13 percent estimate of pass-through spending for CY 2015 and the 0.25 percent estimate of proposed pass-through spending for CY 2016, resulting in a proposed adjustment for CY 2016 of −0.12 percent. Proposed estimated payments for outliers would be 1.0 percent of total OPPS payments for CY 2016. We currently estimate that outlier payments will be 0.95 percent of total OPPS payments in CY 2015; the 1.0 percent for proposed outlier payments in CY 2016 would constitute a 0.05 percent increase in payment in CY 2016 relative to CY 2015.

We also are proposing 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 adjustment to the conversion factor to redress the inflation in the OPPS payment rates 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 this proposed rule, we are proposing 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 proposed rule for a detailed discussion of our laboratory test packaging policy exceptions and to review our proposals 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 expect 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, 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 do not observe a significant change in the number of laboratory services in our claims data, we conclude that the changes in aggregate payments under the OPPS are a result of changes in pricing alone and do 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 are proposing a reduction of 2.0 percentage points to the proposed CY 2016 conversion factor to redress inappropriate inflation in the OPPS payment rates and remove the $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 are proposing 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 believe that a prospective adjustment to remove this $1 billion from the OPPS realigns total aggregate OPPS payments to reflect the resources associated with OPPS services. When we calculate 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. Therefore, we are proposing 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.

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 provide 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 this proposed rule (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*). We note 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 this proposed rule, we also are proposing 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 are proposing 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).

In summary, for CY 2016, we are proposing 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 proposing to use a reduced conversion factor of $72.478 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.451 in the conversion factor relative to hospitals that meet the requirements).

For CY 2016, we are proposing 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 proposed rule.

As a result of these proposed policies, the proposed OPD fee schedule increase factor for the CY 2016 OPPS is 1.9 percent (which is 2.7 percent, the estimate of the hospital inpatient market basket percentage increase, less the proposed 0.6 percentage point MFP adjustment, and less the 0.2 percentage point additional adjustment). For CY 2016, we are proposing to use a conversion factor of $73.929 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 proposed OPD fee schedule increase factor of 1.9 percent for CY 2016, the required wage index budget neutrality adjustment of approximately 0.9993, the proposed cancer hospital payment adjustment of 1.0000, the proposed −2.0 percent adjustment to the 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, and the proposed adjustment of −0.12 percentage point of projected OPPS spending for the difference in the pass-through spending result in a proposed conversion factor for CY 2016 of $73.929.

C. Proposed 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 proposed rule.

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, we are proposing to continue this policy for the CY 2016 OPPS. We refer readers to section II.H. of this proposed rule 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 proposed rule, for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same proposed 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 are proposing 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 2015 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; and for FY 2015, 79 FR 49971.

In addition to the changes required by the Affordable Care Act, we note that the proposed 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 proposed rule (80 FR 24463 through 24472) for a detailed discussion of all proposed 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 proposed rule (80 FR 24463 through 24469), 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.

For the CY 2016 OPPS/ASC proposed rule, we are proposing to use the proposed 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 refer 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 are proposing to continue this policy for CY 2016. The following is a brief summary of the major proposed FY 2016 IPPS wage index policies and adjustments that we are proposing to apply to these hospitals under the OPPS for CY 2016. We further refer readers to the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24463 through 24477) for a detailed discussion of the proposed changes to the FY 2016 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 are proposing 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 proposed 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 would receive the adjustment for FY 2016. (We note that the new FY 2016 proposed IPPS Table 2 consolidates information on counties eligible for the out-migration adjustment that was previously issued as Table 4J.) We are including the proposed out-migration adjustment information from the new consolidated Table 2 from the FY 2016 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under the CY 2016 OPPS. Addendum L is available via the Internet on the CMS Web site.

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 proposed rule (80 FR 24467 through 24468), 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 proposed rule, 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 proposed to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2016 (80 FR 24469 through 24470). For purposes of the CY 2016 OPPS, we also are proposing 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 are proposing 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.

With the exception of the proposed out-migration wage adjustment table (Addendum L to this proposed rule, 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 proposed 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 proposed FY 2016 IPPS wage index tables.

D. Proposed 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, have not accepted assignment of an existing hospital's provider agreement, and 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 proposed rule, we are proposing to update 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.

For CY 2016, we are proposing 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 below lists the proposed CY 2016 default urban and rural CCRs by State and compares them to the CY 2015 default CCRs. These proposed CCRs represent 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 are proposing 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 are proposing 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.

Table 11 below lists the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2016.

TABLE 11—PROPOSED CY 2016 STATEWIDE AVERAGE CCRS

State	Urban/Rural	Proposed CY 2016 default CCR	Previous default CCR (CY 2015 OPPS Final Rule)
ALABAMA	RURAL	0.226	0.235
ALABAMA	URBAN	0.172	0.186
ALASKA	RURAL	0.592	0.439
ALASKA	URBAN	0.286	0.294
ARIZONA	RURAL	0.224	0.228
ARIZONA	URBAN	0.176	0.181
ARKANSAS	RURAL	0.261	0.262
ARKANSAS	URBAN	0.222	0.239
CALIFORNIA	RURAL	0.180	0.178
CALIFORNIA	URBAN	0.196	0.196
COLORADO	RURAL	0.381	0.410
COLORADO	URBAN	0.212	0.219
CONNECTICUT	RURAL	0.337	0.339
CONNECTICUT	URBAN	0.267	0.273
DELAWARE	URBAN	0.316	0.314
DISTRICT OF COLUMBIA	URBAN	0.307	0.299
FLORIDA	RURAL	0.169	0.180
FLORIDA	URBAN	0.154	0.156
GEORGIA	RURAL	0.253	0.256
GEORGIA	URBAN	0.211	0.211
HAWAII	RURAL	0.339	0.337
HAWAII	URBAN	0.310	0.307
IDAHO	RURAL	0.357	0.353
IDAHO	URBAN	0.491	0.463
ILLINOIS	RURAL	0.251	0.252
ILLINOIS	URBAN	0.220	0.217
INDIANA	RURAL	0.332	0.334
INDIANA	URBAN	0.256	0.262
IOWA	RURAL	0.308	0.321
IOWA	URBAN	0.259	0.269
KANSAS	RURAL	0.302	0.300
KANSAS	URBAN	0.219	0.231
KENTUCKY	RURAL	0.223	0.231
KENTUCKY	URBAN	0.217	0.212
LOUISIANA	RURAL	0.264	0.272
LOUISIANA	URBAN	0.213	0.209
MAINE	RURAL	0.465	0.430
MAINE	URBAN	0.415	0.432
MARYLAND	RURAL	0.290	0.296
MARYLAND	URBAN	0.241	0.244
MASSACHUSETTS	RURAL	0.325	0.326
MASSACHUSETTS	URBAN	0.337	0.333
MICHIGAN	RURAL	0.339	0.371
MICHIGAN	URBAN	0.316	0.320
MINNESOTA	RURAL	0.473	0.485
MINNESOTA	URBAN	0.351	0.347
MISSISSIPPI	RURAL	0.240	0.247
MISSISSIPPI	URBAN	0.177	0.181
MISSOURI	RURAL	0.248	0.267
MISSOURI	URBAN	0.259	0.274
MONTANA	RURAL	0.459	0.501
MONTANA	URBAN	0.386	0.386
NEBRASKA	RURAL	0.280	0.290
NEBRASKA	URBAN	0.245	0.255
NEVADA	RURAL	0.221	0.241
NEVADA	URBAN	0.150	0.149
NEW HAMPSHIRE	RURAL	0.383	0.362
NEW HAMPSHIRE	URBAN	0.310	0.280
NEW JERSEY	URBAN	0.200	0.202
NEW MEXICO	RURAL	0.267	0.296
NEW MEXICO	URBAN	0.295	0.294
NEW YORK	RURAL	0.331	0.333
NEW YORK	URBAN	0.314	0.340
NORTH CAROLINA	RURAL	0.280	0.280
NORTH CAROLINA	URBAN	0.245	0.246
NORTH DAKOTA	RURAL	0.443	0.660
NORTH DAKOTA	URBAN	0.357	0.395
OHIO	RURAL	0.301	0.317
OHIO	URBAN	0.216	0.222

TABLE 11—PROPOSED CY 2016 STATEWIDE AVERAGE CCRS—Continued

State	Urban/Rural	Proposed CY 2016 default CCR	Previous default CCR (CY 2015 OPPS Final Rule)
OKLAHOMA	RURAL	0.252	0.282
OKLAHOMA	URBAN	0.198	0.203
OREGON	RURAL	0.267	0.287
OREGON	URBAN	0.366	0.352
PENNSYLVANIA	RURAL	0.282	0.283
PENNSYLVANIA	URBAN	0.195	0.197
PUERTO RICO	URBAN	0.596	0.577
RHODE ISLAND	URBAN	0.298	0.297
SOUTH CAROLINA	RURAL	0.193	0.191
SOUTH CAROLINA	URBAN	0.211	0.207
SOUTH DAKOTA	RURAL	0.366	0.286
SOUTH DAKOTA	URBAN	0.225	0.214
TENNESSEE	RURAL	0.203	0.203
TENNESSEE	URBAN	0.180	0.188
TEXAS	RURAL	0.249	0.251
TEXAS	URBAN	0.183	0.203
UTAH	RURAL	0.476	0.481
UTAH	URBAN	0.336	0.335
VERMONT	RURAL	0.437	0.439
VERMONT	URBAN	0.352	0.353
VIRGINIA	RURAL	0.205	0.219
VIRGINIA	URBAN	0.258	0.241
WASHINGTON	RURAL	0.351	0.300
WASHINGTON	URBAN	0.323	0.330
WEST VIRGINIA	RURAL	0.313	0.312
WEST VIRGINIA	URBAN	0.311	0.300
WISCONSIN	RURAL	0.325	0.328
WISCONSIN	URBAN	0.292	0.294
WYOMING	RURAL	0.441	0.429
WYOMING	URBAN	0.311	0.262

E. Proposed 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 Public Law 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 are proposing 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. Proposed 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,'' including 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 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. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2016

For CY 2016, we are proposing 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 are available at the time of the development of this proposed rule. 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 this 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 are proposing 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 proposed target PCR equal to 0.90 for each cancer hospital. Table 12 below indicates the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2016 due to the cancer hospital payment adjustment policy.

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 note 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.

TABLE 12—ESTIMATED CY 2016 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider number	Hospital name	Estimated percentage increase in OPPS payments for CY 2016
050146	City of Hope Comprehensive Cancer Center	19.0
050660	USC Norris Cancer Hospital	19.3
100079	Sylvester Comprehensive Cancer Center	22.3
100271	H. Lee Moffitt Cancer Center & Research Institute	24.5
220162	Dana-Farber Cancer Institute	47.8
330154	Memorial Sloan-Kettering Cancer Center	42.4
330354	Roswell Park Cancer Institute	19.2
360242	James Cancer Hospital & Solove Research Institute	32.5
390196	Fox Chase Cancer Center	21.0
450076	M.D. Anderson Cancer Center	47.7
500138	Seattle Cancer Care Alliance	53.9

G. Proposed 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 current estimate of total outlier payments as a percent of total CY 2014 OPPS payment, using available CY 2014 claims and the OPPS expenditure estimate for the FY 2016 President's Budget, is approximately 0.9 percent of the total aggregated OPPS payments. Therefore, for CY 2014, we estimate that we paid 1.0 percent 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 0.95 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 XX. of this proposed rule. 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. Proposed Outlier Calculation

For CY 2016, we are proposing to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We are proposing 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 this proposed rule, for CMHCs, we are proposing 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 this proposed rule.

To ensure that the estimated CY 2016 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we are proposing 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 this 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 this 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 are proposing to apply the same CCR inflation adjustment factor that we are proposing 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 are proposing 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).

To model hospital outlier payments for this 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 are proposing 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 are proposing 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 proposed rule.

H. Proposed 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 proposed rule, the proposed payment rate for most services and procedures for which payment is made under the OPPS is the product of the proposed conversion factor calculated in accordance with section II.B. of this proposed rule and the proposed relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (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 proposed rule (which is available via the Internet on the CMS Web site) was calculated by multiplying the proposed CY 2016 scaled weight for the APC by the proposed 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 proposed rule.

We demonstrate below 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,'' ''R,'' ''S,'' ''T,'' ''U,'' or ''V'' (as defined in Addendum D1 to this 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 proposed rule. 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 proposed rule. We are proposing to create new status indicator ''J2'' to reflect the new C–APC 8011 (Comprehensive Observation Services) proposed in this CY 2016 proposed rule, as discussed in section II.A.2.e.(2) of this proposed rule.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (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 proposed 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 proposed 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 proposed 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 proposed full CY 2016 OPPS fee schedule increase factor of 1.9 percent.

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 * (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 proposed 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 proposed rule. The proposed wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are proposed to be 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 proposed changes to the FY 2016 IPPS wage indexes, as applied to the CY 2016 OPPS, we refer readers to section II.C. of this proposed rule.) We are proposing to continue 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 Public Law 108–173. Addendum L to this proposed rule (which is available via the Internet on the CMS Web site) contains the qualifying counties and the proposed associated wage index increase developed for the FY 2016 IPPS, which are listed in Table 4J in the FY 2016 IPPS/LTCH PPS proposed rule 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 * (national unadjusted payment rate) * 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 * (national unadjusted payment rate).

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 proposed 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 proposed renumbered APC 5072 (Level 2 Excision/Biopsy/Incision and Drainage) (existing APC 0019). The proposed CY 2016 full national unadjusted payment rate for APC 5072 is approximately $486.16. The proposed reduced national unadjusted payment rate for proposed renumbered APC 5072 for a hospital

that fails to meet the Hospital OQR Program requirements is approximately $476.44. This proposed reduced rate is calculated by multiplying the proposed reporting ratio of 0.980 by the proposed full unadjusted payment rate for proposed renumbered APC 5072.

The proposed FY 2016 wage index for a provider located in CBSA 35614 in New York is 1.2998. The labor-related portion of the proposed full national unadjusted payment is approximately $379.15 (.60 * $486.16 * 1.2998). The labor-related portion of the proposed reduced national unadjusted payment is approximately $371.57 (.60 * $476.44* 1.2998). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $194.46 (.40 * $486.16). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $190.58 (.40 * $476.44). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $573.61 ($379.15 + $194.46). The sum of the portions of the proposed reduced national adjusted payment is approximately $562.15 ($371.57 + $190.58).

I. Proposed 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. Proposed OPPS Copayment Policy

For CY 2016, we are proposing 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 are proposing 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, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). As discussed in section XIII.E. of this proposed rule, for CY 2016, the proposed 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 this proposed rule hastens this movement toward copayments equal to 20 percent of an APC for reorganized APCs that previously had copayment percentages greater than 20 percent.

3. Proposed 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 proposed renumbered APC 5072 (existing APC 0019), $97.50 is approximately 20 percent of the proposed full national unadjusted payment rate of $486.16. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (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 proposed rule. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this proposed rule.

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 proposed rule, 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 proposed unadjusted copayments for services payable under the OPPS that would be effective January 1, 2016, are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed full CY 2016 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

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. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed 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 indicator (SI) and APC assignments. 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 proposed rule provides a discussion of the various status indicators used under the OPPS. Certain payment indicators provide separate payment while others do not.

In Table 13 below, we summarize our current 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 13—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly update CR	Type of code	Effective date	Comments sought	When finalized
April I, 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 are soliciting public comments in this CY 2016 OPPS/ASC proposed rule or whether we will be soliciting public comments in the 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 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 will respond to public comments and finalize our interim OPPS treatment of these codes in the CY 2016 OPPS/ASC final rule with comment period.

1. Proposed Treatment of New CY 2015 Level II HCPCS and CPT Codes Effective April 1, 2015 and July 1, 2015 for Which We Are Soliciting Public Comments in This 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 below, 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.

TABLE 14—NEW LEVEL II HCPCS CODES IMPLEMENTED IN APRIL 2015

CY 2015 HCPCS Code	CY 2015 Long descriptor	Proposed CY 2016 Status indicator	Proposed CY 2016 APC**
C2623	Catheter, transluminal angioplasty, drug-coated, non-laser	H	2623
C9445	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445
C9448#	Netupitant 300mg and palonosetron 0.5 mg, oral	N/A	N/A
C9449	Injection, blinatumomab, 1 mcg	G	9449
C9450	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	G	9450
C9451	Injection, peramivir, 1 mg	G	9451
C9452	Injection, ceftolozane 50 mg and tazobactam, 25 mg	G	9452
Q9975*	Injection, Factor VIII, FC Fusion Protein (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 Q9975 was replaced with HCPCS code C9136 (Injection, factor viii, fc fusion protein, (recombinant), per i.u.), effective April 1, 2015.

**Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

In this CY 2016 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments, where applicable, for the Level II HCPCS codes implemented on April 1, 2015 and listed in Table 14 of this proposed rule. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

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 below, 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. Table 15 below lists 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 note that HCPCS code Q9978 replaced HCPCS code C9448 (Netupitant 300 mg and palonosetron 0.5 mg, oral), beginning July 1, 2015. HCPCS code C9448 was made effective April 1, 2015, but the code was deleted June 30, 2015, because it was replaced with HCPCS code Q9978. HCPCS code C9448 was granted pass-through payment status when the code was implemented on April 1, 2015. Because HCPCS code Q9978 describes the same drug as HCPCS code C9448, we are proposing to continue the pass-through payment status for HCPCS code Q9978, and assign the HCPCS Q-code to the same APC and status indicator as its predecessor HCPCS C-code, as shown in Table 15. Specifically, we are proposing to assign HCPCS code Q9978 to APC 9448 (Netupitant Palonosetron Oral) and status indicator ''G.''

In addition, the CPT Editorial Panel established CPT codes 0392T and 0393T, effective July 1, 2015. 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 are proposing to assign the CPT code to the same APC and status indicator as its predecessor HCPCS C-code, as shown in Table 15.

In this CY 2016 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments, where applicable, for the CPT and Level II HCPCS codes implemented on July 1, 2015 and listed in Table 15 of this proposed rule.

TABLE 15—NEW CATEGORY III CPT AND LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2015

CY 2015 CPT/ HCPCS Code	CY 2015 Long descriptor	Proposed CY 2016 Status indicator	Proposed CY 2016 APC****
C2613	Lung biopsy plug with delivery system	H	2613
C9453	Injection, nivolumab, 1 mg	G	9453
C9454	Injection, pasireotide long acting, 1 mg	G	9454
C9455	Injection, siltuximab, 10 mg	G	9455
Q5101*	Injection, Filgrastim (G–CSF), Biosimilar, 1 microgram	E	N/A
Q9976	Injection, Ferric Pyrophosphate Citrate Solution, 0.1 mg of iron	E	N/A
Q9977	Compounded Drug, Not Otherwise Classified	N	N/A
Q9978**	Netupitant 300 mg and Palonosetron 0.5 mg, oral	G	9448
0392T***	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (*i.e.*, magnetic band).	Q2	5362
0393T	Removal of esophageal sphincter augmentation device	Q2	5361

*HCPCS code Q5101, Zarxio, was approved by the FDA on March 6, 2015. As the biosimilar is currently not being marketed, pricing information is not yet available. Once Zarxio is marketed we will make pricing information available at the soonest possible date on the OPPS payment files and payment for Zarxio will be retroactive to the date the product is first marketed.

**HCPCS code C9448 (Netupitant 300 mg and palonosetron 0.5 mg, oral) was deleted June 30, 2015, and replaced with HCPCS code Q9978, effective July 1, 2015.

***HCPCS code C9737 (Laparoscopy, surgical, esophageal sphincter augmentation with device (*e.g.*, magnetic band) was deleted June 30, 2015 and replaced with CPT code 0392T, effective July 1, 2015.

****We refer readers to Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

In summary, we are soliciting public comments on the proposed CY 2016 status indicators, APC assignments, and payment rates for the Level II HCPCS codes and the Category III CPT codes that were made effective April 1, 2015, and July 1, 2015. These codes are listed in Tables 14 and 15 of this proposed rule. We also are proposing to finalize the status indicator and APC assignments and payment rates for these codes, if applicable, in the CY 2016 OPPS/ASC final rule with comment period. The proposed payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

2. Proposed Process for New Level II HCPCS Codes That Will Be Effective October 1, 2015 and January 1, 2016 for Which We Will Be Soliciting Public Comments in the 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 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 via the CMS HCPCS Web site, and also through the January OPPS quarterly update CRs. In the past, we also released new Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period, thereby updating the OPPS for the following calendar year.

For CY 2016, we are proposing to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the OPPS/ASC final

rule with comment period to those new Level II HCPCS codes that are effective October 1 and January 1 to indicate that we are assigning them an interim payment status which is subject to public comment. 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 B to the 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 will be inviting public comments in the CY 2016 OPPS/ASC final rule with comment period on the status indicator, APC assignments, and payment rates for these codes, if applicable, that would be finalized in the CY 2017 OPPS/ASC final rule with comment period.

3. Proposed Treatment of New and Revised CY 2016 Category I and III CPT Codes That Will Be Effective January 1, 2016, for Which We Are Soliciting Public Comments in This 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 note 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 the resort to HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, 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 this CY 2016 OPPS/ASC proposed rule. The new and revised CY 2016 Category I and III CPT codes can be found in OPPS Addendum B and 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 this CY 2016 OPPS/ASC proposed rule for further discussion on the new proposed comment indicator ''NP.''

Further, we remind 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 are including the long descriptors for the new and revised CY 2016 CPT codes in Addendum O to this proposed rule (which is available via the Internet on the CMS Web site) so that the public can 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 have developed alternative 5-character placeholder codes for this proposed rule. 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 this proposed rule. The final CPT code numbers will be included in the CY 2016 OPPS/ASC final rule with comment period. We note that not every code listed in Addendum O is subject to comment. For the new/revised Category I and III CPT codes, we are requesting comments on only those codes that are assigned to comment indicator ''NP.'' Comments will not be accepted for new Category I CPT laboratory codes that are not assigned to ''NP'' comment indicator in Addendum O. Comments to these codes must be submitted at the Clinical Laboratory Fee Schedule (CLFS) Public Meeting, which is scheduled for July 16, 2015.

In summary, we are soliciting 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 this proposed rule with short descriptors only. We list them again in Addendum O to this proposed rule with long descriptors. We also are proposing 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. The proposed status indicator, and APC assignment and payment rates for these codes, where applicable, can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

B. Proposed 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 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 ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they

support. 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 proposed rule.

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. For CY 2016, we are proposing 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 are 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 note that, historically, we have proposed APC relative payment weights relative to the hospital costs of services included in existing APC 0634. In this proposed rule, we are proposing 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 are proposing to delete existing APC 0634 and replace it with proposed renumbered APC 5012.

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 this proposed rule, for CY 2016, we are proposing 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 have identified the APCs with violations of the 2 times rule. Therefore, we are proposing changes to the procedure codes assigned to these APCs in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this 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/index.html*. In these cases, to eliminate a violation of the 2 times rule or to improve clinical and resource homogeneity, we are proposing 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 this 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 are proposing changes to the status indicators for some procedure codes that are not specifically and separately discussed in this proposed rule. In these cases, we are proposing 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 are proposing to rename existing APCs or create new clinical APCs to complement the proposed procedure code reassignments. Addendum B to this CY 2016 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we are proposing 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/index.html*).

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we are proposing 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 available for this CY 2016 proposed rule, we found three APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs that we are proposing to make exceptions for under the 2 times rule for CY 2016, and identified three APCs that met the criteria for an exception to the 2 times rule based on the CY 2014 claims data available for this proposed rule. 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 has an APC cost for a single service of $5,653.37. (We note that, in section II.A.2.e. of this proposed rule, we are proposing to convert proposed renumbered APC 5881 to a comprehensive APC for CY 2016. However, the APC cost is still not relevant to determine whether there is a

2 times rule violation in that comprehensive APC.)

Therefore, 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 generally 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 this proposed rule lists the three APCs that we are proposing 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. For the final rule with comment period, we intend 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.

The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this proposed rule 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 16—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2016

Proposed CY 2016 APC*	Proposed CY 2016 APC Title
5221	Level 1 Pacemaker and Similar Procedures.
5673	Level 3 Pathology.
5731	Level 1 Minor Procedures.

*We refer readers to Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a crosswalk of the existing APC numbers to the proposed new APC numbers.

C. Proposed 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 are not proposing to renumber the New Technology APCs in this 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 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. Proposed 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, we are proposing to expand

the New Technology APC groups by adding 9 more levels, specifically, adding New Technology Levels 38 through 46. We are proposing 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 are proposing 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 (T) and the other set not subject to the multiple procedure payment reduction (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 below includes the complete list of the proposed additional 18 New Technology APC groups for CY 2016.

TABLE 17—PROPOSED ADDITIONAL NEW TECHNOLOGY APC GROUPS FOR CY 2016

Proposed new CY 2016 APC	Proposed CY 2016 APC Group title	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
1585	New Technology—Level 38 ($10,000-$15,000)	T
1586	New Technology—Level 39 ($15,000-$20,000)	T
1587	New Technology—Level 40 ($20,000-$25,000)	T
1588	New Technology—Level 41 ($25,000-$30,000)	T
1589	New Technology—Level 42 ($30,000-$40,000)	T
1590	New Technology—Level 43 ($40,000-$50,000)	T
1591	New Technology—Level 44 ($50,000-$60,000)	T
1592	New Technology—Level 45 ($60,000-$70,000)	T
1593	New Technology—Level 46 ($70,000-$80,000)	T

The proposed payment rates for New Technology APC groups 1575 through 1583 and 1585 through 1593 can be found in Addendum A to this proposed rule (which is available via the Internet on the CMS Web site).

3. Proposed 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, for CY 2016, we are proposing 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).

a. Transprostatic Urethral Implant Procedure

Currently, in CY 2015, there is one procedure that is receiving payment through a New Technology APC. Specifically, the procedure described by HCPCS code C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) is assigned to New Technology APC 1564 (New Technology—Level XXVII ($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, we are proposing to maintain the assignment of HCPCS code C9740 to New Technology APC 1564 for CY 2016. As described in section IV.B. of this 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 is included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site).

b. Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis. This surgical procedure is currently assigned to APC 0673 that 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 proposed rule 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 this CY 2016 OPPS/ASC proposed rule shows 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, we are proposing 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)). We 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). Therefore, we are proposing to reassign CPT code 0100T to proposed new APC 1593 with a payment of $75,000 for CY 2016. We refer readers to section III.C.2. of this proposed rule for a discussion of the proposed expansion of the New Technology APC levels. 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 not significantly dissimilar to the payment for the same procedure provided in the hospital inpatient setting. Once we have more claims data, we will reassess the APC placement of the Argus® II Retinal Prosthesis System in light of our standard rate setting methodology. We are inviting public comments on this proposal.

D. Proposed 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, we are proposing 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 are proposing 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 are 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 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 are not proposing to change the numbering of the composite APCs or the New Technology APCs for CY 2016.

Existing CY 2015 APC numbers and their proposed new CY 2016 APC numbers can be found in Addendum Q (Crosswalk of CY 2015 APC Numbers to CY 2016 APC Numbers) to this proposed rule, which is available via the Internet on the CMS Web site.

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. For CY 2016, we are proposing 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 series 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 are proposing to restructure and consolidate the APCs that include airway endoscopy

procedures into a single APC series. Table 18 below lists the current CY 2015 APCs that contain airway endoscopy procedures, and Table 19 below lists the proposed CY 2016 APCs that result from our proposed consolidation and restructuring of the current airway endoscopy procedure APCs into a single APC series. The procedures assigned to each APC are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 18—CY 2015 AIRWAY ENDOSCOPY APCS

CY 2015 APC	CY 2015 APC Group title
0071	Level I Endoscopy Upper Airway.
0072	Level II Endoscopy Upper Airway.
0073	Level III Endoscopy Upper Airway.
0074	Level IV Endoscopy Upper Airway.
0075	Level V Endoscopy Upper Airway.
0076	Level I Endoscopy Lower Airway.
0415	Level II Endoscopy Lower Airway.

TABLE 19—PROPOSED CY 2016 AIRWAY ENDOSCOPY APCS

Proposed restructured/renumbered CY 2016 APC *	Proposed 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.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

2. 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 are proposing 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 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, for CY 2016, we are proposing 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 below lists the current CY 2015 APCs that contain nonimaging diagnostic tests, and Table 21 below lists the proposed CY 2016 APCs that result from our proposed consolidation and restructuring of the current diagnostic test and related services APCs. The procedures assigned to each APC are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 20—CY 2015 APCS THAT CONTAIN DIAGNOSTIC TESTS AND RELATED SERVICES

CY 2015 APC	CY 2015 APC Group title
0360	Level I Alimentary Tests.
0361	Level II Alimentary Tests.
0100	Cardiac Stress Tests.
0099	Electrocardiograms/Cardiography.
0231	Level III Eye Tests & Treatments.
0213	Level I Extended EEG, Sleep, and Cardiovascular Studies.
0209	Level II Extended EEG, Sleep, and Cardiovascular Studies.
0435	Level III Extended EEG, Sleep, and Cardiovascular Studies.
0215	Level I Nerve and Muscle Services.
0218	Level II Nerve and Muscle Services.
0216	Level III Nerve and Muscle Services.
0446	Level IV Nerve and Muscle Services.
0373	Neuropsychological Testing.
0097	Level I Noninvasive Physiologic Studies.
0096	Level II Noninvasive Physiologic Studies.
0363	Otorhinolaryngologic and Related Tests.
0367	Level I Pulmonary Tests.
0369	Level II Pulmonary Tests.
0126	Level I Urinary and Anal Procedures.

TABLE 21—PROPOSED CY 2016 DIAGNOSTIC TESTS AND RELATED SERVICES APCS

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC Group 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.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

3. 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 in one series and excision/biopsy procedures in another series.

Based on our evaluation of the current APC structure and the latest hospital outpatient claims data available for this proposed rule, we are proposing to revise 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 in 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 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 under the hospital OPPS when assigned to clinical APCs with services with similar clinical attributes and resource costs. Therefore, for CY 2016, we are proposing 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 below lists the current CY 2015 APCs that contain incision and drainage as well as excision/biopsy procedures, and Table 23 below lists the proposed CY 2016 APCs that result from the proposed consolidating and restructuring of the APCs into a single APC series. The proposed payment rates for the specific CPT or Level II HCPCS codes for incision and drainage procedures as well as excision/biopsy procedures are included in Addendum B to this proposed rule, while the proposed payment rates for the specific APCs to which these procedures are assigned are included in Addendum A to this proposed rule. Both OPPS Addenda A and B are available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 22—CY 2015 APCs TO WHICH THE INCISION AND DRAINAGE AND EXCISION/BIOPSY PROCEDURES ARE ASSIGNED

CY 2015 APC	CY 2015 APC group title
0006	Level I Incision & Drainage.
0007	Level II Incision & Drainage.
0008	Level III Incision & Drainage.
0019	Level I Excision/Biopsy.

TABLE 22—CY 2015 APCs TO WHICH THE INCISION AND DRAINAGE AND EXCISION/BIOPSY PROCEDURES ARE ASSIGNED—Continued

CY 2015 APC	CY 2015 APC group title
0020	Level II Excision/Biopsy.
0021	Level III Excision/Biopsy.
0022	Level IV Excision/Biopsy.

TABLE 23—PROPOSED CY 2016 APCs FOR EXCISION/BIOPSY/INCISION AND DRAINAGE PROCEDURES

Proposed restructured/renumbered CY 2016 APC *	Proposed 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.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

4. 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, we are proposing 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, for CY 2016, we are proposing to restructure and consolidate the APCs that contain GI procedures. 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 below lists the current CY 2015 APCs that contain GI procedures, and Table 25 below lists the proposed CY 2016 APCs that result from the proposed 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 proposed rule, which is available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 24—CY 2015 APCs THAT CONTAIN GASTROINTESTINAL PROCEDURES

CY 2015 APC	CY 2015 APC Group title
0148	Level I Anal/Rectal Procedures.
0155	Level II Anal/Rectal Procedures.
0149	Level III Anal/Rectal Procedures.
0150	Level IV Anal/Rectal Procedures.
0151	Endoscopic Retrograde Cholangio-Pancreaotography.
0384	GI Procedures with Stents.
0154	Hernia/Hydrocele Procedures.
0652	Insertion of Intraperitoneal and Pleural Catheters.
0143	Lower GI Endoscopy.
0152	Level I Percutaneous Abdominal and Biliary Procedures.
0423	Level II Percutaneous Abdominal and Biliary Procedures.
0153	Peritoneal and Abdominal Procedures.
0146	Level I Sigmoidoscopy and Anoscopy.
0147	Level II Sigmoidoscopy and Anoscopy.
0428	Level III Sigmoidoscopy and Anoscopy.
0142	Level I Small Intestine Endoscopy.
0424	Level II Small Intestine Endoscopy.

TABLE 24—CY 2015 APCs THAT CONTAIN GASTROINTESTINAL PROCEDURES—Continued

CY 2015 APC	CY 2015 APC Group title
0070	Thoracentesis/Lavage Procedures.
0121	Level I Tube or Catheter Changes or Repositioning.
0427	Level II Tube or Catheter Changes or Repositioning.
0141	Level I Upper GI Procedures.
0419	Level II Upper GI Procedures.
0422	Level III Upper GI Procedures.

TABLE 25—PROPOSED CY 2016 APCs FOR GASTROINTESTINAL PROCEDURES

Proposed restructured/renumbered CY 2016 APC *	Proposed 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.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

In addition, we are proposing 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 below be moved from their currently assigned APC to C–APC 0384 (GI Procedures with Stents). 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 this proposed rule, we are proposing to renumber and retitle C–APC 0384 as ''C–APC 5331 (Complex GI Procedures)'' for CY 2016.)

TABLE 26—GASTROINTESTINAL PROCEDURES PROPOSED FOR REASSIGNMENT TO NEW C–APC 5331 IN CY 2016

CY 2015 CPT code	Procedure code description	CY 2015 APC	Proposed CY 2016 APC
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	APC 0142 (Level I Small Intestine APC).	C–APC 5331 (Complex GI Procedures).
44402	Colonoscopy through stoma; with endoscopic stent placement (including pre- and post-dilation and guide wire passage, when performed).	APC 0143 (Lower GI Endoscopy APC)	C–APC 5331 (Complex GI Procedures).
45347	Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	APC 0147 (Level II Sigmoidoscopy and Anoscopy).	C–APC 5331 (Complex GI Procedures).
45389	Colonoscopy, flexible; with endoscopic stent placement (includes pre- and post-dilation and guide wire passage, when performed).	APC 0143 (Lower GI Endoscopy APC)	C–APC 5331 (Complex GI Procedures).

5. 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 are proposing 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, for CY 2016, we are proposing to restructure and consolidate the APCs that include radiology and nuclear medicine services. 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 below lists the current CY 2015 APCs that contain radiology and nuclear medicine services, and Table 28 below lists the proposed CY 2016 APCs that result from the proposed consolidation and restructuring of the current radiology and nuclear medicine services APCs. The procedures assigned to each APC are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 27—CY 2015 IMAGING-RELATED PROCEDURES APCS

CY 2015 APC	CY 2015 APC Group title
0668	Level I Angiography and Venography.
0279	Level II Angiography and Venography.
0280	Level III Angiography and Venography.
0275	Arthrography.
0396	Bone Imaging.
0383	Cardiac Computed Tomographic Imaging.
0398	Level I Cardiac Imaging.
0377	Level II Cardiac Imaging.
0334	Combined Abdomen and Pelvis CT with Contrast.
0331	Combined Abdomen and Pelvis CT without Contrast.
0283	Computed Tomography with Contrast.
0332	Computed Tomography without Contrast.
0333	Computed Tomography without Contrast followed by Contrast.
8006	CT and CTA with Contrast Composite.
8005	CT and CTA without Contrast Composite.
0662	CT Angiography.
0265	Level I Diagnostic and Screening Ultrasound.
0266	Level II Diagnostic and Screening Ultrasound.
0267	Level III Diagnostic and Screening Ultrasound.
0278	Diagnostic Urography.
0276	Level I Digestive Radiology.
0277	Level II Digestive Radiology.
0388	Discography.
0177	Level I Echocardiogram with Contrast.
0178	Level II Echocardiogram with Contrast.
0269	Level I Echocardiogram Without Contrast.
0270	Level II Echocardiogram Without Contrast.
0390	Level I Endocrine Imaging.
0391	Level II Endocrine Imaging.
0272	Fluoroscopy and Other Radiology Services.
0395	Hepatobiliary Imaging.
0400	Hematopoietic Imaging.
0394	Hepatobiliary Imaging.
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast.
0336	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast.
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast.
0263	Level I Miscellaneous Radiology Procedures.
0317	Level II Miscellaneous Radiology Procedures.
8008	MRI and MRA with Contrast Composite.
8007	MRI and MRA without Contrast Composite.
0274	Myelography.
0403	Level I Nervous System Imaging.
0402	Level II Nervous System Imaging.
0260	Level I Plain Film Including Bone Density Measurement.
0261	Level II Plain Film Including Bone Density Measurement.
0308	Positron Emission Tomography (PET) imaging.
0401	Level I Pulmonary Imaging.
0378	Level II Pulmonary Imaging.
0404	Renal and Genitourinary Studies.
0406	Level I Tumor/Infection Imaging.
0414	Level II Tumor/Infection Imaging.
0408	Level III Tumor/Infection Imaging.
8004	Ultrasound Composite.
0393	Hematologic Processing & Studies.

TABLE 28—PROPOSED CY 2016 IMAGING-RELATED PROCEDURES APCS

Proposed restructured/renumbered CY 2016 APC*	Proposed 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.
5551	Level 1 Echocardiogram Without Contrast.
5552	Level 2 Echocardiogram Without Contrast.
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.
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.

*Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

6. 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 are proposing 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, for CY 2016, we are proposing to restructure and consolidate the APCs for orthopedic surgery procedures. 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 below lists the current CY 2015 APCs that contain orthopedic-related procedures, and Table 30 below lists the proposed CY 2016 APCs that result from the proposed restructuring and consolidation of the current orthopedic-related procedures APCs. The procedures assigned to each APC are listed in Addendum B to this proposed rule, which is available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 29—CY 2015 ORTHOPEDIC–RELATED PROCEDURES APCS

CY 2015 APC	CY 2015 APC Group title
0047	Arthroplasty.
0041	Level I Arthroscopy.
0042	Level II Arthroscopy.
0045	Bone/Joint Manipulation Under Anesthesia.
0057	Bunion Procedures.
0129	Level I Closed Treatment Fracture.
0138	Level II Closed Treatment Fracture.
0139	Level III Closed Treatment Fracture.
0431	Level IV Closed Treatment Fracture.
0055	Level I Foot Musculoskeletal Procedures.
0056	Level II Foot Musculoskeletal Procedures.
0053	Level I Hand Musculoskeletal Procedures.
0054	Level II Hand Musculoskeletal Procedures.
0208	Laminotomies and Laminectomies.
0049	Level I Musculoskeletal Procedures Except Hand and Foot.
0050	Level II Musculoskeletal Procedures Except Hand and Foot.
0051	Level III Musculoskeletal Procedures Except Hand and Foot.
0052	Level IV Musculoskeletal Procedures Except Hand and Foot.
0425	Level V Musculoskeletal Procedures Except Hand and Foot.
0058	Level II Strapping and Cast Application.
0059	Level I Strapping and Cast Application.
0062	Level I Treatment Fracture/ Dislocation.
0063	Level II Treatment Fracture/ Dislocation.
0064	Level III Treatment Fracture/ Dislocation.

TABLE 30—PROPOSED CY 2016 ORTHOPEDIC-RELATED PROCEDURES APCS

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC group title
5101	Level 1 Strapping and Cast Application.
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	Level1 Musculoskeletal Procedures.
5122	Level 2 Musculoskeletal Procedures.
5123	Level 3 Musculoskeletal Procedures.
5124	Level 4 Musculoskeletal Procedures.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

7. 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 latest hospital outpatient claims data available for this proposed rule, we are proposing to restructure all of the skin-related procedure APC assignments by combining the debridement and skin procedure APCs to more appropriately reflect the costs and clinical characteristics of the procedures within each APC. Clinically, the services assigned to the current debridement APC series are similar to the services assigned to the current skin procedures APCs. We believe that the services in these two APC series would be more appropriately represented in a single APC series described as skin procedures and related services. We believe that this proposed consolidation and restructuring of APCs more appropriately categorizes all of the skin procedures and related services within a series of APCs with different resources, such that the services within each proposed newly configured APC are comparable based on its clinical homogeneity and resource costs. Therefore, for CY 2016, we are proposing to consolidate and restructure the skin and debridement APCs into a single APC series. Table 31 below lists the current CY 2015 APCs that contain skin and debridement procedures, and Table 32 below lists the proposed CY 2016 APCs that result from the proposed consolidation and restructuring of the current skin-related procedure APCs into a single APC series. The proposed payment rates for the specific CPT or Level II HCPCS skin procedure codes are specified in Addendum B to this proposed rule. The proposed payment rates for the specific APCs to which the skin procedures are proposed to be assigned are specified in Addendum A to this proposed rule. Both OPPS Addenda A and B are available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 31—CY 2015 APCS TO WHICH DEBRIDEMENT AND SKIN PROCEDURES ARE ASSIGNED

CY 2015 APC	CY 2015 APC Group title
0012	Level I Debridement & Destruction.
0015	Level II Debridement & Destruction.
0016	Level III Debridement & Destruction.
0017	Level IV Debridement & Destruction.
0326	Level I Skin Procedures.
0327	Level II Skin Procedures.
0328	Level III Skin Procedures.

TABLE 31—CY 2015 APCs TO WHICH DEBRIDEMENT AND SKIN PROCEDURES ARE ASSIGNED—Continued

CY 2015 APC	CY 2015 APC Group title
0329	Level IV Skin Procedures.

TABLE 32—PROPOSED CY 2016 APCs ASSIGNMENT FOR SKIN PROCEDURES

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC Group 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.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

8. Urology and Related Services Procedures

For the CY 2016 OPPS update, based on our evaluation of the latest hospital outpatient claims data used for this proposed rule, we are proposing to revise all of the urology and related services APCs to more appropriately reflect the resource costs and clinical characteristics of the procedures within each APC. Currently, several of the urology-related APCs are differentiated based on their resource costs rather than clinical similarity. We believe that establishing more inclusive categories of the urology and related procedures is more appropriate for future ratesetting under the hospital OPPS because the restructured APCs have a more clinically appropriate granularity, while improving resource similarity. Further, we believe that this proposed revision and consolidation of APCs would more appropriately categorize all of the urology procedures and services within an APC group such that the services within each proposed newly configured APC are comparable clinically and with respect to resource use. Therefore, for CY 2016, we are proposing to restructure and consolidate the urology and related APCs into a single APC series. Table 33 below shows the CY 2015 urology and related APCs and status indicator assignments, and Table 34 below lists the proposed CY 2016 APCs that result from the proposed consolidation and restructuring of the current urology and related APCs into a single APC series. The proposed payment rates for the specific CPT or Level II HCPCS urology and related procedure codes are included in Addendum B to this proposed rule. The proposed payment rates for the proposed specific APCs to which we are proposing to assign the urology and related procedures codes are included in Addendum A to this proposed rule. Both OPPS Addenda A and B are available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 33—CY 2015 APCs TO WHICH UROLOGY & RELATED SERVICES ARE ASSIGNED

CY 2015 APC	CY 2015 APC Group title
0160	Level I Cystourethroscopy and other Genitourinary Procedures.
0161	Level II Cystourethroscopy and other Genitourinary Procedures.
0162	Level III Cystourethroscopy and other Genitourinary Procedures.
0163	Level IV Cystourethroscopy and other Genitourinary Procedures.
0183	Level I Male Genital Procedures.
0181	Level II Male Genital Procedures.
0205	Level III Male Genital Procedures.
0184	Prostate Biopsy.
0166	Level I Urethral Procedures.
0168	Level II Urethral Procedures.
0126	Level I Urinary and Anal Procedures.
0164	Level II Urinary and Anal Procedures.
0156	Level III Urinary and Anal Procedures.
0165	Level IV Urinary and Anal Procedures.
0385	Level I Urogenital Procedures.
0386	Level II Urogenital Procedures.

TABLE 34—PROPOSED CY 2016 APCs ASSIGNED TO AL UROLOGY AND RELATED SERVICES

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC Group 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.

TABLE 34—PROPOSED CY 2016 APCs ASSIGNED TO AL UROLOGY AND RELATED SERVICES—Continued

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC Group title
5376	Level 6 Urology and Related Services.
5377	Level 7 Urology and Related Services.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

9. Vascular Procedures (Excluding Endovascular Procedures)

For the CY 2016 OPPS update, based on our evaluation of the latest hospital outpatient claims data available for this proposed rule, we are proposing 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 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 below shows the vascular procedures APCs for CY 2015, and Table 36 below shows the proposed vascular procedures APCs for CY 2016. The proposed payment rates for the vascular procedure codes are included in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site). The proposed payment rates for the proposed specific APCs to which we are proposing to assign the urology and related procedures codes are included in Addenda A and B to this proposed rule. Both OPPS Addenda A and B are available via the Internet on the CMS Web site. We are inviting public comments on this proposal.

TABLE 35—CY 2015 VASCULAR PROCEDURE APCs

[Excluding Endovascular Procedures]

CY 2015 APC	CY 2015 APC Group title
0103	Miscellaneous Vascular Procedures.
0624	Phlebotomy and Minor Vascular Access Device.
0088	Thrombectomy.

TABLE 35—CY 2015 VASCULAR PROCEDURE APCS—Continued
[Excluding Endovascular Procedures]

CY 2015 APC	CY 2015 APC Group title
0621	Level I Vascular Access Procedures.
0622	Level II Vascular Access Procedures.
0093	Vascular Reconstruction/Fistula Repair.
0219	Vascular Ligation.

TABLE 36—PROPOSED CY 2016 VASCULAR PROCEDURES APCS
[Excluding Endovascular Procedures]

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC Group title
5181	Level 1 Vascular Procedures.
5182	Level 2 Vascular Procedures.
5183	Level 3 Vascular Procedures.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the new proposed CY 2016 numbers.

IV. Proposed OPPS Payment for Devices

A. Proposed 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. Proposed 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, beginning with CY 2016, we are proposing 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.

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).

2. Proposed 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 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), or meet another FDA exemption from premarket approval or clearance; (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 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 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 initial 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, for CY 2016, we are proposing changes to the OPPS device pass-through payment application process to help achieve the goals of increased transparency and stakeholder input. We are proposing to align a portion of the OPPS device pass-through payment application process with the already established 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 are proposing for the transitional medical device pass-through payment application process under the OPPS in the section below.

b. Proposed Revisions to the Application Process for Device Pass-Through Payments

Beginning in CY 2016, we are proposing to add a rulemaking component to the current quarterly device pass-through payment application process. That is, we are proposing 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 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 proposed rule. 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.

For applications that we deny during the quarterly review process, we are proposing 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 is currently in place for denied applications; we would only provide opportunity to reconsider applications that are denied through the rulemaking process. We are proposing 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 applications 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 are inviting 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.

c. Criterion for Newness

Since the inception of transitional pass-through payments for new categories of medical devices on April 7, 2000, there has not been any specific criteria provided to evaluate the newness of the device for purposes of determining eligibility and receiving device pass-through payment under the OPPS. Section 1833(t)(6)(B)(ii)(I) of the Act requires that the Secretary shall establish criteria that will be used for creation of additional categories other than the initial categories described by section 1833(t)(6)(B)(i) of the Act through rulemaking. We believe that one prong of determining whether a new category should be established is whether or not the device seeking such new category status is itself new. We believe that the payment adjustment for transitional pass-through payments for devices under the OPPS was intended as an interim measure to allow for adequate payment of new innovative technology while we collected 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 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. 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 market for several years. We do not believe that this is the intent of the regulation. Therefore, we are proposing 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 received on or after January 1, 2016, any such device must have received such approval or clearance, as applicable, within 3 years from the date of the application for transitional pass-through payment. That is, we are proposing to add a requirement to ensure that medical devices falling under § 419.66(b)(1) and seeking creation of a category for device pass-through payment must be ''new.'' We believe that the proposed adjustment is consistent with section 1833(t)(6)(B)(ii)(I) of the Act, which allows for establishing criteria that will be used for the creation of additional categories through rulemaking. This proposed adjustment also will 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 are proposing that, beginning with applications received 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 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 are proposing to revise § 419.66(b)(1) to reflect this proposal. We are inviting public comments on this proposal.

3. Proposed 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. Proposed CY 2016 Policy

As we did for CY 2015, we are proposing 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 are proposing 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 are proposing 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 packaged into the existing APC structure are associated with the new category, we are proposing 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 are proposing 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.

B. Proposed 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 procedures within the APC are calculated and the geometric mean device offset of all 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 proposed rule. 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. Proposed Changes to Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period, 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 37 (the formerly device-dependent APCs) is reported on the claim (79 FR 66795).

TABLE 37—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.
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/Pl. Cath.
0655	Level IV Pacemaker.

There are 10 APCs listed in Table 37 that are not device-intensive APCs; that is, their device offsets do not exceed 40 percent. We do not believe that we should continue to require device codes on claims for procedures that are not assigned to device-intensive APCs, as 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 note 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, 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, we are proposing for CY 2016 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 are listed in Table 38 below.

TABLE 38—PROPOSED CY 2016 DEVICE-INTENSIVE APCS

Proposed re-numbered CY 2016 APC *	Proposed CY 2016 APC title
0039	Level III Neurostimulator & Related Procedures.
0061	Level II Neurostimulator & Related Procedures.
0089	Level III Pacemaker & Similar Procedures.
0090	Level II Pacemaker & Similar Procedures.
0105	Level I Pacemaker & Similar Procedures.
0107	Level I ICD & Similar Procedures.
0108	Level II ICD & Similar Procedures.
0227	Implantation of Drug Infusion Device.
0229	Level II Endovascular Procedures.
0259	Level VI ENT Procedures.
0293	Level III Intraocular Procedures.
0318	Level IV Neurostimulator & Related Procedures.
0319	Level III Endovascular Procedures.
0351	Level IV Intraocular Procedures.
0386	Level VII Urology & Related Procedures.
0425	Level IV Musculoskeletal Procedures.
0655	Level IV Pacemaker & Similar Procedures.
1564	New Technology—Level 27.
1593	New Technology—Level 46.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) provides a crosswalk of the existing APC numbers to the proposed APC renumbers.

We are proposing 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, would satisfy the edit. Claims submitted with a procedure code requiring a device assigned to an APC listed in Table 38, but without any device code reported on the claim, would be returned to the provider.

3. Proposed 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 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. Proposed Policy for CY 2016

For CY 2016 and subsequent years, we are proposing 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 are proposing to continue to reduce the OPPS payment, for the device intensive APCs listed in Table 38 above, 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. 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 current policy, the actual amount of the device credit can be appropriately reported in the amount portion of value code ''FD'' and deducted from 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 are proposing 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 are proposing 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, we also are proposing 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.

We examined the offset amounts calculated from the CY 2016 proposed rule claims data and the clinical characteristics of the proposed CY 2016 APCs to determine which APCs meet the criteria for CY 2016. The full list of device-intensive APCs to which we are proposing that the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2016 is included in Table 38 above.

4. Proposed Adjustment to OPPS Payment for Discontinued Device-Intensive Procedures

It has been our longstanding policy to instruct hospitals to utilize an appropriate modifier on a claim to report when a procedure is discontinued, partially reduced, or cancelled. 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 blocks(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 blocks(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, we are proposing 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 are proposing 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. At this time, we are not proposing 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 are soliciting 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.

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed 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 proposed rule, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. ''Biological'' as used in this proposed rule 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. Proposed CY 2016 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this proposed rule, 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 proposed rule, 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. Proposed Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2015

We are proposing that the pass-through status of 12 drugs and biologicals would expire on December 31, 2015, as listed in Table 39 below. 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, 2013. 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 proposed at $100 for CY 2016), as discussed further in section V.B.2. of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would 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 would provide separate payment at the applicable relative ASP-based payment amount

(which is proposed at ASP+6 percent for CY 2016, as discussed further in section V.B.3. of this proposed rule).

TABLE 39—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2015

CY 2015 HCPCS code	CY 2015 long descriptor	CY 2015 SI	CY 2015 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. Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in CY 2016

We are proposing 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, are listed in Table 40 below. The APCs and HCPCS codes for these drugs and biologicals approved for pass-through status through July 1, 2015 are assigned status indicator ''G'' in Addenda A and B to this proposed rule. Addenda A and B to this 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 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 are proposing 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 are proposing 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 is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, 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 are proposing 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 are proposing 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 are proposing 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 are proposing to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we are proposing 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 are proposing to 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 this proposed rule, we implemented a policy whereby payment for the following nonpass-through items is packaged into payment for the associated procedure: policy-packaged drugs which include contrast agents, stress agents, diagnostic radiopharmaceuticals, and 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 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 proposed rule. 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.

According to section 1833(t)(8)(E) of the Act, 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 are proposing 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 are proposing to continue to have pass-through payment status for CY 2016 or have been granted pass-through payment status as of July 2015 are shown in Table 40 below.

TABLE 40—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2016

CY 2015 HCPCS code	Proposed CY 2016 HCPCS code	CY 2016 Long descriptor	Proposed CY 2016 SI	Proposed new CY 2016 APC *
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664
C9025	C9025	Injection, ramucirumab, 5 mg	G	1488
C9026	C9026	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	C9442	Injection, belinostat, 10 mg	G	1658
C9443	C9443	Injection, dalbavancin, 10 mg	G	1659
C9444	C9444	Injection, oritavancin, 10 mg	G	1660
C9445	C9445	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	G	9445
C9446	C9446	Injection, tedizolid phosphate, 1 mg	G	1662
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663
C9449	C9449	Injection, blinatumomab, 1 mcg	G	9449
C9450	C9450	Injection, fluocinolone acetonide intravitreal implant, 0.19 mg	G	9450
C9451	C9451	Injection, peramivir, 1 mg	G	9451
C9452	C9452	Injection, ceftolozane 50 mg and tazobactam 25 mg	G	9452
C9453	C9453	Injection, nivolumab, 1 mg	G	9453
C9454	C9454	Injection, pasireotide long acting, 1 mg	G	9454
C9455	C9455	Injection, siltuximab, 10 mg	G	9455
C9497	C9497	Loxapine, inhalation powder, 10 mg	G	9497
C9022	J1322	Injection, elosulfase alfa, 1 mg	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
C9136	Q9975	Injection, factor viii, fc fusion protein, (recombinant), per i.u.	G	1656
C9448	Q9978	Netupitant (300mg) and palonosetron (0.5 mg), oral	G	9448

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

4. Proposed 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. Proposed 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 are proposing to continue to apply the diagnostic radiopharmaceutical offset policy to payment for pass-through diagnostic radiopharmaceuticals. For CY 2016, there will be one diagnostic radiopharmaceutical with pass-through status under the OPPS, HCPCS code A9586 (Florbetapir f18, diagnostic, per study dose, up to 10 millicuries). We currently apply the established radiopharmaceutical payment offset policy to pass-through payment for this product.

Table 41 below displays 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.

TABLE 41—PROPOSED APCS TO WHICH A DIAGNOSTIC RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2016

Proposed Restructured/ Renumbered CY 2016 APC *	Proposed 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.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

c. Proposed 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, we are proposing 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 are proposing 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).

Although there are currently no contrast agents with pass-through payment status under the OPPS, we believe that a payment offset is necessary in the event that a new contrast agent is approved for pass-through status during CY 2016 to provide an appropriate transitional pass-through payment for new contrast agents. We are proposing 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 above, and these APCs are displayed in Table 42 below. 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 are proposing to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in Table 42 of this proposed rule, 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.

TABLE 42—PROPOSED APCS TO WHICH A CONTRAST AGENT PAYMENT OFFSET MAY BE APPLICABLE FOR CY 2016

Proposed restructured/renumbered CY 2016 APC *	Proposed 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.

TABLE 42.—PROPOSED APCS TO WHICH A CONTRAST AGENT PAYMENT OFFSET MAY BE APPLICABLE FOR CY 2016—Continued

Proposed restructured/renumbered CY 2016 APC *	Proposed CY 2016 APC title
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.
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.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

d. Proposed 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). For CY 2016, as we did in CY 2015, we are proposing to continue to apply the skin substitute and stress agent offset policy to payment for pass-through skin substitutes and stress agents.

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 below displays 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 below displays 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.

TABLE 43—PROPOSED APCS TO WHICH A SKIN SUBSTITUTE PAYMENT OFFSET MAY BE APPLICABLE FOR CY 2016

Proposed new CY 2016 APC *	Proposed CY 2016 APC title
5054	Level 4 Skin Procedures.
5055	Level 5 Skin Procedures.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

TABLE 44—PROPOSED APCS TO WHICH A STRESS AGENT PAYMENT OFFSET MAY BE APPLICABLE FOR CY 2016

Proposed new CY 2016 APC *	Proposed CY 2016 APC title
5722	Level 2 Diagnostic Tests and Related Services.
5593	Level 3 Nuclear Medicine and Related Services.

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

We are proposing to 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. Proposed 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. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Background

As indicated in section V.B.1. of this proposed rule, 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 this CY 2016 OPPS/ASC proposed rule, 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 are proposing 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).

b. Proposed Cost Threshold for Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals (''Threshold-Packaged Drugs'')

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 this proposed rule, or for the following policy-packaged items that we are proposing 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 are proposing for separately payable drugs and biologicals for CY 2016, as discussed in more detail in section V.B.3.b. of this 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 are proposing 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 this proposed rule (which are available via the Internet on the CMS Web site) because these are the most recent data available for use at the time of development of this 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 are proposing 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 display in Addendum B to this proposed rule (which is available via the Internet on the CMS Web site) for proposed payment in CY 2016.

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 proposed rule, we are proposing to use 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 are proposing to use these data for budget neutrality estimates and impact analyses for this CY 2016 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B to the final rule with comment period will be based on ASP data from the second quarter of CY 2015. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2015. These payment rates would 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 are proposing to recalculate their mean unit cost from all of the CY 2014 claims data and updated cost report information available for the 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 this 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 the CY 2016 OPPS/ASC final rule with comment period. Under such circumstances, we are proposing 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 are proposing 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 are 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 are 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 are proposing 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.

c. Proposed 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 cm^2. Skin substitutes that had a July 2013 ASP+6 percent amount above $32 per cm^2 were classified in the high cost group, and skin substitutes that had a July 2013 ASP+6 percent amount at or below $32 per cm^2 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 cm^2 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 cm^2). 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 cm^2 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 cm^2) 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. 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 have 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 cm^2 and a PDC threshold (rounded to the nearest $1) of $1,050.

For CY 2016, based on these calculations, we are proposing to determine the high/low cost status for each skin substitute product based on either a product's MUC exceeding the MUC threshold or the product's PDC exceeding the PDC threshold. 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 note that the majority of high cost products remain high cost under both methodologies. Observing fairly consistent results with both methodologies, we believe that, together, both thresholds constitute a more robust methodology for identifying high cost skin substitute products.

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 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 are proposing 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 are proposing to remove for the skin cost group are identified in Table 45 below. Implantable biologicals are treated as packaged surgical supplies under the OPPS, which are captured under 42 CFR 419.2(b)(4).

TABLE 45—PROPOSED IMPLANTABLE BIOLOGICALS FOR REMOVAL FROM SKIN SUBSTITUTE COST GROUP LIST

Proposed CY 2016 HCPCS code	Proposed CY 2016 short descriptor	Proposed CY 2016 status indicator
C9358	SurgiMend, fetal	N
C9360	SurgiMend, neonatal	N
Q4107	Graft Jacket	N
Q4125	Arthroflex	N
Q4130	Strattice TM	N
Q4142	Xcm biologic tiss matrix 1cm	N

Table 46 below shows the CY 2015 high cost/low cost status for each product based on our combined threshold methodology. As noted earlier, we have 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. For the CY 2016 OPPS/ASC final rule with comment period, we will update the MUC and PDC threshold amounts using the most recently available CY 2014 claims data and CY 2015 pricing information.

We are proposing that a skin substitute that is assigned to the high cost group in CY 2015 and exceeds either the MUC or PDC in this 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 the CY 2016 final rule with comment period.

TABLE 46—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2016

Proposed CY 2016 HCPCS code	CY 2016 Short descriptor	HCPCS Code dosage	Proposed CY 2016 SI	CY 2015 High/Low status based on weighted MUC	Proposed CY 2016 High/Low status based on proposed weighted MUC	Proposed CY 2016 High/Low status based on proposed weighted PDC
Q4100	Skin Substitute, NOS	N/A	N	Low	Low	Low
Q4102	Oasis Wound Matrix	1 cm^2	N	Low	Low	Low
Q4103	Oasis Burn Matrix	1 cm^2	N	Low	High	High
Q4111	Gammagraft	1 cm^2	N	Low	Low	Low
Q4115	Alloskin	1 cm^2	N	Low	Low	Low
Q4117**	Hyalomatrix	1 cm^2	N	Low	Low	Low
Q4119	Matristem Wound Matrix	1 cm^2	N	Low	Low	Low
Q4120	Matristem Burn Matrix	1 cm^2	N	Low	Low	Low
Q4124	Oasis Tri-layer Wound Matrix	1 cm^2	N	Low	Low	Low
Q4135	Mediskin	1 cm^2	N	Low	Low	Low
Q4136	Ezderm	1 cm^2	N	Low	Low	Low
Q4141	Alloskin ac, 1cm	1 cm^2	N	Low	Low	Low
Q4142	Xcm Biologic Tissue Matrix 1cm	1 cm^2	N	Low	Low	High
Q4143**	Repriza, 1cm	1 cm^2	N	Low	Low	Low
Q4146	Tensix, 1CM	1 cm^2	N	Low	Low	Low
Q4150**	Allowrap DS or Dry 1 sq cm	1 cm^2	N	High	Low	Low
Q4151**	AmnioBand, Guardian 1 sq cm	1 cm^2	N	Low	Low	Low
Q4153**	Dermavest 1 square cm	1 cm^2	N	High	Low	Low
Q4157**	Revitalon 1 square cm	1 cm^2	N	Low	Low	Low
Q4158**	MariGen 1 square cm	1 cm^2	N	Low	Low	Low
Q4159**	Affinity 1 square cm	1 cm^2	N	High	Low	Low
C9349*/**	PuraPly/PuraPly Antimicrobial	1 cm^2	G	High	High	High
C9363	Integra Meshed Bil Wound Mat	1 cm^2	N	High	High	Low
Q4101	Apligraf	1 cm^2	N	High	High	High
Q4104	Integra BMWD	1 cm^2	N	High	Low	Low
Q4105	Integra DRT	1 cm^2	N	High	Low	High
Q4106	Dermagraft	1 cm^2	N	High	High	Low
Q4108	Integra Matrix	1 cm^2	N	High	Low	Low
Q4110	Primatrix	1 cm^2	N	High	High	Low
Q4116	Alloderm	1 cm^2	N	High	Low	High
Q4121*	Theraskin	1 cm^2	G	High	High	High
Q4122**	Dermacell	1 cm^2	N	High	High	High
Q4123	Alloskin	1 cm^2	N	High	Low	High
Q4126	Memoderm/derma/tranz/ Integup	1 cm^2	N	High	High	High
Q4127	Talymed	1 cm^2	N	High	High	High
Q4128	Flexhd/Allopatchhd/Matrixhd	1 cm^2	N	High	High	High
Q4129**	Unite Biomatrix	1 cm^2	N	High	Low	Low
Q4131	Epifix	1 cm^2	N	High	High	High
Q4132	Grafix Core	1 cm^2	N	High	High	High
Q4133	Grafix Prime	1 cm^2	N	High	High	High
Q4134	hMatrix	1 cm^2	N	High	Low	Low
Q4137	Amnioexcel or Biodexcel, 1cm	1 cm^2	N	High	High	Low
Q4138	Biodfence DryFlex, 1cm	1 cm^2	N	High	High	High
Q4140	Biodfence 1cm	1 cm^2	N	High	High	High
Q4147**	Architect ecm, 1cm	1 mg	N	High	High	High
Q4148	Neox 1k, 1cm	1 cm^2	N	High	High	High
Q4152**	Dermapure 1 square cm	1 cm^2	N	High	High	High
Q4154**	Biovance 1 square cm	1 cm^2	N	High	High	High
Q4156**	Neox 100 1 square cm	1 cm^2	N	High	High	High
Q4160**	NuShield 1 square cm	1 cm^2	N	High	High	High

*Pass-through status in CY 2016.

**New HCPCS code. Claims data not available in CY 2014.

d. Proposed 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, we are proposing 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 this 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 is displayed in Table 47 below.

TABLE 47—PROPOSED HCPCS CODES TO WHICH THE CY 2016 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY

Proposed CY 2016 HCPCS code	Proposed CY 2016 long descriptor	Proposed 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
J1440	Injection, filgrastim (g-csf), 300 mcg	K
J1441	Injection, filgrastim (g-csf), 480 mcg	K
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
J2270	Injection, morphine sulfate, up to 10 mg	N
J2271	Injection, morphine sulfate, 100mg	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

TABLE 47—PROPOSED HCPCS CODES TO WHICH THE CY 2016 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY WOULD APPLY—Continued

Proposed CY 2016 HCPCS code	Proposed CY 2016 long descriptor	Proposed CY 2016 SI
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

3. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Proposed 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 this CY 2016 OPPS/ASC proposed rule, we are proposing 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. Proposed CY 2016 Payment Policy

For CY 2016 and subsequent years, we are proposing 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 are proposing 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 are proposing 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.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule (available via the Internet on the CMS Web site), which illustrate the proposed 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 April 1, 2015, or WAC, AWP, or mean unit cost from CY 2014 claims data and updated cost report information available for this proposed rule. In general, these published payment rates are not reflective of actual proposed 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 third quarter of 2015 (July 1, 2015 through September 30, 2015) will be used to set the payment rates that are released for the quarter beginning in January 2016 near the end of December 2015. In addition, proposed payment rates for drugs and biologicals in Addenda A and B to this proposed rule for which there was no ASP information available for April 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 proposed rule (reflecting April 2015 ASP data) that do not have ASP information available for the quarter beginning in January 2016. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2014 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2016 payment purposes and are only illustrative of the proposed CY 2016 OPPS payment methodology using the most recently available information at the time of issuance of this proposed rule.

4. Proposed 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, we are proposing 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 are proposing 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 are included in Addenda A and B to this proposed rule (which are available via the Internet on the CMS Web site).

5. Proposed 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 within a 3-year time period. 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 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. 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 have reassessed this payment for CY 2016 and did not identify any new information that would cause us to modify payment. Therefore, for CY 2016, we are proposing to continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources.

6. Proposed 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.

For CY 2016, we are proposing 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, and 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 is 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 are 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 are proposing 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.*

7. Proposed 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.

For CY 2016, we are proposing 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 is proposed to be ASP+6 percent as discussed earlier in this section. 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 are proposing 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 proposed rule.

In accordance with the OPPS ASP methodology, in the absence of ASP data, for CY 2016 and subsequent years, we are proposing 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 note that if the WAC is also unavailable, we would make payment at 95 percent of the product's most recent AWP. We also are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing with new drugs and biologicals, we are proposing 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 are proposing to announce any changes to the payment amounts for new drugs and biologicals in the 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 this proposed rule. However, these drugs, biologicals, and therapeutic radiopharmaceuticals will be included in Addendum B to the CY 2016 OPPS/ASC final rule with comment period (which will be available via the Internet on the CMS Web site), where they will be assigned comment indicator ''NI.'' This comment indicator reflects that their interim final OPPS treatment will be open to public comment in the 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 this 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 are proposing 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 non-pass-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 are proposing to package items for which we estimate the per day administration cost to be less than or equal to $100 and to pay separately for items for which we estimate 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 are proposing to continue to package regardless of cost) in CY 2016. We also are proposing 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 are proposing 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 are displayed in Table 48 of this proposed rule.

Finally, there are 33 drugs and biologicals, shown in Table 49 of this proposed rule, 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 this 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 are proposing 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 are assigned status indicator ''E'' on this basis at the time of this proposed rule for CY 2016 are displayed in Table 49 of this proposed rule. We also are proposing 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.

TABLE 48—DRUGS AND BIOLOGICALS WITHOUT CY 2014 CLAIMS DATA

Proposed CY 2016 HCPCS code	Proposed CY 2016 long descriptor	Estimated average number of units per day	Proposed CY 2016 SI	Proposed New 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
J0717	Injection, certolizumab pegol, 1 mg	361	K	1474
J1324	Injection, enfuvirtide, 1 mg	169	K	1361
J3355	Injection, urofollitropin, 75 IU	2	K	1741
J3489	Injection, Zoledronic Acid, 1 mg	4	K	1356
J7196	Injection, antithrombin recombinant, 50 IU	268	K	1332
J8650	Nabilone, oral, 1 mg	4	K	1424
J9306	Injection, pertuzumab, 1 mg	450	K	1471
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

* Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing APC numbers to the proposed new APC numbers for CY 2016.

TABLE 49—DRUGS AND BIOLOGICALS WITHOUT CY 2014 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

Proposed CY 2016 HCPCS code	Proposed CY 2016 long descriptor	Proposed CY 2016 SI
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
90704	Mumps virus vaccine, live, for subcutaneous use	E
90727	Plague vaccine for intramuscular 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
J1180	Injection, dyphylline, up to 500 mg	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
J2670	Injection, tolazoline hcl, up to 25 mg	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, trifluprom azine hcl, up to 20 mg	E
J7191	Factor viii (antihemophilic factor (porcine)), per i.u.	E
J7505	Muromonab-cd3, parenteral, 5 mg	E
J7513	Daclizumab, parenteral, 25 mg	E
J8562	Fludarabine phosphate, oral, 10 mg	E
J9160	Injection, denileukin diftitox, 300 micrograms	E
J9165	Injection, diethylstilbestrol diphosphate, 250 mg	E
J9213	Injection, interferon, alfa-2a, recombinant, 3 million units	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

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. We are proposing 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 are proposing 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''.

D. Proposed 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. By the end of 2015, we anticipate 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. Proposed 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, we are proposing 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 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 are proposing 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 proposing that nonpass-through biosimilar biological products would be subject to our threshold-packaged policy as described in section V.B.2. of this proposed rule.

Consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, we are proposing that HCPCS coding and modifiers for biosimilar biological products will be based on policy established under the CY 2016 MPFS rule. Public comments on HCPCS codes and modifiers for biosimilar biological products should be submitted in response to the CY 2016 MPFS proposed rule.

3. Proposed 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, we are proposing 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.

We are soliciting 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.

VI. Proposed 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) is the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in this proposed rule, for CY 2016, we are proposing 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 are proposing to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

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 proposed to be reinstated for CY 2016. Because, as we are proposing 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 this proposed rule, which represents the otherwise applicable fee schedule amount associated with most pass-through drugs and biologicals, and because, as we are proposing to pay for CY 2016 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of this 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 proposed rule. We are proposing 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 proposed rule, 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 are proposing 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 are proposing 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 proposed CY 2016 pass-through estimates for these two groups of drugs and biologicals equals the proposed total CY 2016 pass-through spending estimate for drugs and biologicals with pass-through status.

B. Proposed Estimate of Pass-Through Spending

We are proposing 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 estimate 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 estimate 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 estimate 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, we are proposing an estimate for the first group of devices of $126.8 million.

In estimating our proposed CY 2016 pass-through spending for device categories in the second group, we include: Device categories that we knew at the time of the development of this proposed rule will be newly eligible for pass-through payment in CY 2016; additional device categories that we estimate 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. We are proposing 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 this proposed rule, the estimate of CY 2016 pass-through spending for this second group of device categories is $10 million.

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 are proposing 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 are proposing 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 this 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.

To estimate 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 this proposed rule are newly eligible for pass through payment in CY 2016, additional drugs and biologicals that we estimate 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 are proposing 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 are proposing 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.

In summary, in accordance with the methodology described above in this section, for this proposed rule, we estimate that proposed 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 would be approximately $146.6 million (approximately $136.8 million for device categories and approximately $9.8 million for drugs and biologicals), which represents 0.25 percent of total projected OPPS payments for CY 2016. Therefore, we estimate that proposed pass-through spending in CY 2016 would not amount to 2.0 percent of total projected OPPS CY 2016 program spending.

VII. Proposed OPPS Payment for Hospital Outpatient Visits

A. Proposed 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 do 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 this proposed rule, for CY 2016, we are proposing 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 are proposing to reassign HCPCS code G0463 from existing APC 0634 to proposed renumbered APC 5012 (Level 2 Examinations and Related Services), former APC 0632. Proposed 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 are proposing to use CY 2014 claims data to develop the proposed CY 2016 OPPS payment rates 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.

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 this CY 2016 OPPS/ASC proposed rule, we are not proposing any change in ED visit coding. Rather, as we did for CY 2015 and prior years, for CY 2016, we are proposing 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 may propose changes to the coding and APC assignments for ED visits in future rulemaking.

B. Proposed 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, for CY 2016 and subsequent years, we are proposing 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 are proposing 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. Proposed 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. (In this proposed rule, for CY 2016 and subsequent years, we are proposing 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 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 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 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. 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, for CY 2016 and subsequent years, we are proposing additional requirements for hospitals to bill and receive OPPS payment for CPT code 99490. These proposed requirements, discussed below, are in addition to those already required under the OPPS for billing CPT code 99490 in CY 2015.

In accordance with the CPT code descriptor for CPT code 99490, a hospital can only bill 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 CPT code 99490. Therefore, for CY 2016 and subsequent years, we are proposing 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 as they are providing CCM services described by CPT code 99490 to patients for whom they already provide care and treatment. However, we are proposing 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 are proposing to adopt analogous requirements for billing services described by CPT code 99490 under the OPPS. Specifically, we are proposing, 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 are proposing 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 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 are proposing, 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).

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, we are proposing 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 are proposing 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 appropriate 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- and community-based clinical service providers required to support the patient's psychosocial needs and functional deficits. Communication to and from home- 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 are proposing 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 are proposing 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 are proposing, 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 are proposing 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 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.

VIII. Proposed 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 partial hospitalization program (PHP) is a program furnished by a hospital to its outpatients or by a community mental health center (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 community mental health center 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 I Partial Hospitalization) and a higher amount for days with 4 or more services under APC 0173 (Level II 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 I and Level II services) and two for hospital-based PHPs (for Level I and Level II 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 I and Level II 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. Proposed PHP APC Update for CY 2016

1. Proposed PHP APC Geometric Mean Per Diem Costs

For CY 2016, we are proposing 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 are proposing to compute proposed 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 proposed 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 are shown in Tables 50 and 51 of this proposed rule. To prevent confusion, we refer to the per diem information listed in Tables 50 and 51 of this 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 this 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 this proposed rule.

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 are impacting 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 are 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 are excessive. In addition, we found some CMHCs had very low costs per day (less than $25 per day). Without using a trimming process, the data from these providers will 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 is $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 suggest skewing, and as previously noted, examination of the data confirmed that there are a few providers with extreme cost per day values. Level 1 CMHC geometric mean per diem costs were $103.10 before any trim is performed. 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 services), and would affect both CMHC payment tiers.

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 this 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*.

We are concerned that including aberrant data in the calculation of the proposed 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 note 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 is 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 are 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, we are proposing 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 would 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. For example, based on our CY 2014 claims data used for 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 are proposing 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 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, 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.

We are proposing to apply the ±2 standard deviation trim to the geometric mean cost 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, in order to prevent inappropriate fluctuations in the payment rates. The resulting 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 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 consider 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 ratesetting process, we identified only one CMHC that had a CCR >1. That 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 are proposing 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 remain for some hospital-based PHPs. Therefore, for hospital-based PHPs, we are proposing to apply a trim on hospital service days when the CCR is greater than five (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. As expected, 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 are not proposing this alternative because we believe that establishing such a cap would not specifically target aberrant data from a minority of providers, which is 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 are proposing may need refinement. 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 are proposing 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 are $105.82 for Level 1 (3 services per day) CMHC PHP services, and are $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 are $195.73 for Level 1 (3 services per day) hospital-based PHP services, and are $218.93 for Level 2 (4 or more services per day) hospital-based PHP services.

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 are shown in Tables 50 and 51 of this proposed rule. We note that Tables 50 and 51 below display the proposed PHP APC renumbering that is part of the proposed reorganization of OPPS APCs described in section III.D. of this proposed rule. Specifically, we are proposing 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 refer readers to Addendum A to this proposed rule (which is available via the Internet on the CMS Web site) for the proposed PHP APC payment rates.

TABLE 50—PROPOSED CY 2016 PHP APC GEOMETRIC MEAN PER DIEM COSTS FOR CMHC PHP SERVICES

Proposed renumbered CY 2016 APC	Group title	Proposed PHP APC geometric mean per diem costs
5851	Level 1 Partial Hospitalization (3 services) for CMHCs	$105.82
5852	Level 2 Partial Hospitalization (4 or more services) for CMHCs	147.51

TABLE 51—PROPOSED CY 2016 PHP APC GEOMETRIC MEAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

Proposed renumbered CY 2016 APC	Group title	Proposed PHP APC geometric mean per diem costs
5861	Level 1 Partial Hospitalization (3 services) for hospital-based PHPs	$195.73
5862	Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs	218.93

We are inviting public comments on these proposals.

2. PHP Ratesetting Process

While the PHP is part of the OPPS, PHP ratesetting has some unique aspects. To foster understanding and transparency, 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 this proposed rule 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 this proposed rule 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 this proposed rule 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 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 PHPs, 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 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 proposed rule.

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 this 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.

As noted in section II.A.2.c. of this proposed rule 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 have identified the PHP claims that are appropriate and available to use to calculate PHP APC geometric mean per diem costs. These claims include dates of service, revenue codes, HCPCS codes for services provided, charges, and the payments Medicare made (the PHP APC 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 cost reports for these two types of PHPs. PHPs should review section II.A.1.c. of this proposed 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 this proposed rule 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 Outpatient Provider Specific File (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 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 have 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 Healthcare Provider Cost Report Information System (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 this proposed rule and in the OPPS Claims Accounting narrative, by applying the 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 52 below. 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's claims data from ratesetting.

For example, for revenue code 900, 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 900, 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 52—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 proposed rule 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. They 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 53 below:

TABLE 53—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 53 above are those which are used in the four PHP APCs (existing APCs 0172, 0173, 0175, 0176, which are proposed to be renumbered APCs 5851, 5852, 5861, and 5862, respectively), 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 proposed rule, we are proposing to renumber some of the OPPS APCs, and have shown both the proposed 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 proposed rule are applied to the PHP claim charges described in section VIII.B.2.c. of this proposed rule 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 proposed rule). 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 53 above.

e. Development of Service Days and Cost Modeling

Only the claims service lines containing PHP allowable HCPCS codes (shown in Table 53 above) 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, 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 and county 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 this proposed rule, there were several PHP providers with aberrant data. As such, we are proposing 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. If implemented as proposed, this trim would exclude from the ratesetting process any CMHCs with extreme costs per day. We also are proposing 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, if our proposal is implemented, we would exclude 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) are assigned to Level 1 or Level 2 PHP APCs as follows: (We note that we are proposing to renumber some of the OPPS APCs, and are showing both the proposed renumbered APCs and the existing APCs for partial hospitalization services below.)

- Level 1 Partial Hospitalization, proposed renumbered APC 5851 (existing APC 0172): CMHC service days with exactly 3 service units;
- Level 2 Partial Hospitalization, proposed renumbered APC 5852 (existing APC 0173): CMHC service days with 4 or more service units;
- Level 1 Partial Hospitalization, proposed renumbered APC 5861 (existing APC 0175): Hospital-based PHP service days with exactly 3 service units; and
- Level 2 Partial Hospitalization, proposed 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.

These PHP APC geometric mean 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 proposed in section II.A. of this proposed rule, OPPS APC geometric mean per diem costs (including PHP APC geometric mean per diem costs) would be divided by the geometric mean per diem costs for proposed 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 this proposed rule, we compared the estimated aggregated weight using the CY 2015 scaled relative payment weights to the estimated aggregate weight using the proposed 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 proposed rule for more information on scaling the weights, and for details on the final steps of the process that lead to PHP APC per diem rates.

f. Issues Regarding Correct Coding and Reasonable Charges

PHP claims with revenue codes other than those listed as allowable in Table 53 above, 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 which are not allowable for ratesetting purposes. In reviewing 2013 and 2014 claims, we noticed that CMHCs were using correct revenue coding for nearly all claims, but that hospital-based PHPs were sometimes 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 II 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.

C. Proposed 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 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 this CY 2016 proposed rule, we are proposing 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. CMHCs are projected to receive 0.04 percent of total OPPS payments in CY 2016, excluding outlier payments. Therefore, we are proposing to designate 0.49 percent of the estimated 1.0 percent outlier target amount for CMHCs. Based on our simulations of CMHC payments for CY 2016, in this proposed rule, we are proposing to continue to set the threshold for CY 2016 at 3.40 times the highest CMHC PHP APC payment rate (that is, proposed 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 are proposing to continue to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2016, we are proposing to continue to pay 50 percent of CMHC APC geometric mean per diem costs over the threshold. In section II.G. of this proposed rule, for the hospital outpatient outlier payment policy, we are proposing 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 are not proposing to set a dollar threshold for CMHC outlier payments.

In summary, in this CY 2016 proposed rule, we are proposing to establish 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 APC 5852, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the renumbered APC 5852 payment rate. We are inviting public comments on these proposals.

IX. Proposed Procedures That Would 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. Proposed Changes to the Inpatient Only List

For the CY 2016 OPPS, we are proposing to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65835)) 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, we identified seven procedures that could potentially be removed from the inpatient only list for CY 2016. We have reviewed the clinical characteristics and related evidence for these procedures for removal from the inpatient only list and found them to be appropriate candidates.

For CY 2016, we are proposing 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 we are proposing to remove from the inpatient only list for CY 2016 and their CPT codes, long descriptors, proposed APC assignments, and proposed status indictors are displayed in Table 54 below.

The complete list of codes that we are proposing to be paid by Medicare in CY 2016 only as inpatient procedures is included as Addendum E to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 54—PROCEDURES PROPOSED TO BE REMOVED FROM THE INPATIENT ONLY LIST FOR CY 2016

CPT/HCPCS code	Long descriptor	Proposed CY 2016 APC assignment *	Proposed 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.	5463	J1
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, 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
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

* We refer readers to Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) for a crosswalk from the existing APC numbers to the proposed new APC numbers for CY 2016.

X. Proposed Nonrecurring Policy Changes

A. 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, new 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.'' New 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 a hospital outpatient department that indicates whether an applicable CT service was furnished 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 makes 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, we are proposing to establish a new modifier to be used on claims that describes CT services furnished using equipment that does not meet each of the attributes of the NEMA Standard XR–29–2013. Beginning January 1, 2016, hospitals and suppliers would be required to use this modifier on claims for CT scans described by any of the CPT codes identified above (and any successor codes) that are furnished on non-NEMA Standard XR–29–2013-compliant CT scans. The use of this proposed modifier would result in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act.

B. 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 GXXX1 (Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and share decision making)) and HCPCS code GXXX2 (Low dose CT scan (LDCT) for lung cancer screening). For the CY 2016 OPPS, we are proposing to assign HCPCS code GXXX1 to proposed renumbered APC 5822 (Level 2 Health and Behavior Services) (existing APC 0432) and HCPCS code GXXX2 to proposed renumbered APC 5570 (Computed Tomography without Contrast) (existing APC 0332).

C. Payment for Corneal Tissue in the HOPD and the ASC

1. Background

In both the HOPD and the ASC, we have a longstanding policy of making separate payment for corneal tissue. 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). In the ASC, we pay separately for corneal tissue procurement as a covered ancillary service when it is 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 corneal tissue 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. 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). This 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. 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 integral to the performance of an ASC covered surgical procedure and pay separately for this service, so 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 procedures, 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 (CPT code 66180) or revision (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 complained about 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. Proposed CY 2016 Change to Corneal Tissue Payment Policy in the HOPD and the ASC

For CY 2016, we are proposing to limit the separate payment policy for corneal tissue acquisition costs in the HOPD and the ASC to only corneal tissue that is used in a corneal transplant procedure. In the HOPD, corneal tissue acquisition costs 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). In the ASC, we would include corneal tissue procurement as a covered ancillary service only when it is integral to the performance of a corneal transplant procedure that is an ASC covered surgical procedure, and pay separately for this service under the ASC payment system. We would implement this proposal as final by providing 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 via change requests. This proposal would mean that, in the HOPD and the ASC, we would not make separate payment for corneal tissue when used in any nontransplant procedure (payment for the corneal tissue in that instance will be packaged with the surgical procedure). This proposal also would

mean that we would make packaged payment for all tissues used as patch grafts in glaucoma shunt surgery. We are not proposing to change any other aspect of the corneal tissue payment policy in either the HOPD or the ASC.

We believe that 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 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.
- 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.

We also are proposing 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 are inviting public comments on these proposals.

XI. Proposed CY 2016 OPPS Payment Status and Comment Indicators

A. Proposed 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 that we are proposing for CY 2016 is displayed in Addendum D1 to this proposed rule, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The proposed CY 2016 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

For CY 2016, we are proposing to create two new status indicators:

- ''J2'' to identify certain combinations of services that we are proposing to pay through new proposed C–APC 8011 (Comprehensive Observation Services). We refer readers to section II.A.2.e. of this proposed rule for a detailed discussion of this proposed change.
- ''Q4'' to identify conditionally packaged laboratory tests. We refer readers to section II.A.3. of this proposed rule for a detailed discussion of this proposed new status indicator.

B. Proposed CY 2016 Comment Indicator Definitions

For the CY 2016 OPPS, we are proposing to use three comment indicators. Two comment indicators, ''CH'' and ''NI,'' which were in effect in CY 2015 would continue in CY 2016. In this proposed rule, we are proposing 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 that would 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 have 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 are proposing to use the ''CH'' comment indicator in this 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 believe that using the ''CH'' indicator in this proposed rule will facilitate the public's review of the changes that we are proposing for CY 2016. We are proposing 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, will 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 are proposing 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. 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 are proposing to use comment indicator ''NI'' to indicate that these HCPCS codes will 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 will 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 are proposing 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 are proposing 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 are included in Addendum B to this CY 2016 OPPS/ASC proposed rule would be labeled with new comment indicator ''NP'' in Addendum B to indicate that these CPT codes will be open for comment as part of this CY 2016 OPPS/ASC proposed rule. We will respond to public comments and finalize their OPPS assignment in the CY 2016 OPPS/ASC final rule with comment period.

For further discussion on the treatment of new CY 2016 CPT codes that will be effective January 1, 2016, for which we are soliciting public comments in this CY 2016 OPPS/ASC proposed rule, we refer readers to section III. of this proposed rule.

The proposed definitions of the OPPS comment indicators for CY 2016 are listed in Addendum D2 to this proposed rule, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

XII. Proposed 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 ASC covered surgical procedures (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 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). In addition, as discussed in detail in section XII.C. of this proposed rule, because we base ASC payment policies for 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 to the public or 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. Thus, these updates are to implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payment and to 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, therefore, are implemented only through the January quarterly update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly 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 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. Proposed 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 this proposed rule.

We have separated our discussion below based on when the codes are released and whether we are proposing to solicit public comments in this proposed rule (and respond to those comments in the CY 2016 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the 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. We will respond to public comments and finalize the treatment of these codes under the ASC payment system in the CY 2016 OPPS/ASC final rule with comment period.

2. Proposed Treatment of New and Revised Level II HCPCS Codes and Category III CPT Codes Implemented in April 2015 and July 2015 for Which We Are Soliciting Public Comments in This 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 below lists 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 below lists 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 this 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 below, along with their proposed payment indicators. The proposed payment rates for these new Category III CPT codes, can be found in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting 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 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2016 OPPS/ASC final rule with comment period.

TABLE 55—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2015

CY 2015 HCPCS code	CY 2015 long descriptor	Proposed CY 2016 payment indicator
C2623	Catheter, transluminal angioplasty, drug-coated, non-laser	J7
C9445	Injection, c-1 esterase inhibitor (recombinant), Ruconest, 10 units	K2
C9448*	Netupitant 300mg and palonosetron 0.5 mg, oral	D5
C9449	Injection, blinatumomab, 1 mcg	K2
C9450	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	K2
C9451	Injection, peramivir, 1 mg	K2
C9452	Injection, ceftolozane 50 mg and tazobactam 25 mg	K2
Q9975	Injection, Factor VIII, FC Fusion Protein (Recombinant), per iu	K2

*HCPCS code C9448 was deleted June 30, 2015 and replaced with HCPCS code Q9978 effective July 1, 2015.

TABLE 56—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2015

CY 2015 HCPCS code	CY 2015 long descriptor	Proposed CY 2016 payment indicator
C2613	Lung biopsy plug with delivery system	J7
C9453	Injection, nivolumab, 1 mg	K2
C9454	Injection, pasireotide long acting, 1 mg	K2
C9455	Injection, siltuximab, 10 mg	K2
Q9978*	Netupitant 300 mg and Palonosetron 0.5 mg, oral	K2

*HCPCS code Q9978 replaced HCPCS code C9448 effective July 1, 2015.

TABLE 57—NEW CATEGORY III CPT CODES FOR COVERED SURGICAL PROCEDURES OR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2015

CY 2015 CPT code	CY 2015 long descriptor	Proposed CY 2016 payment indicator
0392T	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (*i.e.,* magnetic band).	G2
0393T	Removal of esophageal sphincter augmentation device	G2

3. Proposed 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. Proposed Modification of the Current Process for Accepting Comments on New and Revised Category I and III CPT Codes That Are Effective January 1

In this CY 2016 OPPS/ASC proposed rule, we are proposing 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 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 need to propose corresponding 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, we are proposing that, for new and revised Category I and III CPT codes 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 the 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 are proposing to adopt these conforming coding and payment policies 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. Because the changes in CPT codes are effective on January 1 of each year, and we would not have established payment indicators for these new or revised codes, it would not be practicable for Medicare to use those CPT codes. In this circumstance, we are proposing to create HCPCS G-codes to describe the predecessor codes for any codes that were revised or deleted as part of the annual CPT coding changes. 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. 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 proposed 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 description 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.

For new codes that describe wholly new services, as opposed to new or revised codes that describe services for which ASC payment indicator assignments are already established, 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 need to establish interim ASC payment indicator assignments for the initial year. We are proposing 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 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 hopeful 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 proposed rule. We are proposing 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 are proposing 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 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. We are proposing to follow this revised process except 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 codes that describe wholly new services for which we do not receive timely information from the AMA, we are proposing to establish interim ASC payment indicators in the OPPS/ASC final rules with comment period, as is our current process. 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 are inviting public comment on these proposals.

For the CY 2016 ASC update, we received the CY 2016 Category I and Category III CPT codes from AMA in time for inclusion in this CY 2016 OPPS/ASC proposed rule. The new and revised CY 2016 Category I and III CPT codes can be found in ASC Addendum AA and Addendum BB (which are available via the Internet on the CMS Web site) and are 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. We refer readers to section XII.F. of this proposed rule for further discussion on the new proposed comment indicator ''NP.'' Therefore, in this CY 2016 OPPS/ASC proposed rule, we are soliciting 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.

Further, we remind readers that the CPT code descriptors that appear in ASC Addendum AA and BB are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the long descriptors for the new and revised CY 2016 CPT codes in Addendum O to this proposed rule (which is available via the Internet on the CMS Web site) so that the public can adequately comment on our proposed ASC payment indicators. Because CPT procedure codes are 5 alpha-numeric characters and CMS systems only utilize 5 characters HCPCS codes, we have developed alternative 5-character placeholder codes for this proposed rule. The placeholder codes can be found in Addendum O to this proposed

rule, specifically under the column labeled ''CY 2016 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code.'' The final CPT code numbers would be included in the CY 2016 OPPS/ASC final rule with comment period.

4. Proposed Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2015 and January 1, 2016 for Which We Will Be Soliciting Public Comments in the CY 2016 OPPS/ASC Final Rule With Comment Period

Although we are proposing to revise our process for requesting public comments on the new and revised Category I and III CPT codes, we are not proposing 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.

We are proposing 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 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 58 below, we summarize the CY 2016 process described in this section XII.B. of this 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 58—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 I, 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 are inviting public comment on this proposed process.

C. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Proposed 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) Proposed Changes for CY 2016 to Covered Surgical Procedures Designated as Office-Based

In developing this 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 are proposing to permanently designate as office-based are listed in Table 59 below.

We are inviting public comment on this proposal.

TABLE 59—ASC COVERED SURGICAL PROCEDURES NEWLY PROPOSED AS PERMANENTLY OFFICE-BASED FOR CY 2016

Proposed CY 2016 CPT code	Proposed CY 2016 long descriptor	CY 2015 ASC payment indicator	Proposed 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
43198	Esophagoscopy, flexible, transnasal; with biopsy, single or multiple	G2	P3

* Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed 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 proposed rule.

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, we are proposing to maintain the temporary office-based designations for these five codes for CY 2016. We list all of these codes in Table 60, 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 reflects 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 are proposing 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 are displayed in Table 60. The procedures for which the proposed office-based designations for CY 2016 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

TABLE 60—PROPOSED 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 2015 CPT code	CY 2015 long descriptor	CY 2015 ASC payment indicator	Proposed 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.
**Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed 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 proposed rule.

For CY 2016, we also are proposing to designate certain new CY 2016 codes for ASC covered surgical procedures as temporary office-based, displayed in Table 61. 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 made the office-based designations 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 this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comment on these proposals.

TABLE 61—PROPOSED CY 2016 PAYMENT INDICATORS FOR NEW CY 2016 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE–BASED

Proposed CY 2016 OPPS/ASC proposed rule 5-digit CMS placeholder code***	Proposed CY 2016 long descriptor	Proposed CY 2016 ASC payment indicator**
6446A	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	*R2
6446C	Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed).	*R2
03XXB	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed).	*R2
657XG	Implantation of intrastromal corneal ring segments	P2*

*If designation is temporary.
**Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed 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 proposed rule.
***New CPT codes (with CMS 5-digit placeholder codes) that will be effective January 1, 2016. The proposed 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 Proposed 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 comprehensive 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 comprehensive 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 comprehensive APCs continue to be separately paid under the ASC payment system instead of being packaged into the payment for the comprehensive APC as under the OPPS. To avoid duplicating payment we provided that the CY 2015 ASC payment rates for these comprehensive 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 comprehensive APCs for purposes of identifying device-intensive procedures and to calculate payment rates for device-intensive procedures assigned to comprehensive APCs. Because we implemented the comprehensive 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) Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2016

For CY 2016, we are proposing to continue our CY 2015 policies. Specifically, for CY 2016, we are proposing 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 are proposing 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 below. 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 below. All of these procedures are included in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site).

We are inviting public comment on these proposals.

(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 non-comprehensive 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 (nondevice) 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 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 are soliciting public comments for alternative methodologies for establishing device-intensive status for ASC covered surgical procedures.

c. Proposed 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. For CY 2014, 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 for CY 2014 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 for CY 2014 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.

We are proposing 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 below displays the ASC covered device-intensive procedures that we are proposing 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 are proposing to reduce the payment for implantation procedures listed in Table 62 of this 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 are inviting public comment on these proposals.

TABLE 62—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DESIGNATION AS DEVICE-INTENSIVE FOR CY 2016, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE PROPOSED NO COST/FILL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY

HCPCS code	Short descriptor	Proposed CY 2016 ASC PI	Proposed CY 2016 OPPS APC**	Proposed CY 2016 device offset percentage	Proposed FB/FC policy would apply
0100T	Prosth retina receive&gen	J8	1593	99.99%	Y
0171T	Lumbar spine proces distract	J8	5124	49.60%	Y
0238T	Trluml perip athrc iliac art	J8	5193	60.43%	Y
0282T	Periph field stimul trial	J8	5462	56.27%	Y
0283T	Periph field stimul perm	J8	5464	86.77%	Y
0302T	Icar ischm mntrng sys compl	J8	5223	68.50%	Y
0303T	Icar ischm mntrng sys eltrd	J8	5222	72.88%	Y
0304T	Icar ischm mntrng sys device	J8	5222	72.88%	Y
0307T	Rmvl icar ischm mntrng dvce	J8	5221	45.44%	Y
0308T	Insj ocular telescope prosth	J8	5494	81.62%	Y
0316T	Replc vagus nerve pls gen	J8	5463	85.69%	Y
0387T	Leadless c pm ins/rpl ventr	J8	5193	60.43%	Y
04XX1*	Insj/rplc cardiac modulj sys	J8	5223	68.50%	Y
04XX2*	Insj/rplc cardiac modulj pls gn	J8	5223	68.50%	Y
04XX3*	Insj/rplc car modulj atr elt	J8	5222	72.88%	Y
04XX4*	Insj/rplc car modulj vnt elt	J8	5222	72.88%	Y

TABLE 62—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DESIGNATION AS DEVICE-INTENSIVE FOR CY 2016, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE PROPOSED NO COST/FILL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

HCPCS code	Short descriptor	Proposed CY 2016 ASC PI	Proposed CY 2016 OPPS APC**	Proposed CY 2016 device offset percentage	Proposed FB/FC policy would apply
04XX5*	Rmvl cardiac modulj pls gen	J8	5222	72.88%	Y
04XX7*	Rmvl & rpl car modulj pls gn	J8	5224	72.68%	Y
19298	Place breast rad tube/caths	J8	5093	41.08%	Y
19325	Enlarge breast with implant	J8	5093	41.08%	Y
19342	Delayed breast prosthesis	J8	5093	41.08%	Y
19357	Breast reconstruction	J8	5093	41.08%	Y
22551	Neck spine fuse&remov bel c2	J8	5124	49.60%	Y
22554	Neck spine fusion	J8	5124	49.60%	Y
22612	Lumbar spine fusion	J8	5124	49.60%	Y
23465	Repair shoulder capsule	J8	5124	49.60%	Y
23485	Revision of collar bone	J8	5124	49.60%	Y
23491	Reinforce shoulder bones	J8	5124	49.60%	Y
23552	Treat clavicle dislocation	J8	5124	49.60%	Y
23615	Treat humerus fracture	J8	5124	49.60%	Y
23616	Treat humerus fracture	J8	5124	49.60%	Y
23680	Treat dislocation/fracture	J8	5124	49.60%	Y
23800	Fusion of shoulder joint	J8	5124	49.60%	Y
23802	Fusion of shoulder joint	J8	5124	49.60%	Y
24346	Reconstruct elbow med ligmnt	J8	5124	49.60%	Y
24361	Reconstruct elbow joint	J8	5124	49.60%	Y
24363	Replace elbow joint	J8	5124	49.60%	Y
24365	Reconstruct head of radius	J8	5124	49.60%	Y
24366	Reconstruct head of radius	J8	5124	49.60%	Y
24370	Revise reconst elbow joint	J8	5124	49.60%	Y
24371	Revise reconst elbow joint	J8	5124	49.60%	Y
24410	Revision of humerus	J8	5124	49.60%	Y
24430	Repair of humerus	J8	5124	49.60%	Y
24435	Repair humerus with graft	J8	5124	49.60%	Y
24498	Reinforce humerus	J8	5124	49.60%	Y
24515	Treat humerus fracture	J8	5124	49.60%	Y
24516	Treat humerus fracture	J8	5124	49.60%	Y
24545	Treat humerus fracture	J8	5124	49.60%	Y
24546	Treat humerus fracture	J8	5124	49.60%	Y
24575	Treat humerus fracture	J8	5124	49.60%	Y
24579	Treat humerus fracture	J8	5124	49.60%	Y
24586	Treat elbow fracture	J8	5124	49.60%	Y
24587	Treat elbow fracture	J8	5124	49.60%	Y
24666	Treat radius fracture	J8	5124	49.60%	Y
24802	Fusion/graft of elbow joint	J8	5124	49.60%	Y
25391	Lengthen radius or ulna	J8	5124	49.60%	Y
25420	Repair/graft radius & ulna	J8	5124	49.60%	Y
25441	Reconstruct wrist joint	J8	5124	49.60%	Y
25442	Reconstruct wrist joint	J8	5124	49.60%	Y
25444	Reconstruct wrist joint	J8	5124	49.60%	Y
25446	Wrist replacement	J8	5124	49.60%	Y
25575	Treat fracture radius/ulna	J8	5124	49.60%	Y
25800	Fusion of wrist joint	J8	5124	49.60%	Y
25810	Fusion/graft of wrist joint	J8	5124	49.60%	Y
27279	Arthrodesis sacroiliac joint	J8	5124	49.60%	Y
27415	Osteochondral knee allograft	J8	5124	49.60%	Y
27428	Reconstruction knee	J8	5124	49.60%	Y
27429	Reconstruction knee	J8	5124	49.60%	Y
27438	Revise kneecap with implant	J8	5124	49.60%	Y
27440	Revision of knee joint	J8	5124	49.60%	Y
27442	Revision of knee joint	J8	5124	49.60%	Y
27443	Revision of knee joint	J8	5124	49.60%	Y
27446	Revision of knee joint	J8	5124	49.60%	Y
27745	Reinforce tibia	J8	5124	49.60%	Y
27758	Treatment of tibia fracture	J8	5124	49.60%	Y
27759	Treatment of tibia fracture	J8	5124	49.60%	Y
27823	Treatment of ankle fracture	J8	5124	49.60%	Y
27827	Treat lower leg fracture	J8	5124	49.60%	Y
27828	Treat lower leg fracture	J8	5124	49.60%	Y
27870	Fusion of ankle joint open	J8	5124	49.60%	Y
27871	Fusion of tibiofibular joint	J8	5124	49.60%	Y
28320	Repair of foot bones	J8	5124	49.60%	Y
28420	Treat/graft heel fracture	J8	5124	49.60%	Y

TABLE 62—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DESIGNATION AS DEVICE-INTENSIVE FOR CY 2016, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE PROPOSED NO COST/FILL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

HCPCS code	Short descriptor	Proposed CY 2016 ASC PI	Proposed CY 2016 OPPS APC**	Proposed CY 2016 device offset percentage	Proposed FB/FC policy would apply
28705	Fusion of foot bones	J8	5124	49.60%	Y
28715	Fusion of foot bones	J8	5124	49.60%	Y
28725	Fusion of foot bones	J8	5124	49.60%	Y
28730	Fusion of foot bones	J8	5124	49.60%	Y
28735	Fusion of foot bones	J8	5124	49.60%	Y
28737	Revision of foot bones	J8	5124	49.60%	Y
28740	Fusion of foot bones	J8	5124	49.60%	Y
29889	Knee arthroscopy/surgery	J8	5124	49.60%	Y
29899	Ankle arthroscopy/surgery	J8	5124	49.60%	Y
29907	Subtalar arthro w/fusion	J8	5124	49.60%	Y
33206	Insert heart pm atrial	J8	5223	68.50%	Y
33207	Insert heart pm ventricular	J8	5223	68.50%	Y
33208	Insrt heart pm atrial & vent	J8	5223	68.50%	Y
33210	Insert electrd/pm cath sngl	J8	5222	72.88%	Y
33211	Insert card electrodes dual	J8	5222	72.88%	Y
33212	Insert pulse gen sngl lead	J8	5222	72.88%	Y
33213	Insert pulse gen dual leads	J8	5223	68.50%	Y
33214	Upgrade of pacemaker system	J8	5223	68.50%	Y
33216	Insert 1 electrode pm-defib	J8	5222	72.88%	Y
33217	Insert 2 electrode pm-defib	J8	5222	72.88%	Y
33218	Repair lead pace-defib one	J8	5221	45.44%	Y
33220	Repair lead pace-defib dual	J8	5221	45.44%	Y
33221	Insert pulse gen mult leads	J8	5224	72.68%	Y
33224	Insert pacing lead & connect	J8	5223	68.50%	Y
33227	Remove&replace pm gen singl	J8	5222	72.88%	Y
33228	Remv&replc pm gen dual lead	J8	5223	68.50%	Y
33229	Remv&replc pm gen mult leads	J8	5224	72.68%	Y
33230	Insrt pulse gen w/dual leads	J8	5231	77.49%	Y
33231	Insrt pulse gen w/mult leads	J8	5232	80.65%	Y
33233	Removal of pm generator	J8	5221	45.44%	Y
33234	Removal of pacemaker system	J8	5221	45.44%	Y
33235	Removal pacemaker electrode	J8	5221	45.44%	Y
33240	Insrt pulse gen w/singl lead	J8	5231	77.49%	Y
33241	Remove pulse generator	J8	5221	45.44%	Y
33249	Insj/rplcmt defib w/lead(s)	J8	5232	80.65%	Y
33262	Rmvl& replc pulse gen 1 lead	J8	5231	77.49%	Y
33263	Rmvl & rplcmt dfb gen 2 lead	J8	5231	77.49%	Y
33264	Rmvl & rplcmt dfb gen mlt ld	J8	5232	80.65%	Y
33270	Ins/rep subq defibrillator	J8	5232	80.65%	Y
33271	Insj subq impltbl dfb elctrd	J8	5222	72.88%	Y
33273	Repos prev impltbl subq dfb	J8	5221	45.44%	Y
33282	Implant pat-active ht record	J8	5222	72.88%	Y
36261	Revision of infusion pump	J8	5221	45.44%	Y
36262	Removal of infusion pump	J8	5221	45.44%	Y
37221	Iliac revasc w/stent	J8	5192	50.56%	Y
37225	Fem/popl revas w/ather	J8	5192	50.56%	Y
37226	Fem/popl revasc w/stent	J8	5192	50.56%	Y
37227	Fem/popl revasc stnt & ather	J8	5193	60.43%	Y
37228	Tib/per revasc w/tla	J8	5192	50.56%	Y
37229	Tib/per revasc w/ather	J8	5193	60.43%	Y
37230	Tib/per revasc w/stent	J8	5193	60.43%	Y
37231	Tib/per revasc stent & ather	J8	5193	60.43%	Y
37236	Open/perq place stent 1st	J8	5192	50.56%	Y
37238	Open/perq place stent same	J8	5192	50.56%	Y
50080	Removal of kidney stone	J8	5376	53.72%	Y
50081	Removal of kidney stone	J8	5376	53.72%	Y
53440	Male sling procedure	J8	5376	53.72%	Y
53444	Insert tandem cuff	J8	5376	53.72%	Y
53445	Insert uro/ves nck sphincter	J8	5377	70.25%	Y
53447	Remove/replace ur sphincter	J8	5377	70.25%	Y
54112	Treat penis lesion graft	J8	5376	53.72%	Y
54400	Insert semi-rigid prosthesis	J8	5376	53.72%	Y
54401	Insert self-contd prosthesis	J8	5377	70.25%	Y
54405	Insert multi-comp penis pros	J8	5377	70.25%	Y
54410	Remove/replace penis prosth	J8	5377	70.25%	Y
54416	Remv/repl penis contain pros	J8	5377	70.25%	Y
55873	Cryoablate prostate	J8	5376	53.72%	Y

TABLE 62—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DESIGNATION AS DEVICE-INTENSIVE FOR CY 2016, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH THE PROPOSED NO COST/FILL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY—Continued

HCPCS code	Short descriptor	Proposed CY 2016 ASC PI	Proposed CY 2016 OPPS APC**	Proposed CY 2016 device offset percentage	Proposed FB/FC policy would apply
57120	Closure of vagina	J8	5415	19.94%	Y
57310	Repair urethrovaginal lesion	J8	5416	18.21%	Y
58260	Vaginal hysterectomy	J8	5415	19.94%	Y
58262	Vag hyst including t/o	J8	5415	19.94%	Y
58543	Lsh uterus above 250 g	J8	5362	16.68%	Y
58544	Lsh w/t/o uterus above 250 g	J8	5362	16.68%	Y
58553	Laparo-vag hyst complex	J8	5362	16.68%	Y
58554	Laparo-vag hyst w/t/o compl	J8	5362	16.68%	Y
58573	Tlh w/t/o uterus over 250 g	J8	5362	16.68%	Y
61885	Insrt/redo neurostim 1 array	J8	5463	85.69%	Y
61886	Implant neurostim arrays	J8	5464	86.77%	Y
61888	Revise/remove neuroreceiver	J8	5462	56.27%	Y
62360	Insert spine infusion device	J8	5471	79.84%	Y
62361	Implant spine infusion pump	J8	5471	79.84%	Y
62362	Implant spine infusion pump	J8	5471	79.84%	Y
63650	Implant neuroelectrodes	J8	5462	56.27%	Y
63655	Implant neuroelectrodes	J8	5463	85.69%	Y
63663	Revise spine eltrd perq aray	J8	5462	56.27%	Y
63664	Revise spine eltrd plate	J8	5462	56.27%	Y
63685	Insrt/redo spine n generator	J8	5464	86.77%	Y
64553	Implant neuroelectrodes	J8	5462	56.27%	Y
64555	Implant neuroelectrodes	J8	5462	56.27%	Y
64561	Implant neuroelectrodes	J8	5462	56.27%	Y
64565	Implant neuroelectrodes	J8	5462	56.27%	Y
64568	Inc for vagus n elect impl	J8	5464	86.77%	Y
64569	Revise/repl vagus n eltrd	J8	5462	56.27%	Y
64575	Implant neuroelectrodes	J8	5462	56.27%	Y
64580	Implant neuroelectrodes	J8	5463	85.69%	Y
64581	Implant neuroelectrodes	J8	5462	56.27%	Y
64590	Insrt/redo pn/gastr stimul	J8	5463	85.69%	Y
65770	Revise cornea with implant	J8	5493	62.97%	Y
69714	Implant temple bone w/stimul	J8	5124	49.60%	Y
69715	Temple bne implnt w/stimulat	J8	5124	49.60%	Y
69718	Revise temple bone implant	J8	5124	49.60%	Y
69930	Implant cochlear device	J8	5166	83.03%	Y
C9740	Cysto impl 4 or more	J8	1564	63.71%	Y

* New CPT codes (with CMS 5-digit placeholder codes) that would be effective January 1, 2016. The long descriptors for these new codes can be found in Addendum O to this proposed rule (which is available via the Internet on the CMS Web site).

** Addendum Q to this proposed rule (which is available via the Internet on the CMS Web site) contains a crosswalk of the existing CY 2015 APC numbers to the proposed new CY 2016 APC numbers.

d. Proposed Adjustment to ASC Payments for Discontinued Device-Intensive Procedures

As discussed in section IV.B.4. of this proposed rule, we are proposing to modify the calculation of OPPS payment when modifiers indicating that the procedure was discontinued appear on the claim. 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, that it would be appropriate to remove the estimated cost of the device, since it would have presumably not been used.

We believe these same issues exist in the ASC setting, and thus are proposing 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 system beginning in CY 2016, with modifiers 52 (reduced services) and 73 (Discontinued outpatient procedure prior to anesthesia administration), which are the same modifiers proposed 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 are proposing 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 are not proposing to deduct the device offset amount from a procedure that was discontinued after anesthesia was administered (modifier 74) as we believe that it may be more likely that devices involved with such procedures are more likely to no longer be sterile such that they could be restocked and used for another case. However, we are soliciting 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 are proposing to revise 42 CFR 416.172 to reflect this proposal.

We are inviting public comment on this proposal and this proposed codification.

e. Proposed 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 are proposing 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 are proposing to include them on the list of ASC covered surgical procedures for CY 2016.

The 11 procedures that we are proposing to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2016 payment indicators, are displayed in Table 63 below.

We are inviting public comment on this proposal.

TABLE 63—PROPOSED ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2016

Proposed CY 2016 HCPCS code	Proposed CY 2016 long descriptor	Proposed 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
57120	Colpocleisis (Le Fort type)	J8
57310	Closure of urethrovaginal fistula	J8
58260	Vaginal hysterectomy, for uterus 250 g or less	J8
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)	J8
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g	J8
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	J8
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g	J8
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	J8
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	J8

f. ASC Treatment of Surgical Procedures Proposed for Removal 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 list for possible inclusion on the ASC list of covered surgical procedures. We evaluated each of the seven procedures we are proposing to remove from the OPPS inpatient list for CY 2016 according to the criteria for exclusion from the list of covered ASC surgical procedures. We believe that these seven 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. The CPT codes for these seven procedures and their long descriptors are listed in Table 64 below.

We are inviting public comment on the continued exclusion of these codes from the ASC list of covered surgical procedures.

TABLE 64—PROCEDURES PROPOSED FOR EXCLUSION FROM THE ASC LIST OF COVERED SURGICAL PROCEDURES FOR CY 2016 THAT ARE PROPOSED FOR REMOVAL FROM THE CY 2016 OPPS INPATIENT LIST

CPT Code	Long descriptor
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 (eg, 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

TABLE 64—PROCEDURES PROPOSED FOR EXCLUSION FROM THE ASC LIST OF COVERED SURGICAL PROCEDURES FOR CY 2016 THAT ARE PROPOSED FOR REMOVAL FROM THE CY 2016 OPPS INPATIENT LIST—Continued

CPT Code	Long descriptor
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. Proposed List of Covered Ancillary Services

Consistent with the established ASC payment system policy, we are proposing 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 are proposing that these services also would be packaged under the ASC payment system for CY 2016. We are proposing to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator ''CH,'' discussed in section XII.F. of this proposed rule, is used in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we are proposing 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 are included in Addendum BB to this proposed rule. We are inviting public comment on this proposal.

b. Proposal To Exclude Corneal Tissue Procurement From the Covered Ancillary Services List When Used for Nontransplant Procedures

We refer readers to section X.C. of this proposed rule for a discussion of our proposal to include corneal tissue procurement as a covered ancillary service only when it is integral to the performance of a corneal transplant procedure that is an ASC covered surgical procedure.

c. Proposal to Remove Certain Services From the Covered Ancillary Services List That Are Not Used as Ancillary and Integral To a Covered Surgical Procedure

It has come to our attention that we include codes for services on our covered ancillary services list that are not used as ancillary and integral to a covered ASC 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. Several radiation therapy treatment services, including gamma knife stereotactic radiosurgery (SRS), are most frequently provided in the hospital outpatient setting and paid through the OPPS and also are infrequently furnished in freestanding radiation therapy centers and paid under the MPFS. Claims data indicate that it is not furnished in the ASC setting. Since ASCs do not appear to be utilizing these services as integral and ancillary to covered ASC surgical procedures, and given the specialized nature of the SRS treatment services, we would not expect them to be integral and ancillary to an ASC covered surgical procedure, we are proposing to remove radiation treatment codes for SRS services from the list of ASC covered ancillary services. Specifically, we are proposing 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 note that while we are proposing to remove these three codes from the list of ancillary covered services for CY 2016 and subsequent years, we will continue to monitor the claims data to identify services for which clinical practice patterns indicate they are not provided in the ASC setting.

We are inviting public comment on this proposal.

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. Proposed 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 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. Therefore, no Medicare payment would be 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. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2016

We are proposing 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 are proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2.''

We are proposing 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 are proposing 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 is 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 are proposing to continue our policy for device removal procedures such that 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 are inviting public comment on these proposals.

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 are not proposing 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 proposed rule (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 (eg, 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 CPT code 33249, the primary code for CRT–D services, continue to be assigned to APC 0108, and that payment for CPT code 33225 be packaged under the OPPS. We also finalized our proposals under the ASC payment system that CPT code 33249, the primary code for CRT–D services, will continue to be assigned to APC 0108, and payment for CPT code 33225 will be packaged into the payment for the primary covered surgical procedure (for example, CPT code 33249). We are not proposing any changes to these policies for CY 2016. We note that, in this proposed rule, we are proposing to renumber APC 0108 as APC 5232.

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 this 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 this 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). We are not proposing any changes to our current policy regarding ASC payment for LDR prostate brachytherapy services for CY 2016.

2. Proposed 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. 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 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. Proposed Payment for Covered Ancillary Services for CY 2016

For CY 2016 and subsequent years, we are proposing 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 are proposing 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 are proposing 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 would make this same proposal for subsequent years. For CY 2016 and subsequent years, we also are proposing 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 this 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 are proposing 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 (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 are proposing to continue this modification to the payment methodology for CY 2016 and subsequent years and, therefore, are proposing 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 and, therefore, will include the cost for the contrast agent. We are proposing to continue this modification to the payment methodology for CY 2016 and subsequent years and, therefore, are proposing to assign the payment indicator ''Z2'' to radiology services that use contrast agents.

We are proposing 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 this proposed rule. We are proposing, 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 are proposing 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 are proposing 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 are proposing 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 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 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 are proposing 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 this proposed rule (which is available via the Internet on the CMS Web site).

E. New Technology Intraocular Lenses (NTIOLs)

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 are not proposing to revise the payment adjustment amount for CY 2016.

4. Proposed 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, we are proposing that, beginning in CY 2016, any application for a new NTIOL class must fulfill an additional criterion. Specifically, we are proposing 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 are proposing to revise § 416.195(a)(1) of the regulations to reflect this proposal. We are inviting public comments on this proposal.

F. Proposed 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). 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 this 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. Proposed ASC Payment and Comment Indicators

For CY 2016 and subsequent years, we are proposing 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 are proposing 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 this 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 this CY 2016 OPPS/ASC proposed rule. Proposed new comment indicator ''NP'' means a 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 ASC payment indicator; comments will be accepted on the proposed ASC payment indicator for the new code.

For the CY 2016 update, we also are proposing to add ASC payment indicator ''B5'' (Alternative code may be available; no payment made) to ASC Addendum DD1 to this 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 are proposing 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 this 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 will 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 this 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.

G. Calculation of the Proposed ASC Conversion Factor and the Proposed 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 one-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).

2. Proposed 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). Consistent with our established policy, we are proposing 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 are proposing 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 are proposing 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 proposed rule, 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 this 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 are proposing 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.

For this proposed rule, 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 is 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 is 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 this proposed rule, 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are inviting public comment on these proposals.

3. Display of Proposed CY 2016 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) display the proposed 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 proposed rates under the ASC standard ratesetting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed MPFS rates that would be effective January 1, 2016. For a discussion of the MPFS rates, we refer readers to the CY 2016 MPFS proposed rule.

The proposed 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 proposed CY 2016 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''Proposed to be 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 assignments for the new code.

The values displayed in the column titled ''Proposed CY 2016 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2016. The proposed 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 proposed CY 2016 payment rate displayed in the ''Proposed CY 2016 Payment Rate'' column, each ASC payment weight in the ''Proposed CY 2016 Payment Weight'' column was multiplied by the proposed CY 2016 conversion factor of $44.605. The proposed 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 proposed rule).

In Addendum BB, there are no relative payment weights displayed in the ''Proposed CY 2016 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2016 Payment'' column displays the proposed CY 2016 national unadjusted ASC payment rates for all items and services. The proposed 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 April 2015.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be 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.

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. We are not proposing any changes to our measure selection policy.

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. We are not proposing any

changes to our retention policy for previously adopted measures.

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. We are not proposing 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. We are not proposing any changes to our measure removal policy.

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). We are not proposing any changes to our ''topped-out'' criteria policy.

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 No.	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 are proposing 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 6947).

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 (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. We note that we are proposing one new measure for the CY 2018 payment determination and subsequent years in section XIII.B.6.a. of this proposed rule.

HOSPITAL OQR PROGRAM MEASURE SET PREVIOUSLY ADOPTED FOR THE CY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	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.***
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 are proposing 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).

5. Proposed Hospital OQR Program Quality Measure for Removal for CY 2017 Payment Determination and Subsequent Years

We are proposing 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 however, we 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 are proposing to remove OP–15 for the CY 2017 payment determination and subsequent years.

Based on our analysis, OP–15 meets the following criterion for removal: (iii) 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.[1] 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.[2] Based upon guidelines for use of CT scans published in peer-reviewed literature, we believe that OP–15,[3] 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 are proposing to remove OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache from the Hospital OQR Program beginning with the CY 2017 payment determination. Set out in the table below is the measure we are proposing to remove for the CY 2017 payment determination and subsequent years.

HOSPITAL OQR PROGRAM MEASURE PROPOSED FOR REMOVAL FOR THE CY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure
N/A	OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.

We are inviting public comment on this proposal.

6. Proposed New Hospital OQR Program Quality Measures for the CY 2018 and CY 2019 Payment Determinations and Subsequent Years

We are proposing 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. Proposed 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.[4] EBRT is a widely used modality [5] to provide pain relief in 50 to 80 percent of patients with painful bone metastases.[6] 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.[7] Despite the recommendations, the actual doses applied for EBRT continue to include dosing schedules as high as 25 fractions.[8] 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.[9] 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.[10] 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.[11]

To address concerns associated with unnecessary exposure to radiation and a desire for shorter and less painful treatment options, we are proposing 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.'' [12] 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 proposed measure may be found at: *https://www.qualityforum.org/QPS/1822*. 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

[1] *Available at: http://www.acepnow.com/article/proposed-measures-ct-scans-cause-concern/2/.*

[2] Ibid.

[3] 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.

[4] Coleman RE. Metastatic bone disease: clinical features, pathophysiology and treatment strategies. Cancer Treat Rev. 2001;27:165–176.

[5] 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

[6] 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.

[7] Ibid.

[8] Available at: *http://www.qualityforum.org/Measure_Evaluation_Form/Cancer_Project/1822.aspx*.

[9] 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.

[10] Available at: *http://www.qualityforum.org/Measure_Evaluation_Form/Cancer_Project/1822.aspx*.

[11] 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.

[12] Available at: *http://www.qualityforum.org/Measure_Evaluation_Form/Cancer_Project/1822.aspx*.

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.[13]

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.'' [14] The MAP, 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.'' [15]

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.'' [16]

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 are inviting public comment on the proposal to include the following measure in the Hospital OQR Program for the CY 2018 payment determination and subsequent years.

NQF #	Proposed measure for the CY 2018 payment determination and subsequent years
1822	OP–33: External Beam Radiotherapy for Bone Metastases

The proposed and previously finalized measures for CY 2018 payment determination and subsequent years are listed below.

PROPOSED 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.
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*.

[13] Measure Submission and Evaluation Worksheet. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70374*.

[14] ''List of Measures under Consideration for December 1, 2014.'' Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78318*.

[15] ''Spreadsheet of MAP 2015 Final Recommendations.'' Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711*.

[16] Ibid.

** 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 proposed for the CY 2018 payment determination and subsequent years.

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)

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.[17] Additionally, information deficits frequently result when patients transfer between hospitals and primary care physicians in the community [18] and between hospitals and long-term care facilities.[19] According to patient safety studies,[20] the highest percentage of preventable and negligent adverse events within a hospital occur in the Emergency Department.[21] The prevention of medical errors in the Emergency Department setting is gaining attention throughout the nation,[22] but performance measures for Emergency Department care are lacking.[23]

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.[24]

To address concerns associated with care when patients are transferred from Emergency Departments to other facilities, we are proposing 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 are proposing 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 three to six 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.'' [25] 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.[26] The measure has been rigorously peer reviewed and extensively tested with field tests from 2004 to 2014 across 16 States in 249 hospitals.[27]

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 twenty-seven 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; but 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.

[17] Available at: *http://www.jointcommission.org/Improving_Americas_Hospitals_The_Joint_Commissions_Annual_Report_on_Quality_and_Safety_-_2007/*..

[18] 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.

[19] 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.

[20] Leape, L., Brennan, T., Laird, N. et al. The Nature of Adverse Events in Hospitalized Patients. Results of the Harvard Medical Practice Study II. New England Journal of Medicine 324:377–384, 1991.

[21] Thomas, E., Studdert, D., Burstin, H. et al. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. Medical Care 38:261–271, 2000.

[22] Schenkel, S. Promoting Patient Safety and Preventing Medical Error in Emergency Departments. Academic Emergency Medicine 7:1204–1222, 2000.

[23] Welch, S., Augustine, J., Camago, C. and Reese, C. Emergency Department Performance Measures and Benchmarking Summit. Academic Emergency Medicine, 13(10):1074–1080, 2006.

[24] Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization. *Ann Intern Med* 2009; 150:178–187.

[25] Available at: *http://www.qualityforum.org/QPS/0291*.

[26] Medicare Payment Advisory Commission. Promoting Greater Efficiency in Medicare. June 2007. Available at: *http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf*.

[27] 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—Continued
(EDTC) Measure (NQF #0291)

	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 are proposing 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.

EXAMPLE 1 OF CALCULATION FOR OP–34: EMERGENCY DEPARTMENT TRANSFER COMMUNICATION—Continued
(EDTC) Measure (NQF #0291) by Case

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	
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.

EXAMPLE 2 OF CALCULATION FOR OP–34: EMERGENCY DEPARTMENT TRANSFER COMMUNICATION—Continued
(EDTC) Measure (NQF #0291) by Case

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.'' [28] 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

[28] US DHHS. ''National Healthcare Disparities Report 2013.'' Available at: *http://www.ahrq.gov/research/findings/nhqrdr/nhdr13/chap7.html*.

Consideration for December 1, 2014.'' [29] 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.'' [30]

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.'' [31] 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 are inviting 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 proposed and previously finalized measures for the CY 2019 payment determination and subsequent years are listed below.

PROPOSED 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.
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.****
0291	OP–34: Emergency Department Transfer Communication Measure.****

*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 proposed for the CY 2018 payment determination and subsequent years.

****New measure proposed for the CY 2019 payment determination and subsequent years.

[29] ''List of Measures under Consideration for December 1, 2014.'' Available at: *www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78318*.

[30] MAP. February 2015. ''Spreadsheet of MAP 2015 Final Recommendations''. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711*.

[31] Ibid.

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. 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 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.[32] 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*.

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 to, at a minimum, 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 proposed rule (80 FR 24581 through 24582), the Hospital IQR Program proposed to make reporting of electronic clinical quality measures required rather than voluntary. Under the proposal, hospitals would be required to submit both Q3 and Q4 of 2016 data for 16 electronic clinical quality measures (80 FR 24581 through 24582).

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.

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 proposals for the Hospital IQR Program (80 FR 24581 through 24582; 24587). Therefore, we are considering proposing a policy in future rulemaking that would give hospitals an option to voluntarily submit data for this measure electronically 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 are inviting public comment on our intention to make this proposal in the future.

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

[32] HHS August 2013 Statement, ''Principles and Strategies for Accelerating Health Information Exchange.'' Available at: *http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf*.

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). We are not proposing 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). We are not proposing any changes to our public display policy.

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).

We are not proposing any changes to these requirements.

2. Proposed 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 these procedural requirements at 42 CFR 419.46(b).

In this proposed rule, we are proposing 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 are proposing 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 proposed change to the withdrawal deadline is consistent with the ASCQR Program withdrawal deadline described in section XIV.C.2. of this proposed rule and in proposed 42 CFR 416.305(b). We believe aligning deadlines across programs will reduce provider burden by streamlining processes and procedures.

In addition, as we discuss below in section XIII.D.1. of this proposed rule, we are proposing 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 are proposing 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 are inviting public comment on our proposals to change the withdrawal deadline and to revise 42 CFR 419.46(b) to reflect this change.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Proposed 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,[33] explains that the chart-abstracted data on which we base APU determinations on 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, we are proposing to change the timeframe on which we base APU determinations for the Hospital OQR Program. 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 are proposing 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 are proposing to transition to the newly proposed timeframe for the CY 2018 payment determination and subsequent

[33] 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&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DHOQR_CY2016_MsrTmlns_0315.pdf&blobcol=urldata&blobtable=MungoBlobs*.

years and use only three quarters of data for determining the CY 2017 payment determination as illustrated in the tables below. However, we note 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.8. of this proposed rule, where we are proposing to update our validation processes to reflect these changes.

We are inviting public comment on our proposals.

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);
- 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.

We are not proposing 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 proposed rule, we are proposing to remove 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. If this proposal is adopted, for the CY 2018 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.

We are not proposing any changes to our claims-based measure data submission requirements.

4. Proposed 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 2017 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).

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.

We are proposing 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 are proposing 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 are proposing this new data submission period to be consistent with the data submission deadlines proposed by the ASCQR Program in section XIV.D.3. of this proposed rule 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 are inviting public comment on our proposal to change the data submission period for measures submitted via the CMS Web-based tool.

b. Proposed 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 this proposed rule, we are proposing 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). For data submission for the CY 2018 payment determination and subsequent years, we are proposing 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 above in section XIII.D.4.a. of this proposed rule; 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 [34]) 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 believe 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 are inviting public comment on our proposal.

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 this proposed rule, we are proposing one new Web-based measure for the CY 2019 payment determination and subsequent years, OP–34: Emergency Department Transfer Communication (EDTC) Measure (NQF #0291). For data submission for the CY 2019 payment determination and subsequent years, we are proposing 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 above in section XIII.D.4.a. of this proposed rule; 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 [35]) 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 believe 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 are inviting public comment on our proposal.

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.

We are not proposing 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

[34] Data Submission Requirements will be available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228775181731.*

[35] Data Submission Requirements will be available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228775181731.*

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 above in section XIII.D.1. of this proposed rule, we are proposing 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 are proposing that validation be based on three quarters of data (quarter 2, quarter 3 and quarter 4 of 2015). In addition, for the CY 2018 payment determination and subsequent years, we are proposing 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 are proposing to make one editorial correction to 42 CFR 419.46(e)(2) to replace the term ''fiscal year'' with the term ''calendar year.''

We are inviting public comment on our proposals.

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.

We are proposing to change the name of this process from extension and exception to extension and exemption. We also are proposing to make corresponding changes to the regulation text at 42 CFR 419.46(d). These proposed changes would align the Hospital OQR Program policies with those of the Hospital IQR Program (79 FR 50101) and ASCQR Program (79 FR 66987).

We are inviting public comment on our proposals.

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). We are proposing 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 are proposing this new reconsideration submission deadline to be consistent with the proposed ASCQR Program reconsideration submission deadline in section XIV.D.8. of this proposed rule. As stated above, we believe that aligning deadlines across programs leads to decreased provider burden by streamlining processes and procedures.

We also are proposing to make a conforming change to 42 CFR 419.46(f)(1) 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 are proposing to make an editorial correction to 42 CFR 419.46(f)(1) to replace the term ''fiscal year'' with the term ''calendar year.''

We are inviting public comment on these proposals.

E. Proposed 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 this 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 are proposing 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 proposed rule. 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 proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2016

We are proposing 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 are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2016 OPPS, we are proposing 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 are proposing to continue to exclude services paid under New Technology APCs. We are proposing 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 are proposing 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 are proposing 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 are inviting public comments on these proposals.

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 proposed rule 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 for subsequently enacted policies (79 FR 66966 through 66987).

In this proposed rule, we are proposing to establish a new Subpart H under 42 CFR part 416 to codify many of the administrative policies regarding

the ASCQR Program. We are proposing 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 are inviting public comment on our proposals to codify the scope and basis for the ASCQR Program.

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. We are not proposing any changes to this policy.

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). We are not proposing any changes to this policy; however, we are proposing 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. We are not proposing any changes to this process. However, we are proposing 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 raises specific 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. In any given situation, we will focus only on the criteria that are relevant to a particular set of circumstances.

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. We are not proposing any changes to this process for measure removal, suspension, or replacement. However, we are proposing to codify this measure removal process at proposed new 42 CFR 416.320(c).

We are inviting public comment on our proposals to codify these existing policies.

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 Seven-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).[36] 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 [37] and the measure steward will be continuing to support the measure.[38] 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 No.	NQF No.	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.**

*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 No.	NQF No.	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 Seven-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 FR 66970 through 66979).

[36] *http://www.qualityforum.org/Publications/2015/02/NQF-Endorsed_Measures_for_Surgical_Procedures.aspx*.

[37] 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.

[38] *http://ascquality.org/documents/ASC_QC_ImplementationGuide_3.0_January_2015.pdf*.

4. ASCQR Program Quality Measures for the CY 2018 Payment Determination and Subsequent Years

We are not proposing to adopt any additional measures for the ASCQR Program for the CY 2018 payment determination and subsequent years in this proposed rule.

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 value-based purchasing 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.

In this proposed rule, we also are inviting 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; [39] surgical site infections; [40] impaired coagulation; [41] and colligation of drug effects.[42] When intraoperative normothermia is maintained, patients experience fewer adverse outcomes and their overall care costs are lower.[43] This measure is 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.[44] It also addresses the MAP-identified priority measure area for the ASCQR Program of anesthesia-related complications.[45]

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.[46] Each year, approximately 1.5 million patients undergo cataract surgery to improve their vision.[47] 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.[48] 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.[49] It also addresses the MAP-identified priority measure area of procedure complications for the ASCQR Program.[50]

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 are inviting public comment on the possible inclusion of these measures in the ASCQR Program measure set in the future. As stated previously, we are not proposing to adopt any new measures for the CY 2018 payment determination or subsequent years in this proposed rule.

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

[39] Frank S.M., Fleisher L.A., Breslow M.J., et al. Perioperative maintenance of normothermia reduces the incidence of morbid cardiac events: A randomized clinical trial. *JAMA.* 1997; 277(14): 1127–1134.

[40] Kurz A., Sessler D.I., 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.

[41] Rajagopalan S., Mascha E., Na J., Sessler D.I. The effects of mild hypothermia on blood loss and transfusion requirements during total hip arthroplasty. *Lancet.* 1996; 347(8997): 289–292.

[42] Kurz A. Physiology of thermoregulation. *Best Pract Res Clin Anaesthesiol.* 2008; 22(4): 627–644.

[43] Mahoney C.B., Odom J. Maintaining intraoperative normothermia: A meta-analysis of outcomes with costs. *AANA Journal.* 1999; 67(2): 155–164.

[44] MAP Hospital Workgroup Transcript.

[45] 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*.

[46] National Eye Institute. ''*Cataracts.*'' Cataracts. National Institutes of Health, n.d. Available at: *https://www.nei.nih.gov/eyedata/cataract#1*.

[47] ''Measure Application Partnership Hospital Workgroup'', National Quality Forum. Dec. 2014, Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369*.

[48] Chen M., Lamattina K.C., 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.

[49] ''Measure Application Partnership Hospital Workgroup'', National Quality Forum. Dec. 2014, Transcript. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369*.

[50] 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*.

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 would be necessary. We will continue to use rulemaking to adopt substantive updates to measures in the ASCQR Program. We are not proposing any changes to these policies. However, we are proposing 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 in addition to posting this information on QualityNet for the ASCQR Program.

We are inviting public comment on our proposal to codify our existing policies.

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. We are proposing 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, we are now proposing 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 also 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 are proposing 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 also help ASCs to better understand their performance on measures collected under the ASCQR Program. We also are proposing, 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, 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 are proposing to codify this proposal at proposed new 42 CFR 416.315.

We are inviting 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.

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. We are not proposing any changes to these policies. We are proposing to codify these existing requirements at proposed new 42 CFR 416.310(c)(1)(i).

We are inviting public comment on our proposal to codify our existing requirements.

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 four 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. We are not proposing any changes to these policies. However, we are proposing 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 are not proposing any changes to these existing requirements. However, we are proposing to codify these existing requirements at proposed new 42 CFR 416.305(c).

We are inviting public comment on our proposal to codify our existing policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

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 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. In this proposed rule, we are not proposing any changes to these existing requirements. However, we are proposing to codify these existing requirement at proposed new 42 CFR 416.310(a)(1) and (2).

We are inviting public comment on our proposal to codify our existing policies.

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 QDC. 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 this proposed rule, we are not proposing any changes to these existing requirements. However, we are proposing to codify these existing requirements at proposed new 42 CFR 416.310(a)(3).

We are inviting public comment on our proposal to codify our existing policies.

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).

We are proposing 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).[51] Therefore, we are proposing 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 are proposing 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 are proposing to codify these proposed and existing requirements at proposed new 42 CFR 416.310(c)(1)(ii) and (2).

We are inviting 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.

4. Claims-Based Measure Data Requirements for the ASC–12: Facility Seven-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 FFS claims from the calendar year 2 years before the payment determination year. We are now proposing 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 are proposing 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 are proposing to codify this policy at proposed new 42 CFR 416.310(b).

We are inviting public comment on our proposal regarding the paid claims to be included in the data used for the payment determination year beginning with the CY 2018 payment determination, and our proposal to codify this proposal and our existing policies.

5. Proposal for Indian Health Service (IHS) Hospital Outpatient Departments To Not Be Considered ASCs for the Purposes 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.

We now are proposing 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 are proposing 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 are proposing to codify this proposal at proposed new 42 CFR 416.305(d).

We are inviting public comment on this proposal and our proposal to codify it.

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

[51] We note that this 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.

Program. In this proposed rule, we are not proposing 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.[52] 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 this proposed rule, we are not proposing any changes to these requirements. However, we are proposing to codify these existing procedures at proposed new 42 CFR 416.310(d).

We are inviting public comment on our proposal to codify our existing policies.

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 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 this proposed rule, we are proposing 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 are proposing 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 are proposing to codify these existing procedures at proposed new 42 CFR 416.330.

We are inviting public comment on our proposal to change the reconsideration request submission deadline and our proposal to codify these policies.

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 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 proposed rule.

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

[52] 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 ''Extraneous Circumstances Extensions or Exemptions'' process rather than the ''Extraordinary Circumstances Extensions or Waivers'' process.

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 proposed rule, which are available via the Internet on the CMS Web site): ''A2,'' ''G2,'' ''P2,'' ''R2,'' ''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 copayment 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 copayment 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 this CY 2016 OPPS/ASC proposed rule, we are not proposing 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 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.

With respect to the 2-midnight benchmark, the starting point is when the beneficiary begins receiving hospital care as either 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 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 such factors 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. For those admissions in which the basis for the physician expectation of care surpassing 2 midnights is reasonable and well-documented, reviewers may apply the 2-midnight benchmark to incorporate all of the time a beneficiary received care in the hospital.

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, as 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 revised 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 medically necessary, newly initiated mechanical ventilation (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 ''probe and educate'' reviews 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 imposed a moratorium on 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 probe and educate process through March 31, 2015. The same law also extended the CMS moratorium on recovery auditor reviews of inpatient hospital patient status for claims with dates of admission through March 31, 2015. 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 inpatient hospital probe and educate process and extended the moratorium that precludes recovery auditor reviews of inpatient hospital patient status for claims with dates of admission through September 30, 2015. MACs have completed the first and second rounds of probe reviews and provider education and are starting on a third round of probe reviews, to be completed 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 for post-probe reviews was effective in promoting better understanding of the policy.

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. 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 are changing 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 have established limits on additional documentation requests (ADRs) that are based on a hospital's compliance with Medicare rules, incrementally applied ADR limits for providers that are new to recovery auditor reviews, and diversified ADR limits across all types of claims for a certain provider. We also have established 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 will require recovery auditors to wait 30 days before sending a claim to the MAC for adjustment. This 30-day period will allow the provider to submit a discussion period request to the recovery auditor before the MAC makes any payment adjustments. These changes will be effective with the next recovery audit program contract awards.

B. Proposed 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, although we acknowledge that our current payment policy and medical review policy focus on physician judgment regarding the expected duration of medically necessary hospital care. 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, we are proposing 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 note 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 believe 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. Such circumstances would be determined on a case-by-case basis. Under the proposed revised policy, for purposes of Medicare payment, an inpatient admission will 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 are proposing 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 are proposing 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. 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 but acknowledge that the patient can be unexpectedly discharged or transferred to another hospital and not actually use a hospital bed overnight. Cases for which the physician determines that an inpatient admission is necessary, but that do not span at least 1 midnight, will be prioritized for medical review. In addition to the proposed substantive changes discussed earlier in this section, we also proposing 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 are not proposing 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 are not proposing 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. This proposed change also would 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 rule, 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. As under our current policy, 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 are inviting 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 our longstanding policy, which recognizes 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 will monitor the number of these types of admissions and plan to prioritize these types of cases for medical review.

Currently, the MACs perform ''probe and educate'' audits under the 2-midnight rule. Regardless of whether we finalize the policy proposals outlined above, we are announcing that, no later than October 1, 2015, we are changing the medical review strategy and plan to have Quality Improvement Organization (QIO) contractors conduct these reviews of short inpatient stays rather than the MACs. 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, recovery auditors, 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. 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. 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.

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 medical review short-stay inpatient review process that we will adopt by October 1, 2015, QIOs will review a sample of post-payment claims and make 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.

QIOs will refer claim denials to the MACs for payment adjustments. Providers' appeals of denied claims will be addressed under the provisions of section 1869 of the Act. 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 payment audit.

In addition to the formal medical review process, we intend to continuously monitor and evaluate the proposed 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 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 prohibits recovery auditors from performing patient status reviews for claims with dates of admission 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. After that date, the recovery auditors will conduct patient status reviews focused on those providers that are referred from the QIOs and have 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 will 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 are not proposing 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.

We welcome stakeholder comment and feedback on this proposed change and on future changes to the 2-midnight rule. We note that several stakeholder groups have examined short-stay payment policies, but that there is no consensus on what a short-stay payment policy should be. We also note that MedPAC has recently recommended repealing the 2-midnight rule in its entirety, in Chapter 7 of its June Report to Congress. MedPAC has not recommended a short-stay payment policy. We have requested public comment on three different occasions on issues related to when a patient is appropriately admitted as an inpatient or when the patient is appropriately treated as an outpatient, including potential payment policy options to address this issue. The public comment process has not produced any consensus on a recommended payment policy proposal to address this issue. In a letter earlier this year, the American Hospital Association provided us with its analysis for several payment policy alternatives and their potential impact. The association did not recommend adoption of a particular payment policy in this area. We continue to be open to considering potential payment policy options that have the potential to address this issue.

XVI. Proposed Transition for Medicare-Dependent, Small Rural Hospitals (MDHs) in All-Urban States 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 Public Law 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, provides 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 inserting ''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, included 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 recently extended to expire effective October 1, 2017, by section 205 of the MACRA, 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.

We are proposing 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 are proposing 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 are proposing 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. For FY 2018, that is, for discharges occurring on or after October 1, 2018, we are proposing that these former MDHs would be solely paid based on the Federal rate.

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 gradual 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 are inviting public comments on our proposal.

XVII. 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 proposed rule pertaining to proposed 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–P'' from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder entitled ''Proposed 2016 OPPS 1633–P Addenda'' at the bottom of the page. To view the Addenda to this proposed rule pertaining to the proposed 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–P'' from the list of regulations. All ASC Addenda to this proposed rule are contained in the zipped folders entitled ''Addendum AA, BB, DD1 and DD2'' and ''Addendum EE''.

For CY 2016, we are proposing to add two new Addenda: Proposed Addendum O, which lists the proposed new and revised CPT codes for CY 2016; and proposed Addendum Q, which includes a crosswalk from CY 2015 APC numbers to proposed new CY 2016 APC numbers.

XVIII. 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.

We are soliciting 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 this CY 2016 OPPS/ASC proposed rule, we make 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.

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 proposed rule.

a. Estimated Burden of Hospital OQR Program Proposals for the CY 2017 Payment Determination and Subsequent Years

In section XIII. of this proposed rule, we are proposing to make several changes to the Hospital OQR Program for the CY 2017 payment determination and subsequent years. Specifically, we are proposing 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 from November 1 to August 31; (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) from July 1 through November 1 to January 1 through May 15; (5) rename our extension and exception policy to extension and exemption policy; (6) change the deadline for submitting a reconsideration request 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; 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 would increase burden, as further discussed below.

We are proposing 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 are proposing that validation 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 would be reduced by 25 percent because hospitals would submit validation data for three quarters instead of four.

(1) Measure Proposed for Removal for the CY 2017 Payment Determination and Subsequent Years

As discussed in section XIII.B.5. of this proposed rule, we are proposing to remove OP–15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache 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''). We estimate that there would be no change in burden based on our proposal to remove this measure.

(2) Changes to Reporting Requirements for the CY 2017 Payment Determination and Subsequent Years

In section XIII.E. of this proposed rule, we are proposing to make several changes to the reporting requirements for the Hospital OQR Program. Specifically, we are proposing to: (1) Change the deadline for withdrawing from the program from November 1 to up to and including August 31; (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) from July 1 through November 1 to January 1 through May 15; (4) rename our extension and exception policy to extension and exemption policy; (5) change the deadline for submitting a reconsideration request 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. Although we are proposing 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 would remain the same.

In addition, we are proposing 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 are proposing that validation be based on three quarters of data (quarter 2, quarter 3 and quarter 4 of 2015.) 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 would reduce the number of hours required by 25 percent (from 12 hours to 9 hours per hospital). 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. In summary, for the CY 2017 payment determination, we estimate a total burden of 3.5 million hours across all hospitals for a total of $105 million. This is a reduction of 1,500 hours and $45,000 across all hospitals from last year's estimate.

b. Estimated Burden of Hospital OQR Program Proposals for the CY 2018 Payment Determination and Subsequent Years

For the CY 2018 payment determination and subsequent years, we are making two new proposals. First, in section XIII.B.6.a. of this proposed rule, we are proposing one new measure for the CY 2018 payment determination and subsequent years: OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822). In section XIII.E.5. of this proposed rule, we are proposing that hospitals can either: (1) Report aggregate level data for OP–33 submitted via the CMS Web-based tool (QualityNet Web site); or (2) submit an aggregate data file for this measure through a vendor (via the QualityNet infrastructure).

For hospitals choosing the first data submission method, and consistent with prior years, we believe that submitting a measure through the Web-based tool has two burden components: first, the time required to abstract the data for the measure; and second, the time required to enter these data into the 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 (35) previously estimated by the number of measures (12). Therefore, we estimate 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 would submit 48 cases per year for OP–33. Therefore, we believe that the average hospital would 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 would spend 10 minutes (0.167 hours) per measure per year to collect and submit the data via the Web-based tool. Therefore, we estimate that, in total, the proposed measure would 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 participate in the Hospital OQR Program for the CY 2017 payment determination. Therefore, we estimate a total increase in burden across all participating hospitals of approximately 8,313 hours (2.519 hours/hospital × 3,300 hospitals) (rounded) 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.

For hospitals choosing the second data submission method, we do not have any baseline data on which to estimate how many hospitals might elect to submit data through a vendor. However, we generally estimate that burden will be less than the first data submission method. In future years, we will adjust the burden estimate to account for hospitals that elect to submit data through a vendor.

The second proposal we are proposing for the CY 2018 payment determination and subsequent years, is 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 is an increase of 1,500 hours and $45,000 across all hospitals from the CY 2017 estimate.

Therefore, we estimate a total financial increase in burden would be $89.21 per hospital (2.97 hours × $30/hour) or $294,000 (9,813 hours × $30/hour) (rounded) across all participating hospitals as a result of our proposals for the CY 2018 payment determination and subsequent years.

c. Estimated Burden of Hospital OQR Program Proposals for the CY 2019 Payment Determination and Subsequent Years

For the CY 2019 payment determination and subsequent years, we are making one new proposal. In section XIII.B.6.b. of this proposed rule, we are proposing one new measure for the CY 2019 payment determination and subsequent years: OP–34: Emergency Department Transfer Communication (EDTC) (NQF #0291). In section XIII.E.6. of this proposed rule, we are proposing that hospitals can either: (1) Report aggregate level data for OP–34 submitted via the CMS Web-based tool (QualityNet Web site); or (2) submit an aggregate data file for this measure through a vendor (via QualityNet infrastructure). For hospitals choosing the first data submission method, and consistent with prior years, we believe that submitting a measure through the Web-based tool has two burden components: first, the time required to abstract the data for the measure; and second, the time required to enter this data into the 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 number of minutes (35) previously estimated by the number of measures (12). Therefore, we estimate 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, ED-Throughput measures OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF# 0496) (75 FR 72086) and OP–20: Door to Diagnostic Evaluation by a Qualified Medical Professional (75 FR 72087 through 72088), we estimate that the average hospital would submit 495 cases per year for OP–34. Therefore, we believe that the average hospital would spend 24.255 hours (0.049 hours/case × 495 cases) chart-abstracting data for this measure.

In addition, consistent with prior years (78 FR 75171), we estimate that each participating hospital would spend 10 minutes (0.167 hours) per measure per year to collect and submit the data via the Web-based tool. Therefore, we estimate that, in total, the proposed measure would increase burden by 24.422 hours (24.255 hours + 0.167 hours) per hospital per year. Consistent with prior years (79 FR 67013), we believe that approximately 3,300 hospitals participate in the Hospital OQR Program for the CY 2017 payment determination. Therefore, we estimate a total increase in burden across all participating hospitals of 80,592.6 hours (24.422 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 this data.

For hospitals choosing the second data submission method, we do not have any baseline data on which to estimate how many hospitals might elect to submit data through a vendor. However, we generally estimate that burden will be less than the first data submission method. In future years, we will adjust the burden estimate to account for hospitals that elect to submit data through a vendor.

Therefore, we estimate a total financial increase in burden would be $732.66 per hospital (24.422 hours × $30/hour) or $2.4 million (80,592.6 hours × $30/hour) (rounded) across all participating hospitals as a result of our proposals for the CY 2019 payment determination and subsequent years.

We are inviting public comment on the burden associated with these proposed information collection 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 Effective Beginning With the CY 2017 Payment Determination

We are proposing 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 policy proposals discussed below. For existing policies with proposed 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.

In terms of our proposals for the ASCQR Program in this proposed rule, we are proposing 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. We do not anticipate additional burden as the data collection and submission requirements have not changed, only the deadline has moved to a slightly earlier date that we anticipate would alleviate burden by aligning data submission deadlines. We also are proposing, 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 proposal would 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 further proposing 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 would be any additional burden as the materials to be submitted are unchanged and the deadline does not result in reduced time to submit a reconsideration request. In addition, we are proposing to display data by the NPI if data are submitted by the NPI or by the CCN if data are submitted by the CCN for any public reporting that occurs on or after January 1, 2016. Again, we do not anticipate any additional burden because it does not alter the administrative or reporting requirements governing ASC's participation in the ASCQR Program.

Finally, we are proposing, 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 proposal affecting the CY 2017 payment determination or subsequent years because it does not alter the administrative or reporting requirements governing 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 Seven-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, it 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 would be nominal. We do not anticipate that ASC–12 would 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 would be 1,757 hours (5,260 ASCsx × x2 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 would 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 would 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). We are not proposing to make any changes to this process.

e. Reconsideration

In this proposed rule, we are proposing a minor change to the reconsideration request deadline to ensure our deadline for these requests would always fall on a business day. We do not anticipate that there would be any additional burden as the materials to be submitted are unchanged and the deadline does not result in reduced time to submit a reconsideration request. We also are proposing 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 are inviting public comment on the burden associated with these information collection requirements.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–1633–P; Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*.

XIX. 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 proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XX. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this proposed rule, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the 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 proposed rule contains the impact and other economic analyses for the provisions that we are proposing 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 proposed rule 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 proposed rule 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 proposed rule. We are soliciting comments on the regulatory impact analysis in this proposed rule, and we will address the public comments we receive in the final rule with comment period as appropriate.

2. Statement of Need

This proposed rule is necessary to propose updates to the Medicare hospital OPPS rates. It is necessary to make proposed 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 proposing to revise 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 December 31, 2014, and updated cost report information.

This proposed rule also is necessary to propose updates to 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 Proposed 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 proposed changes in this proposed rule, would be approximately $43 million. Taking into account our estimated changes in enrollment, utilization, and case-mix, we estimate that the proposed OPPS expenditures for CY 2016 would be approximately $3.2 billion higher relative to expenditures in CY 2015. We note that this estimate of $3.2 billion does not include the proposed 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 proposed rule. Because this proposed 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 65 displays the distributional impact of the proposed CY 2016 changes in OPPS payment to various groups of hospitals and for CMHCs.

We estimate that the proposed update to the conversion factor and other proposed adjustments (not including the effects of proposed outlier payments, the proposed pass-through estimates, and the proposed application of the frontier State wage adjustment for CY 2016) would decrease total OPPS payments by 0.1 percent in CY 2016. The proposed changes to the APC weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase OPPS payments because these proposed changes to the OPPS are budget neutral. However, these proposed updates would change the distribution of payments within the budget neutral system. We estimate that the proposed total change in payments between CY 2015 and CY 2016, considering all payments, including the proposed adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests, proposed 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, would decrease total estimated OPPS payments by 0.2 percent.

We estimate the proposed total increase (from proposed changes to the ASC provisions in this proposed rule 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 $169 million. Because the proposed provisions for the ASC payment system are part of a proposed rule that is economically significant as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the proposed changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of the proposed rule. Table 66 and Table 67 of this proposed rule display the redistributive impact of the proposed 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 Effects of Proposed OPPS Changes in This Proposed Rule

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2016 policy changes on various hospital groups. We post on the CMS Web site our proposed hospital-specific estimated payments for CY 2016 with the other supporting documentation for this proposed rule. To view the proposed 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–P'' 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 proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 65 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 proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed individual policy changes by estimating payments per service, while holding all other proposed 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. We are soliciting 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 receive will be addressed in the applicable sections of the final rule with comment period that discuss the specific policies.

(2) Estimated Effects of Proposed OPPS Changes on Hospitals

Table 65 below shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the proposed 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 65, 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 proposing to continue to pay CMHCs under proposed renumbered APC 5851 (existing APC 0172) (Level 1 Partial Hospitalization (3 services) for CMHCs) and proposed renumbered APC 5852 (existing APC 0173) (Level 2 Partial Hospitalization (4 or more services) for CMHCs), and we are proposing to pay hospitals for partial hospitalization services under proposed 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).

The estimated decrease in the proposed total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology and the proposed 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 proposed rule. 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 proposed IPPS market basket percentage increase for FY 2016 is 2.7 percent (80 FR 24477). Section 1833(t)(3)(F)(i) of the Act reduces that 2.7 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.6 percentage point for FY 2016 (which is also the proposed MFP adjustment for FY 2016 in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24478)); 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 proposed OPD fee schedule increase factor of 1.9 percent. We are using the proposed OPD fee schedule increase factor of 1.9 percent in the calculation of the CY 2016 OPPS conversion factor. We are also applying a proposed 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 65.

To illustrate the impact of the proposed 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 65 shows the estimated redistribution of the proposed 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 proposed APC reconfiguration and recalibration changes between CY 2015 and CY 2016 (Column 2); the proposed wage indexes and the proposed provider adjustments (Column 3); the combined impact of all of the proposed changes described in the preceding columns plus the proposed 1.9 percent OPD fee schedule increase factor update to the conversion factor and the proposed −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 proposed payments for CY 2016 relative to all payments for CY 2015, including the impact of proposed changes in estimated outlier payments, the frontier State wage adjustment, and proposed 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 proposing to maintain the current adjustment percentage for CY 2016. Because the proposed updates to the conversion factor (including the proposed update of the OPD fee schedule increase factor), the estimated cost of the proposed rural adjustment, and the estimated cost of proposed 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 proposed wage index changes on the hospital. However, proposed total payments made under this system and the extent to which this proposed rule would 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.

Overall, we estimate that the proposed rates for CY 2016 would decrease Medicare OPPS payments by an estimated 0.2 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 a proposed estimated 0.2 percent decrease in Medicare payments to all other hospitals. These proposed estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 65 shows the total number of facilities (3,912), 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 proposed 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 proposed 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 proposed rule. 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 (3,791), 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 58 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Proposed Changes

Column 2 shows the estimated effect of proposed APC recalibration. Column 2 also reflects any proposed changes in multiple procedure discount patterns or conditional packaging that occur as a result of the proposed changes in the relative magnitude of payment weights. As a result of proposed APC recalibration, we estimate that urban hospitals would experience no change, with the impact ranging from an increase of 0.1 percent to a decrease of 0.2 percent, depending on the number of beds. Rural hospitals would experience a 0.2 percent increase, with the impact ranging from an increase of 0.7 percent to a decrease of 0.1 percent, depending on the number of beds. Major teaching hospitals would experience a decrease of 0.1 percent overall.

Column 3: Proposed Wage Indexes and the Effect of the Proposed Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the proposed APC recalibration; the proposed updates for the wage indexes with the proposed fiscal year (FY) 2016 IPPS post-reclassification wage indexes; and the proposed rural adjustment. We modeled the independent effect of the proposed budget neutrality adjustments and the proposed 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 proposed updated wage indexes, including the application of proposed budget neutrality for the proposed rural floor policy on a nationwide basis. This column excludes the effects of the proposed frontier State wage index adjustment, which is not budget neutral and is included in Column 5. We did not model a proposed budget neutrality adjustment for the proposed rural adjustment for SCHs because we are proposing to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2016, as described in section II.E. of this proposed rule.

We modeled the independent effect of proposing to update the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the proposed CY 2016 scaled weights and a CY 2015 conversion factor that included a budget neutrality adjustment for the effect of the proposed changes to the wage indexes between CY 2015 and CY 2016. The proposed FY 2016 wage policy results in modest redistributions.

There is no difference in impact between the CY 2015 cancer hospital payment adjustment and the proposed CY 2016 cancer hospital payment adjustment because we are proposing to use the same payment-to-cost ratio target in CY 2016 as in the CY 2015 OPPS/ASC final rule with comment period correction notice (80 FR 9629 through 9636).

Column 4: All Proposed Budget Neutrality Changes Combined With the Proposed Market Basket Update and the Proposed Adjustment To Address Excess Packaged Payment for Laboratory Tests

Column 4 demonstrates the combined impact of all of the proposed changes previously described, the proposed update to the conversion factor of 1.9 percent, and the proposed 2.0 percent reduction due to the proposed 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 proposed changes would decrease payments to urban hospitals by 0.1 percent and to rural hospitals by 0.3 percent. Most classes of hospitals would receive a decrease in line with the proposed 0.1 percent overall decrease after the proposed update and the proposed adjustment to the conversion factor to address excess packaged payment for laboratory tests are applied to the proposed budget neutrality adjustments.

Column 5: All Proposed Changes for CY 2016

Column 5 depicts the full impact of the proposed CY 2016 policies on each hospital group by including the effect of all of the proposed 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 proposed OPD fee schedule increase; the impact of the proposed frontier State wage index adjustment; the impact of estimated proposed OPPS outlier payments as discussed in section II.G. of this proposed rule; the proposed 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 proposed rule); and the difference in proposed 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 60 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 proposed changes for CY 2016 would decrease payments to all facilities by 0.2 percent for CY 2016. We modeled the independent effect of all of the proposed changes in Column 5 using the final relative payment weights for CY 2015 and the proposed relative payment weights for CY 2016. We used the final conversion factor for CY 2015 of $74.173 and the proposed CY 2016 conversion factor of $73.929 discussed in section II.B. of this proposed rule.

Column 5 contains simulated outlier payments for each year. We used the proposed 1-year charge inflation factor used in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24632) of 4.8 percent (1.048116) to increase individual costs on the CY 2014 claims, and we used the most recent overall CCR in the April 2015 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2015. Using the CY 2014 claims and a proposed 4.8 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 would be approximately 0.95 percent of total payments. The estimated current outlier payments of 0.95 percent are incorporated in the comparison in Column 5. We used the same set of claims and a proposed charge inflation factor of 9.8 percent (1.098547) and the CCRs in the April 2015 OPSF, with an adjustment of 0.9795, to reflect relative changes in cost and charge inflation between CY 2014 and CY 2016, to model the proposed CY 2016 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a proposed fixed-dollar threshold of $3,650. The charge inflation and CCR inflation factors are discussed in detail in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24632 through 24633).

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 would be negligible. Overall, we estimate that facilities would experience a decrease of 0.2 percent under this proposed rule in CY 2016 relative to total spending in CY 2015. This projected decrease (shown in Column 5) of Table 65 reflects the proposed 1.9 percent OPD fee schedule increase factor, less 2.0 percent for the proposed 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 0.12 percent for the proposed change in the pass-through estimate between CY 2015 and CY 2016, plus 0.05 percent for the difference in estimated outlier payments between CY 2015 (0.95 percent) and CY 2016 (proposed 1.0 percent). We estimate that the combined effect of all of the proposed changes for CY 2016 would decrease payments to urban hospitals by 0.2 percent. Overall, we estimate that rural hospitals would experience a 0.3 percent decrease as a result of the combined effects of all of the proposed changes for CY 2016.

Among hospitals by teaching status, we estimate that the impacts resulting from the combined effects of all proposed changes would include a decrease of 0.3 percent for major teaching hospitals and a decrease of 0.2 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated decrease of 0.1 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience a decrease of 0.2 percent, proprietary hospitals would experience a decrease of 0.2 percent, and governmental hospitals would experience a decrease of 0.4 percent.

TABLE 65—ESTIMATED IMPACT OF THE PROPOSED CY 2016 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	APC Recalibration (all proposed changes)	New wage index and provider adjustments	All proposed budget neutral changes (combined cols 2,3) with proposed market basket update and proposed adjustment to address excess packaged payment for laboratory tests	All proposed changes
	(1)	(2)	(3)	(4)	(5)
ALL FACILITIES *	3,912	0.0	0.0	−0.1	−0.2
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs):	3,791	0.0	0.0	−0.1	−0.2
URBAN HOSPITALS	2,942	0.0	0.1	−0.1	−0.2
LARGE URBAN (GT 1 MILL.)	1,613	0.0	0.1	0.0	−0.1
OTHER URBAN (LE 1 MILL.)	1,329	−0.1	0.0	−0.1	−0.2
RURAL HOSPITALS:	849	0.2	−0.4	−0.3	−0.3
SOLE COMMUNITY	379	0.1	−0.3	−0.3	−0.3
OTHER RURAL	470	0.3	−0.5	−0.3	−0.3
BEDS (URBAN):					
0–99 BEDS	1,015	0.0	−0.2	−0.4	−0.5
100–199 BEDS	844	0.1	0.1	0.0	−0.1
200–299 BEDS	463	0.1	0.1	0.1	0.0
300–499 BEDS	406	0.0	0.1	0.0	−0.1
500+ BEDS	214	−0.2	0.0	−0.3	−0.4
BEDS (RURAL):					
0–49 BEDS	337	0.7	−0.3	0.3	0.2
50–100 BEDS	311	0.3	−0.2	−0.1	−0.1
101–149 BEDS	114	0.1	−0.5	−0.5	−0.5
150–199 BEDS	46	0.3	−0.2	−0.1	−0.3
200+ BEDS	41	−0.1	−0.7	−1.0	−1.1
REGION (URBAN):					
NEW ENGLAND	150	0.7	−0.5	0.0	0.0
MIDDLE ATLANTIC	352	−0.1	0.2	0.0	−0.1
SOUTH ATLANTIC	469	−0.1	0.2	−0.1	−0.3
EAST NORTH CENT.	475	−0.1	0.0	−0.2	−0.3
EAST SOUTH CENT.	181	−0.3	−0.3	−0.8	−0.9
WEST NORTH CENT.	183	0.0	−0.3	−0.4	−0.5

TABLE 65—ESTIMATED IMPACT OF THE PROPOSED CY 2016 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	APC Recalibration (all proposed changes)	New wage index and provider adjustments	All proposed budget neutral changes (combined cols 2,3) with proposed market basket update and proposed adjustment to address excess packaged payment for laboratory tests	All proposed changes
	(1)	(2)	(3)	(4)	(5)
WEST SOUTH CENT.	509	0.2	−0.2	−0.1	−0.2
MOUNTAIN	193	0.0	0.3	0.2	−0.1
PACIFIC	381	−0.1	0.7	0.5	0.4
PUERTO RICO	49	−1.6	−1.7	−3.3	−3.4
REGION (RURAL):					
NEW ENGLAND	22	0.5	−0.6	−0.2	−0.2
MIDDLE ATLANTIC	58	0.4	−0.9	−0.6	−0.3
SOUTH ATLANTIC	126	−0.1	0.2	0.0	−0.1
EAST NORTH CENT.	120	0.1	−0.1	−0.1	−0.2
EAST SOUTH CENT.	162	0.3	−0.7	−0.5	−0.6
WEST NORTH CENT.	102	0.2	−0.5	−0.4	−0.3
WEST SOUTH CENT.	174	0.8	−1.1	−0.5	−0.6
MOUNTAIN	61	0.0	0.1	−0.1	−0.4
PACIFIC	24	0.0	0.3	0.1	0.1
TEACHING STATUS:					
NON-TEACHING	2758	0.0	0.0	−0.1	−0.2
MINOR	709	0.1	0.0	0.0	−0.1
MAJOR	324	−0.1	0.1	−0.2	−0.3
DSH PATIENT PERCENT:					
0	24	−1.2	−0.4	−1.7	−1.4
GT 0–0.10	324	−0.3	0.0	−0.4	−0.5
0.10–0.16	331	0.1	0.0	0.0	0.0
0.16–0.23	650	0.0	0.0	−0.2	−0.2
0.23–0.35	1086	0.0	−0.1	−0.2	−0.3
GE 0.35	817	0.0	0.1	0.0	−0.1
DSH NOT AVAILABLE**	559	3.1	−0.1	2.8	2.4
URBAN TEACHING/DSH:					
TEACHING & DSH	941	0.0	0.1	−0.1	−0.2
NO TEACHING/DSH	1456	0.0	0.0	−0.1	−0.2
NO TEACHING/NO DSH	23	−1.2	−0.3	−1.6	−1.5
DSH NOT AVAILABLE**	522	3.2	0.1	3.0	2.6
TYPE OF OWNERSHIP:					
VOLUNTARY	2000	0.0	0.1	−0.1	−0.2
PROPRIETARY	1271	0.4	−0.2	0.0	−0.2
GOVERNMENT	520	−0.1	0.0	−0.2	−0.4
CMHCs	58	22.2	−0.4	21.1	14.8

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed 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 proposed 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 1.000 because the payment-to-cost ratio target remains the same as in the CY 2015 OPPS/ASC final rule with comment period correction notice (80 FR 9629 through 9636).

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 1.9 percent OPD fee schedule update factor (2.7 percent reduced by 0.6 percentage points for the proposed 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 proposed −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 3,912 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 Proposed OPPS Changes on CMHCs

The last line of Table 65 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) (proposed renumbered APC 5851 for CY 2016) and existing APC 0173 (Level 2 Partial Hospitalization (4

or more services) for CMHCs) (proposed 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) (proposed renumbered APC 5861 for CY 2016) and existing APC 0176 (Level 2 Partial Hospitalization (4 or more services) for hospital-based PHPs) (proposed renumbered APC 5862 for CY 2016). We use our standard ratesetting methodology to derive the proposed 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 proposing 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 would 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 proposed rule. 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 would experience an overall 14.8 percent increase in payments from CY 2015 (shown in Column 5). We note that this would include the proposed trimming methodology described in section VIII.B. of this proposed rule.

Column 3 shows that the estimated impact of adopting the proposed FY 2016 wage index values would result in a small decrease of 0.4 percent to CMHCs. Column 4 shows that combining this proposed OPD fee schedule increase factor, proposed 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 proposed changes in APC policy for CY 2016 and the proposed FY 2016 wage index updates, would result in an estimated increase of 21.1 percent. Column 5 shows that adding the proposed changes in outlier and pass-though payments would result in a total 14.8 percent increase in payment for CMHCs. This reflects all proposed changes to CMHCs for CY 2016.

(4) Estimated Effect of Proposed 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 would increase for services for which the OPPS payments would rise and would decrease for services for which the OPPS payments would fall. For further discussion on the calculation of the proposed national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this proposed rule. 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 would 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 proposed recalibration of the APC relative payment weights, proposed APC reorganization, proposed change in the portion of OPPS payments dedicated to pass-through payments, and the proposed CY 2016 comprehensive APC payment policy discussed in section II.A.2.e. of this proposed rule.

(5) Estimated Effects of Proposed 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 proposed rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs would be affected by the proposed changes in this proposed rule.

(6) Estimated Effects of Proposed OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be a decrease of $43 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 XX.A. of this proposed rule.

(7) Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are proposing and the reasons for our selected alternatives are discussed throughout this proposed rule. 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 proposed rule 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 proposed rule 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, but did not propose, to apply the device offset to procedures for which anesthesia has already been administered (that is, those identified by Modifier 74).

b. Estimated Effects of Proposed 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 proposed rule, we are proposing to set the CY 2016 ASC relative payment weights by scaling the proposed CY 2016 OPPS relative payment weights by the ASC scalar of 0.9180. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 66 and 67 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 proposed CY 2016 ASC conversion factor by adjusting the CY 2015 ASC conversion factor by 1.0014 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2015 and CY 2016 and by applying the

proposed CY 2016 MFP-adjusted CPI–U update factor of 1.1 percent (projected CPI–U update of 1.7 percent minus a proposed projected productivity adjustment of 0.6 percentage point). The proposed CY 2016 ASC conversion factor is $44.605.

(1) Limitations of Our Analysis

Presented here are the projected effects of the proposed 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 proposed CY 2016 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

(2) Estimated Effects of Proposed ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform the gamut 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 on an individual ASC of the proposed update to the CY 2016 payments would 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 proposed 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 66 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 proposed CY 2016 payments, and Table 67 shows a comparison of estimated CY 2015 payments to estimated proposed CY 2016 payments for procedures that we estimate would receive the most Medicare payment in CY 2015.

Table 66 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 66.

- 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 Proposed 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 proposed updates to ASC payment rates for CY 2016 compared to CY 2015.

As seen in Table 66, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC rates for CY 2016 would result in a 1-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 3-percent increase in aggregate payment amounts for digestive system procedures, a 1-percent increase in aggregate payment amounts for nervous system procedures, a 2-percent decrease in aggregate payment amounts for musculoskeletal system procedures, a 2-percent increase in aggregate payment amounts for genitourinary system procedures, and no change in aggregate payment amounts for integumentary system procedures.

Also displayed in Table 66 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 would remain at $21 million for CY 2016.

TABLE 66—ESTIMATED IMPACT OF THE PROPOSED CY 2016 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PROPOSED CY 2016 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical specialty group	Estimated CY 2015 ASC payments (in millions)	Estimated proposed CY 2016 percent change
(1)	(2)	(3)
Total	$3,899	1
Eye and ocular adnexa	1,537	1
Digestive system	809	3
Nervous system	618	1
Musculoskeletal system	486	−2
Genitourinary system	176	2
Integumentary system	135	0
Respiratory system	55	4

TABLE 66—ESTIMATED IMPACT OF THE PROPOSED CY 2016 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PROPOSED CY 2016 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP—Continued

Surgical specialty group	Estimated CY 2015 ASC payments (in millions)	Estimated proposed CY 2016 percent change
(1)	(2)	(3)
Cardiovascular system	42	1
Ancillary items and services	21	0
Auditory system	14	5
Hematologic & lymphatic systems	6	−5

Table 67 below shows the estimated impact of the proposed 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 Proposed CY 2016 Percent Change reflects the percent differences between the estimated ASC payment for CY 2015 and the estimated proposed payment for CY 2016 based on the proposed update.

TABLE 67—ESTIMATED IMPACT OF THE PROPOSED CY 2016 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS code	Short descriptor	Estimated CY 2015 ASC payment (in millions)	Estimated CY 2016 percent change
(1)	(2)	(3)	(4)
66984	Cataract surg w/iol 1 stage	$1,094	1
43239	Egd biopsy single/multiple	177	2
45380	Colonoscopy and biopsy	181	−2
45385	Colonoscopy w/lesion removal	117	−2
66982	Cataract surgery complex	95	1
64483	Inj foramen epidural l/s	94	−10
62311	Inject spine lumbar/sacral	75	−10
45378	Diagnostic colonoscopy	69	−3
66821	After cataract laser surgery	65	3
64493	Inj paravert f jnt l/s 1 lev	53	32
G0105	Colorectal scrn; hi risk ind	46	18
64635	Destroy lumb/sac facet jnt	50	−2
63650	Implant neuroelectrodes	52	5
G0121	Colon ca scrn not hi rsk ind	43	18
64590	Insrt/redo pn/gastr stimul	44	−6
15823	Revision of upper eyelid	33	1
63685	Insrt/redo spine n generator	54	2
29827	Arthroscop rotator cuff repr	50	11
64721	Carpal tunnel surgery	30	4
29881	Knee arthroscopy/surgery	28	15
29824	Shoulder arthroscopy/surgery	21	−43
29880	Knee arthroscopy/surgery	24	15
43235	Egd diagnostic brush wash	24	2
62310	Inject spine cerv/thoracic	23	−10
29823	Shoulder arthroscopy/surgery	13	−43
52000	Cystoscopy	22	−4
G0260	Inj for sacroiliac jt anesth	22	−10
45384	Colonoscopy w/lesion removal	20	−2
67042	Vit for macular hole	22	0
26055	Incise finger tendon sheath	21	23

(3) Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2016 update to the ASC payment system would be generally positive for beneficiaries with respect to the new procedures that we are proposing to add to the ASC list of covered surgical procedures and for those that we are proposing to designate 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 proposing to designate as office-based in CY 2016, the beneficiary coinsurance amount under the ASC payment system generally would 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 proposed rule 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. As discussed in that section, we considered, but did not propose, to apply the device offset to procedures for which anesthesia has already been administered (that is, those identified by Modifier 74).

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 proposed rule. The first accounting statement, Table 68 below, illustrates the classification of expenditures for the proposed CY 2016 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2016 OPD fee schedule increase, based on the 2015 Trustee's Report, and the proposed 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 69 below, illustrates the classification of expenditures associated with the proposed 1.1 percent CY 2016 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs in the 2015 Trustee's Report. Lastly, the tables classify most estimated impacts as transfers.

TABLE 68—ACCOUNTING STATEMENT: PROPOSED CY 2016 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2015 TO CY 2016 ASSOCIATED WITH THE PROPOSED CY 2016 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE AND THE PROPOSED ADJUSTMENT TO ADDRESS EXCESS PACKAGED PAYMENT FOR LABORATORY TESTS

Category	Transfers
Annualized Monetized Transfers.	−$43 million
From Whom to Whom.	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS
Total	−$43 million

TABLE 69—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2015 TO CY 2016 AS A RESULT OF THE PROPOSED CY 2016 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers.	$35 million
From Whom to Whom.	Federal Government to Medicare Providers and Suppliers
Total	$35 million

d. Effects of Proposed 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 OPPS changes on hospitals for the CY 2017 payment determination. In section XIII. of this proposed rule, we are proposing 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. 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 would not receive the full OPD fee schedule increase factor for the CY 2018 payment determination and subsequent years.

In section XIII. of this proposed rule, we are proposing to make several changes to the Hospital OQR Program for the CY 2017 payment determination and subsequent years, the CY 2018 payment determination and subsequent years, and the CY 2019 payment determination and subsequent years. For the CY 2017 payment determination and subsequent years, we are proposing 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 from November 1 to August 31; (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) from July 1 through November 1 to January 1 through May 15; (5) rename our extension and exception

policy to extension and exemption policy; (6) change the deadline for submitting a reconsideration request 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; 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 proposing would increase burden, as further discussed below.

In addition, we are proposing 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 are proposing that validation be based on three quarters of data (quarter 2, quarter 3, and quarter 4 of 2015). For the CY 2017 transition year, we estimate that the burden associated with validation reporting would be reduced by 25 percent because hospitals would submit validation data for three quarters instead of four. 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 would reduce the number of hours required by 25 percent (from 12 hours to 9 hours per hospital). Therefore, we estimate a total burden of approximately 4,500 hours (500 hospitals x 9 hours/hospital) and a total financial impact of $135,000 ($30/hour x 4,500 hours) for the CY 2017 payment determination. In summary, for the CY 2017 payment determination, we estimate a total burden of 3.5 million hours across all hospitals for a total of $105 million. This is a reduction of 1,500 hours and $45,000 across all hospitals from last year's estimate.

For the CY 2018 payment determination and subsequent years, we are proposing two changes to the program. First, we are proposing a new measure OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822). As discussed in section XVIII.B.1.b. of this proposed rule, we believe that this measure would result in a total increase in burden across all participating hospitals of 8,313 hours or $249,000 per year (rounded). Second, we are proposing for the CY 2018 payment determination and subsequent years, 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 x 12 hours/hospital) and a total financial impact of $180,000 ($30/hour x 6,000 hours) in burden associated with validation 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.

For the CY 2019 payment determination and subsequent years, we are proposing one change to the program; we are proposing a new measure OP–34: Emergency Department Transfer Communication (EDTC) (NQF #0291). As discussed in section XVIII.B.1.c. of this proposed rule, we believe that this measure would result in a total increase in burden across all participating hospitals of 80,593 hours or $2.41 million per year (rounded). In summary, we estimate that all of the proposals made in this proposed rule for the Hospital OQR Program would result in a total increase in burden across all participating hospitals of 88,905 hours or $2.67 million (rounded).

We refer readers to the information collection requirements section XVIII.B.1. of this proposed rule for a detailed discussion of the financial and hourly burden of the proposed additional requirements for submitting data to the Hospital OQR Program.

e. Effects of Proposed Requirements for the ASCQR Program

As discussed in section XIV. of this proposed rule, we are proposing 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 proposing to add 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 would 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 proposing in this proposed rule would increase the number of ASCs that do not receive a full annual payment update for the CY 2018 payment determination. We expect a reduction due to our proposal that IHS hospital outpatient departments billing as ASCs would no longer be considered ASCs for the purposes of the ASCQR Program. Thus, as 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 would 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 made in this proposed rule, 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 [53] (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 XVIII.B.2 of this proposed rule for a detailed discussion of the financial and

[53] 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).

hourly burden of the ASCQR Program's current and proposed requirements.

We are inviting public comment on the burden associated with these proposals.

f. Impact of the Proposed Policy Change for Medical Review of Inpatient Hospital Admissions Under Medicare Part A

As discussed in section XV. of this proposed rule, we are proposing 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 proposed policy change described in section XV of this proposed rule. We also discuss the estimate by our actuaries of the overall impact of the 2-midnight rule adopted in the FY 2014 IPPS/LTCH PPS rulemaking, including a review by our actuaries of the claims data since the implementation of the 2-midnight rule.

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 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.

There were several components of the −0.2 percent adjustment estimate. First, in estimating the number of inpatient stays that would shift to the outpatient setting, inpatient claims containing a surgical MS–DRG were analyzed. These claims were from FY 2011, although FY 2009 and FY 2010 claims data were also examined and the results were consistent with the FY 2011 results. Claims containing medical MS–DRGs and those that resulted in death or a transfer were excluded because it was assumed that these cases would be unaffected by the policy change. In making this assumption, the actuaries believed that behavioral changes by hospitals and admitting practitioners would mitigate some of the impact of cases shifting between the inpatient hospital setting and the outpatient hospital setting. Specifically, the actuaries assumed that most inpatient medical encounters spanning less than 2 midnights before the current 2-midnight rule was implemented might extend past 2 midnights after its implementation and still be considered inpatient. They believed that the clinical assessments and protocols used by physicians to develop an expected length of stay for medical cases were, in general, more variable and less defined than those used to develop an expected length of stay for surgical cases. Under our proposed policy, our actuaries assume that some of these medical encounters might revert back to no longer extending past 2-midnights. However, they would not generally cause a significant increase or decrease in expenditures because they are inpatient under the current policy and could remain inpatient under the proposed policy. With respect to surgical encounters, under the current policy our actuaries assumed that cases spanning less than two midnights containing a surgical MS–DRG would shift from the inpatient setting to the outpatient setting. Under the proposed policy, our actuaries assume that as a result of the experience that hospitals have gained under the current 2-midnight rule and the continued potential for medical review of these cases, these cases generally would not shift back to the inpatient setting in significant numbers.

A second component of the −0.2 percent adjustment estimate was the number of outpatient encounters assumed to shift to the inpatient setting. Outpatient claims that included spending for observation care or a major procedure were analyzed. Outpatient stays that were shorter than 2 midnights and those that were not for observation care or for a major procedure were excluded because it was assumed that these cases would be unaffected by the policy change. Under the current policy, our actuaries assumed that the cases for observation care or a major procedure that spanned more than 2 midnights would shift from the outpatient setting to the inpatient setting. Because the proposed policy only impacts cases spanning less than 2 midnights after admission, our actuaries do not assume any significant additional shifts in outpatient encounters spanning more than 2 midnights to the inpatient setting if our proposal is adopted. With respect to outpatient encounters that span less than 2 midnights, as a result of the experience that hospitals have gained under the current 2-midnight rule, the continued potential for medical review of these cases, and the fact that our experience indicates that the majority of these cases were generally not inpatient prior to the current 2-midnight policy, our actuaries assume that these cases would generally remain in the outpatient setting under our proposed policy.

Another component of the −0.2 percent adjustment estimate was the assumption that payment under the OPPS would be roughly 30 percent of the payment under the IPPS for encounters shifting between the two systems, and the beneficiary would be responsible for 20 percent of the payment under the OPPS. Our actuaries continue to assume this payment differential under our proposed policy.

Because our actuaries do not assume any significant additional shifts between the inpatient setting and the outpatient setting as a result of our proposed policy, and because there is also no change in the assumption regarding the 30-percent outpatient/inpatient payment differential, our actuaries do not estimate that overall IPPS expenditures would be significantly different under the proposed policy change for the medical review of inpatient hospital admissions under Medicare Part A described in section XV. of this proposed rule.

As we indicated for the original −0.2 percent adjustment estimate, there is a certain degree of uncertainty surrounding any cost estimate. Our actuaries have determined that the methodology, data, and assumptions used here are reasonable for the purpose of estimating the overall impact of the proposed policy. It is important to note that the assumptions used for purposes of reasonably estimating overall impacts should not be construed as absolute statements about every individual encounter. For example, under our current policy, our actuaries did not expect that every single surgical MS–DRG encounter spanning less than 2 midnights would shift to the outpatient setting, that every single medical MS–DRG encounter would remain in the inpatient setting, and that every single outpatient observation stay or major surgical encounter spanning more than 2 midnights would shift to the inpatient setting. However, for purposes of developing the −0.2 percent adjustment estimate under the current policy, a *model* where cases involving a surgical

MS–DRG spanning less than 2 midnights in the historical data shifted to the outpatient setting, cases involving a medical MS–DRG spanning less than 2 midnights in the historical data remained in the inpatient setting, and outpatient observation stays and major surgical encounters spanning more than 2 midnights in the historical data shifted to the inpatient setting yielded a reasonable estimate of the net effect of the 2-midnight policy. To the extent the actual experience might vary for each of the individual assumptions, our actuaries estimated that the total net effect of that variation would not significantly impact the estimate. Similarly, under our proposed policy, our actuaries do not expect that every single inpatient case would remain an inpatient case and every single outpatient case would remain an outpatient case. Rather, they estimate that total net effect of variation between their assumptions and actual experience would not significantly impact the estimate.

Our actuaries also provided some important caveats with the original estimate that continue to hold true for the estimate of the proposed policy. They noted that the actual costs or savings would depend substantially on possible changes in behavior by hospitals and the medical review entities, and that such changes could not be anticipated with certainty. They also noted that the estimates did depend critically on the assumed utilization changes in the inpatient and outpatient hospital settings. While they believed that the assumptions were reasonable, they indicated that relatively small changes would have a disproportionate effect on the estimate. For this reason, the estimate was subject to a much greater degree of uncertainty than usual, and the actual results could have differed significantly from the estimate. All of these caveats also apply to the estimate that the proposed policy would not have a significant impact on expenditures.

Our actuaries have been periodically reviewing the claims experience to date under the 2-midnight rule and comparing it to the experience of the previous time period. Below are a few observations from this review. Our actuaries have attempted to complete the claims data (that is, to adjust for lags between the time when claims were incurred but not yet received) in performing the review. Full incurred experience for the more recent time periods, when available, could result in a different outcome.

Our actuaries found that the proportion of outpatient long-stay observation encounters (more than 2 days) as compared to all outpatient encounters decreased by 11 percent in FY 2014 compared to FY 2013 (6 percent in the fourth quarter of CY 2013; 11 percent in the first quarter of CY 2014; 13 percent in the second quarter of CY 2014; and 14 percent in the third quarter of CY 2014) and also by 11 percent in CY 2014 compared to CY 2013 (6 percent in the fourth quarter of CY 2014).

They found the proportion of 2–4 day inpatient stays as compared to all inpatient stays increased by 3.0 percent in FY 2014 compared to FY 2013 (3.4 percent in the fourth quarter of CY 2013; 3.5 percent in the first quarter of CY 2014; 2.8 percent in the second quarter of CY 2014; and 2.4 percent in the third quarter of CY 2014) and increased by 2.7 percent in CY 2014 compared to CY 2013 (2 percent in the fourth quarter of CY 2014).

They found the proportion of very short stay inpatient admissions (0 and 1 days) decreased by 9.0 percent in FY 2014 compared to FY 2013 (10.5 percent in the fourth quarter of CY 2013; 8.2 percent in the first quarter of CY 2014; 8.2 percent in the second quarter of CY 2014; and 7.7 percent in the third quarter of CY 2014) and decreased by 7.3 percent in CY 2014 compared to CY 2013 (3.4 percent in the fourth quarter of CY 2014).

Overall, the cumulative effect of these inpatient shifts show no change in the proportion of inpatient stays of 4 days or more.

The data thus far is consistent with the assumptions used by our actuaries to develop the original −0.2 percent adjustment estimate: Outpatient long stay observations (more than 2 days) have declined; 2–4 day inpatient stays have increased; and very short inpatient stays (1 day or less) have decreased. The fact that there has been no change in the proportion of inpatient stays of 4 days or more is consistent with the assumption that the decrease in very short stay inpatient cases under the current policy would be offset by the shift of longer outpatient encounters to inpatient. Our actuaries will continue to review the claims experience under the 2-midnight rule, and we will take those reviews into account when considering future rulemaking.

As was the case when our actuaries developed the original −0.2 percent adjustment estimate and continues to be the case now, the outpatient and inpatient data files are publicly available. The CMS Web site at *http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/HospitalOutpatientPPS/index.html* provides information about ordering the ''OPPS Limited Data Set'' containing the outpatient hospital data. The CMS Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/* provides information about ordering the ''MedPAR Limited Data Set (LDS)-Hospital (National)'' containing the inpatient hospital data.

g. Impact of Proposed Transition for MDHs in All-Urban States Under the IPPS

In section XVI. of this proposed rule, we discuss our proposal to provide a transition period under the IPPS 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. A facility is eligible for designation as an MDH only if it is either physically located in a rural area or has been reclassified under 42 CFR 412.103. However, a hospital that is located in an all-urban State cannot apply for reclassification as rural under 42 CFR 412.103 because its State does not have a rural area into which it can reclassify. We are proposing that, for discharges occurring on or after January 1, 2016, and before October 1, 2016, under the IPPS, 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 are proposing that such 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. For FY 2018, that is, for discharges occurring on or after October 1, 2018, we are proposing that these former MDHs would be solely paid based on the Federal rate. We estimate that there is one provider that was classified an MDH prior to the effective date of the new OMB delineations on October 1, 2014, and is located in a newly all-urban State. We estimate the costs associated with the transition period for this hospital 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule may have a significant impact on approximately 648 small rural hospitals.

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 proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

D. Conclusion

The changes we are proposing to make in this proposed rule would affect all classes of hospitals paid under the OPPS and would affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2015. Table 65 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 0.2 percent decrease in payments for all services paid under the OPPS in CY 2016, after considering all of the proposed changes to APC reconfiguration and recalibration, as well as the proposed OPD fee schedule increase factor, proposed adjustment to the conversion factor to address the inflation in OPPS payment rates resulting from excess packaged payment under the OPPS for laboratory tests, proposed wage index changes, including the proposed frontier State wage index adjustment, proposed estimated payment for outliers, and proposed 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 proposed updates to the ASC payment system for CY 2016 would 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 66 demonstrates the estimated distributional impact among ASC surgical specialties of the proposed MFP-adjusted CPI–U update factor of 1.1 percent for CY 2016.

XXI. 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 proposed rule 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 65 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would decrease payment by 0.2 percent under this proposed rule. 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 proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule 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 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 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 proposing to amend 42 CFR Chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. 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).

■ 2. 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

■ 3. 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.

■ 4. 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 416—AMBULATORY SURGICAL SERVICES

■ 5. 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).

■ 6. 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;

* * * * *

■ 7. 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 ASC device-intensive procedure is removed prior to determining the Medicare program payment amount and beneficiary copayment amount identified in paragraphs (f)(1)(ii) and (f)(1)(iii) of this section.

* * * * *

■ 8. 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. Under this provision, 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.

* * * * *

■ 9. Subpart H is added to read as follows:

Subpart H—Requirements Under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

Sec.

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 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 is submitted via a CMS online data submission tool is for services furnished during the calendar year 2 years prior to the payment determination year. Beginning with the CY 2017 payment determination year, data collected must be submitted during the time period of January 1 to May 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 calendar 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 display ASC data by the National Provider Identifier (NPI) when data are submitted by the NPI. CMS will display ASC data by the CMS Certification Number (CCN) when data are submitted by the CCNs, such that all NPIs associated with that CCN will be assigned the CCN's value.

§ 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 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

■ 10. 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).

■ 11. 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.

■ 12. 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.

* * * * *

■ 13. 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 paragraphs (b)(1)(ii) and (b)(1)(iii) of this section.

■ 14. 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.

* * * * *

■ 15. 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 from premarket approval or clearance. Under this provision, CMS will consider only applications for a medical device submitted within 3 years from the date of the initial FDA approval or clearance, if required.

* * * * *

Dated: June 26, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: June 26, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–16577 Filed 7–1–15; 4:15 pm]

BILLING CODE 4120–01–P

Reader Aids

Federal Register

Vol. 80, No. 130

Wednesday, July 8, 2015

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**
TTY for the deaf-and-hard-of-hearing	**741–6086**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and Code of Federal Regulations are located at: **www.ofr.gov.**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings);* then follow the instructions.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

FEDERAL REGISTER PAGES AND DATE, JULY

CFR PARTS AFFECTED DURING JULY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Executive Orders:
13699 37529
Administrative Orders:
1 37921

5 CFR

Proposed Rules:
Ch. XXII 38019

7 CFR

929 37531
932 37533
Proposed Rules:
986 38021
1211 37555

9 CFR

94 ..... 37923, 37935

10 CFR

430 ..... 37953, 37954
Proposed Rules:
Ch. II 38019
Ch. III 38019
Ch. IX 38019
431 38032

12 CFR

Proposed Rules:
701 37898
723 37898
741 37898

14 CFR

33 38913
39 ..... 38391, 38613, 38615, 38617
Proposed Rules:
39 ..... 38033, 38036, 38038, 38406, 38408, 38656, 38990, 38992

16 CFR

Proposed Rules:
313 38410
1112 38041
1233 38041

17 CFR

231 37536
232 37537
241 37536
271 37536
275 37538
276 37536
Proposed Rules:
240 38995
275 38050
279 38050

18 CFR

Proposed Rules:
342 39010

20 CFR

404 37970
416 37970

21 CFR

20 38915
310 38915
314 38915
600 38915
601 37971
610 37971
680 37971
Proposed Rules:
601 38145
1100 37555
1140 37555
1143 37555

22 CFR

121 37974

24 CFR

Proposed Rules:
203 38410

25 CFR

83 ..... 37538, 37862

26 CFR

1 ..... 38940, 38941

27 CFR

Proposed Rules:
9 38147

28 CFR

527 38620
571 38622
Proposed Rules:
506 38658

29 CFR

18 37539
Proposed Rules:
541 38516

31 CFR

Proposed Rules:
315 37539
353 37539
360 37539

33 CFR

100 ..... 38394, 38397
165 ..... 37540, 37542, 37545, 37976, 37978, 37980, 37982, 38623, 38941, 38943, 38944,

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List July 2, 2015

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.